AMA
AMERICAN MEDICAL ASSOCIATION

ama-assn.org
t (312) 464-5000

December 17, 2015

The Honorable Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1631-FC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: File Code-CMS-1631-FC; Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2016 Final Rule; (November 16, 2015).

Dear Acting Administrator Slavitt:

The American Medical Association (AMA)/Specialty Society RVS Update Committee (RUC) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) Final Rule on the revisions to Medicare payment policies under the Physician Payment Schedule for calendar year 2016, published in the November 16, 2015 *Federal Register (Vol. 80, No. 220 FR, pages 70886-71386, November 16, 2015)*.

The Final Rule includes a number of policy and technical modifications within the Resource-Based Relative Value Scale (RBRVS). This letter includes RUC recommendations and comments regarding the following:

I. RUC Work Value Recommendations Not Addressed in Final Rule
- **A.** Pre-time Analysis

II. Technical Corrections Needed
- **A.** Global Period Errors
- **B.** Echo Guidance for Ova Aspiration (CPT Code 76948)
- **C.** Errors on Phase In
- **D.** Technical Corrections to Direct PE Inputs

III. Establishing 2016 Interim Final Work Relative Values
- **A.** CMS' Inappropriate Physician Time Ratio Calculation

B. Repair Flexor Tendon (CPT Codes 26356, 26357, and 26358)

C. Esophagogastric Fundoplasty Trans-Oral Approach (CPT Code 43210)

D. Percutaneous Biliary Procedures (CPT Codes 47531, 47532, 47533, 47534, 47535, 47536, 47537, 47538, 47539, 47540, 47541, 47542, 47543, and 47544)

E. Percutaneous Image Guided Sclerotherapy (CPT Code 49185)

F. Genitourinary Catheter Procedures (CPT Codes 50606, 50705, and 50706)

G. Laparoscopic Radical Prostatectomy (CPT Code 55866)

H. Intracranial Endovascular Intervention (CPT Codes 61645, 61650 and 61651)

I. Paravertebral Block Injection (CPT Codes 64461, 64462 and 64463)

J. Ocular Reconstruction Transplant (CPT Code 65780)

K. Trabeculoplasty by Laser Surgery (CPT code 65855)

L. Glaucoma Surgery (CPT Codes 66170 and 66172)

M. Retinal Detachment Repair (CPT Codes 67107, 67108, 67110, and 67113)

N. Fetal MRI (CPT Codes 74712 and 74713)

O. Interstitial Radiation Source Codes (CPT Codes 77778 and 77790)

P. Colon Transit Imaging (CPT Codes 78264, 78265, and 78266)

Q. Reflectance Confocal Microscopy (CPT Codes 96931-96936)

IV. CY 2016 Identification and Review of Potentially Misvalued Services

V. Resource-Based Practice Expense (PE) Relative Value Units (RVUs)
- **A.** Practice Expense Inputs for Digital Imaging Services
- **B.** Clinical Labor Tasks associated with Digital Imaging
- **C.** Pathology Clinical Labor Tasks
- **D.** Methodology for Establishing the Direct PE Inputs Used to Develop PE RVUs
  - **1.** New Supply and Equipment Items
  - **2.** Refinement Table

I. RUC Work Value Recommendations Not Addressed in Final Rule

The RUC noticed that the Pre-Time Analysis recommendations submitted in October 2014 were never addressed. In light of this omission, we have reiterated the recommendation below and attached the associated action plans (*see 00 Addendum - Pre-Time Analysis Action Plans*). The RUC requests that the Agency conduct a full review as soon as possible.

A. Pre-Time Analysis

The RUC continues efforts in identifying and providing recommendations for potentially misvalued services. In January 2014, the RUC identified codes reviewed prior to April 2008 (prior to the creation of pre-time packages) with pre-time greater than *pre-time package 4 Facility - Difficult Patient/Difficult Procedure* (63 minutes), the longest standardized package, for services with 2012 Medicare Utilization over 10,000.

The Relativity Assessment Workgroup noted that all services were valued by magnitude estimation; therefore the readjustments in pre-service time category did not alter the work RVU. Additionally, crosswalks for each service were presented validating the pre-time adjustment recommended. The Workgroup determined that this screen was useful, however the screen did not reveal any large outliers and therefore the utilization threshold does not need to be lowered to identify more services.

In September 2014, the RUC reviewed action plans submitted by the specialty societies and recommended the specific adjustments below. The submitted action plans and pre-time recommendations were also included in the submission attachments and the physician time file sent on October 6, 2014.

CMS did not address these recommendations in Rulemaking for 2015 or 2016. The RUC requests that the Agency consider the pre-time recommendations below in the notice for proposed rulemaking for 2017.

CPT Code	Recommendation	Eval	Positioning	SDW	Total
15002	Maintain work RVU and adjust the times from pre-time package 4 to be consistent with pre-time packages for this family of services.	40	15	15	70
15004	Maintain work RVU and adjust the times from pre-time package 4 to be consistent with pre-time packages for this family of services.	40	15	15	70
15100	Maintain work RVU and adjust the times from pre-time package 4 to be consistent with pre-time packages for this family of services.	40	10	10	60
15240	Maintain work RVU and adjust the times from pre-time package 4 to be consistent with pre-time packages for this family of services.	40	3	10	53
20680	Maintain work RVU and adjust the times from pre-time package 3 to be consistent with pre-time packages for this family of services.	33	15	15	63
22612	Maintain work RVU and adjust the times from pre-time package 4 to be consistent with pre-time packages for this family of services.	40	18	15	73
23412	Maintain work RVU and adjust the times from pre-time package 4 to be consistent with pre-time packages for this family of services.	40	15	15	70
25609 25606 25607 25608	Maintain work RVU and adjust the times from pre-time package 3. Change the pre-time for codes 25606, 25607 and 25608.	33	10	15	58
27134	Maintain work RVU and adjust the times from pre-time package 4 to be consistent with pre-time packages for this family of services.	40	15	20	75
27814	Maintain work RVU and adjust the times from pre-time package 3 to be consistent with pre-time packages for this family of services.	33	10	15	58
29827	Maintain work RVU and adjust the times from pre-time package 3 to be consistent with pre-time packages for this family of services.	33	15	15	63

47562	Maintain work RVU and adjust the times from pre-time package 3 to be consistent with pre-time packages for this family of services.	33	10	15	58
63030	Maintain work RVU and adjust the times from pre-time package 4 to be consistent with pre-time packages for this family of services.	40	18	17	75
63042	Maintain work RVU and adjust the times from pre-time package 4 to be consistent with pre-time packages for this family of services.	40	18	20	78
93641	Maintain work RVU and adjust the times from pre-time package 2B.	33	1	5	39

II. Technical Corrections Needed

The RUC has identified several errors which are detailed below. We anticipate all the changes in this section will be implemented as technical corrections immediately in CMS files to be ready for January 1, 2016 payments.

A. Global Period Errors

Following the publication of the 2016 MFS Final Rule, the AMA notified CMS of the below global period discrepancies:

CPT	Mod	Status	Short Descriptor	Global from CMS - Addendum B	Global on RUC Recommendation
20240		A	Bone biopsy excisional	010	000
43210		A	Egd esophagogastrc fndoplsty	YYY	000
61650		A	Evasc prlng admn rx agnt 1st	ZZZ	000
67227		A	Dstrj extensive retinopathy	090	010
67228		A	Treatment x10sv retinopathy	090	010
73060	TC	A	X-ray exam of humerus	000	XXX
73060	26	A	X-ray exam of humerus	000	XXX
73560	26	A	X-ray exam of knee 1 or 2	000	XXX

RUC Comments:

- The AMA believes these discrepancies to be typos for the following reasons:
    - CMS officials explicitly approved the global period changes for CPT codes 20240, 67227 and 67228 in a communication to the AMA on February 24, 2015.
    - For CPT codes 73060 and 73560, Addendum B lists two separate global periods for these codes depending on the modifier.
    - For CPT code 61650, this service is a base code and not an add-on service, making a ZZZ global incorrect.
    - For CPT code 43210, the RUC recommended and CMS implemented valuation for this service and the Medicare status is active. It would not make sense for the global period to be determined by the carrier (YYY).
- **The RUC believes all of these changes would be technical corrections. We look forward to these issues being corrected immediately in the CMS files and the correct global periods being ready for January 1, 2016 payments.**

B. Echo Guidance for Ova Aspiration (CPT Code 76948)

In the RUC comment letter on the NPRM for CY 2016, the RUC noted a typo for CPT code 76948 *Ultrasonic guidance for aspiration of ova, imaging supervision and interpretation* that was not addressed in the Final Rule for 2016.

CPT code	Descriptor	RUC Rec RVU	CMS Proposed RVU	CMS Work RVU Decision
76948	Ultrasonic guidance for aspiration of ova, imaging supervision and interpretation	0.85	0.56	Disagree

Summary of CMS Actions:

- In the CY 2014 PFS Final Rule, CMS requested additional information to assist them in the valuation of ultrasound guidance codes. They nominated a series of codes as potentially misvalued, which included CPT Code 76948. CPT code 76948 was surveyed by the specialty societies and the RUC issued a recommendation for CY 2016.
- CMS proposed to crosswalk CPT Code 76948 to the work RVU of CPT Code 76945. In the RUC comment letter in response to the Proposed Rule, the RUC indicated that **CPT Code 76945 currently has a work RVU of 0.67, not 0.56 as indicated.**

- CMS finalized the crosswalk of 76948 to 76945 – but still needs to correct the work RVU as it should be 0.67. Additionally, the Final Rule Addendum B has a work RVU of 0.38 for CPT code 76948.

RUC Comments:

- Immediately following the publication of the 2016 MFS Final Rule, the AMA requested a technical correction for CPT Code 76948 (November 3, 2015).

- The RUC fully discussed the comparison of 76948 to key reference services 76945 *Ultrasonic guidance for chorionic villus sampling, imaging supervision and interpretation* (work RVU = 0.67) and 76942 *Ultrasonic guidance for needle placement (e.g., biopsy, aspiration, injection, localization device), imaging supervision and interpretation* (work RVU = 0.67) and noted both reference codes require less physician work. CPT code 76948 requires multiple follicle punctures whereas 76945 and 76942 require one single needle placement.

- **The RUC urges CMS to accept the RUC survey 25th percentile work RVU of 0.85 for CPT code 76948.**

- **The RUC expects that CMS will address the typo in the crosswalk RVU listed for 76945 immediately as a technical correction. We look forward to this issue being corrected immediately in the CMS files and the correct value being ready for January 1, 2016 payments.**

C. Errors on Phase In

- Following the publication of the 2016 MFS Final Rule, the AMA notified CMS of the below errors on phase in:

    - In the same family of retina codes, CPT codes 67108 and 67113 were not included, as others in the family were, in phase in. Thus, the percent change is higher in error.

CPT Code	Short Descriptor	2015 Total FAC RVUs	2016 Total FAC RVUs	FAC Pct Change
67108	Repair detached retina	45.39	30.83	-32%
67113	Repair retinal detach cplx	49.34	38.09	-23%

- **The RUC expects CMS will address these errors immediately in the CMS files and appropriately include CPT codes 67108 and 67113 in phase in to be ready for January 1, 2016 payments.**

D. Technical Corrections to Direct PE Inputs

- Please also find a list of potential technical corrections to direct PE inputs that the RUC has identified in the CMS CY 2016 direct PE input database (*see 01 Addendum – Tech Corrections to CY2016 PE Database*).

III. Establishing 2016 Interim Final Work Relative Values

The RUC appreciates that CMS accepted 76% of the RUC's work relative value recommendations submitted for 2016. However, we have significant concerns regarding the recommendations rejected by CMS, particularly the methodology and rationale utilized for many codes. In preparing the RUC comments, specialties were provided with the opportunity to share additional information for CMS consideration. It is the RUC's intention that the following comments will provide enough clarity to persuade the Agency to reconsider the interim recommendations that differ from the RUC recommendations and instead affirm the RUC's recommended values in final rulemaking next year.

A. CMS' Inappropriate Physician Time Ratio Calculations

Prior to reviewing each individual recommendation in which CMS has disagreed with the RUC recommendation, the RUC would like to outline its concerns over the Agency's growing use of time ratios to determine derived physician work values.

Summary of CMS Actions:

- CMS has, for many codes, opted for an inappropriate ratio calculation to determine the work values for services which have RUC recommended physician time less than the current time.

- CMS employs these ratios seemingly arbitrarily through an inconsistent set of base assumptions, for instance below is a brief review of some of the permutations of the ratio covering the CPT 2016 codes under review:

    - Ratio of total time difference to current work RVU (65780, Final Rule).

    - Ratio of intra-service time difference to current work RVU (65855, 66170, 66172, 67107, Final Rule).

    - Ratio of the sum of intra-service time differences for a bundled code to the sum of the current work RVUs (31652, NPRM).

    - Ratio of the total time difference to RUC recommended work RVU (38570, NPRM).

    - Ratio of the total time difference, in which current total time is Harvard-based (46500, NPRM).

RUC Comments:

- CMS cannot take one modified element and apply an overall ratio reduction based on changes to that single data component; this renders the value no longer resource-based.

- The Agency's inconsistent use of the time ratio methodology has rendered it ineffective for valuation purposes. By choosing the starting base work value and/or physician time at random, CMS is essentially reverse engineering the work value it wants under the guise of a standard algorithm.

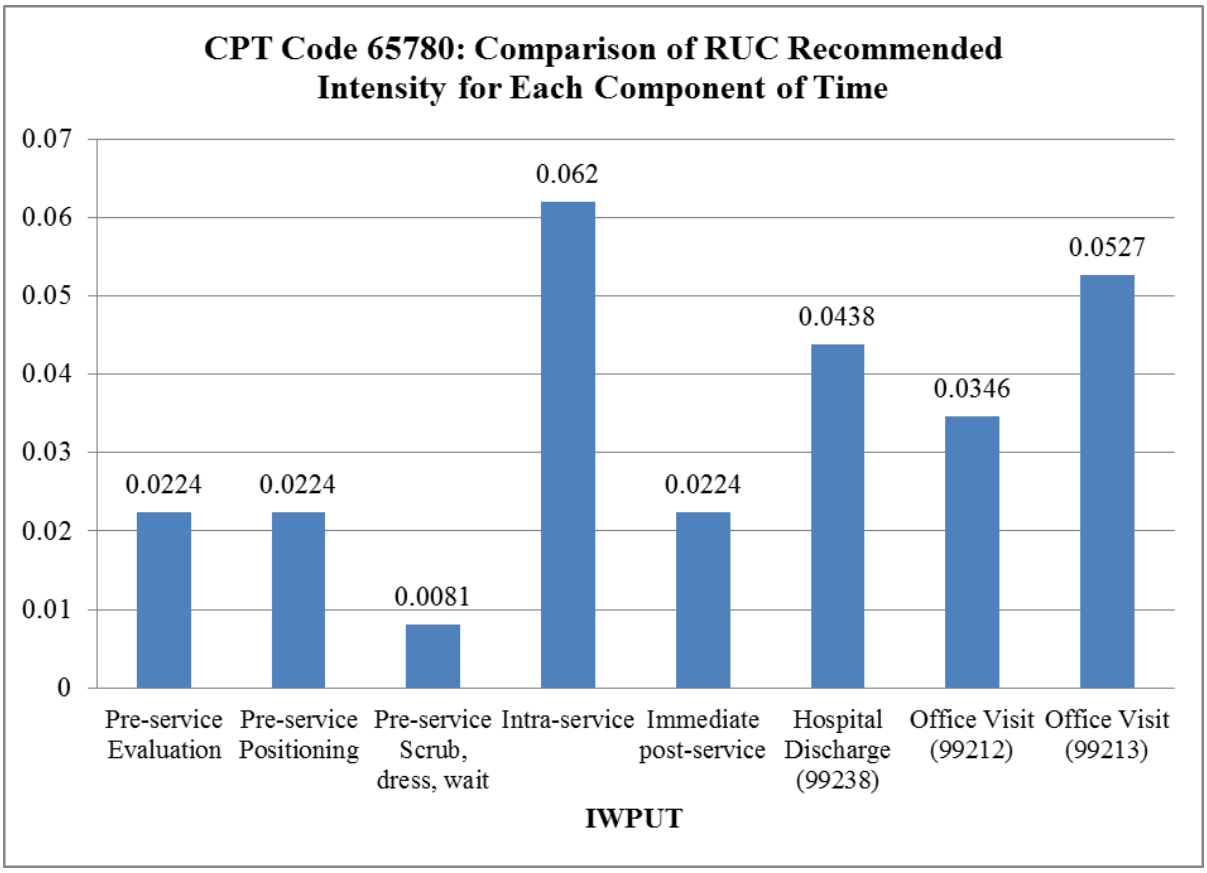
- This rough calculation distills the valuation of this service into a basic formula with the only variable being either the new total physician time or the new intra-service physician time. These methodologies are based on the incorrect assumption that the per minute physician work intensity established is permanent regardless of when the service was last valued.

- Treating all components of physician time (pre-service, intra-service, post-service and post-operative visits) as having identical intensity is incorrect and inconsistently applying it to only certain services under review creates inherent payment disparities in a payment system which is based on relative valuation. Furthermore, when physician times are updated in the Medicare payment schedule, the ratio of intra-service time to total time, the number and level of bundled post-operative visits, the length of pre-service and length of immediate post-service time may all potentially change for the same service *(see 02 Addendum - Ocular Reconstruction Transplant)*. These changing components of physician time make CMS' simplistic formulas have widely variable and inaccurate outputs.

- This valuation methodology also appears to be in opposition to statute Sec. 1848. [42 U.S.C. 1395w–4] (a) (i), which states: The Secretary shall determine a number of work relative value units for the service based on the relative resources incorporating physician time and intensity required in furnishing the service.

    - As an example, in the 2016 NPRM, CMS noted that for CPT code 39402, the Agency scaled the work in accordance with the change in the intraservice times between CPT codes 39401 and 39402. CMS goes on to explain that the work RVU for CPT code 39402 was higher than would be expected based on the difference in time between these two procedures, even considering the more difficult clinical nature of CPT code 39402. Thus, CMS acknowledges the increased intensity of the additional time present in 39402 compared to 39401, but calculates the value based on time only, ignoring the intensity difference.

- Included below is a graph to provide an additional example *(Ocular Reconstruction Transplant, CPT Code 65780*) of why the time ratios referenced by CMS are inappropriate. As graphically displayed, the different components of a physician service have vastly different intensities of physician work and thus comparing only on time is flawed.



- **The RUC urges CMS to correct these inappropriate ratio calculations to accurately reflect relative resources incorporating physician time and intensity required in furnishing services.**

B. Repair Flexor Tendon (CPT Codes 26356, 26357, and 26358)

CPT code	Descriptor	RUC Rec RVU	CMS Proposed Interim RVU	CMS Work RVU Decision
26356	Repair or advancement, flexor tendon, in zone 2 digital flexor tendon sheath (e.g., no man's land); primary, without free graft, each tendon	10.03	9.56	Disagree
26357	secondary, without free graft, each tendon	11.50	10.53	Disagree
26358	secondary, with free graft (includes obtaining graft), each tendon	13.10	12.13	Disagree

Summary of CMS Actions:

- For each of the three CPT codes in the repair of flexor tendon family (26356, 26357 26358) and CMS disagreed with the RUC recommendation citing an anomalous relationship between the drop in intra-service time and the median work RVUs.

    - CMS crosswalked 26356 to 25607 *Open treatment of distal radial extra-articular fracture or epiphyseal separation, with internal fixation.*

    - CMS crosswalked 26357 to 27654 *Repair, secondary, Achilles tendon, with or without graft*.

    - For CPT code 26358, CMS maintained the RUC recommended incremental increase 1.60 work RVUs for "with graft" (i.e., 26358-26357).

RUC Comments:

- The RUC again disagrees with the CMS decision to disregard all clinical and compelling evidence presented at the RUC meeting and instead apply an an arbitrary reduction based on a perceived imbalance in the change in time from current to the survey compared to the change in work RVUs. Below are specific concerns for the family of services:

    - CMS completely fails to even acknowledge the flaws in the current physician time for CPT code 26356. The RUC specifically addressed the drop in physician work noting that there is an anomalous relationship between the current work RVU and the imputed time components in the RUC database. Also, in 1995, fabrication of a splint was included in the intra-service work. In the current survey instrument, however, a splint is considered a dressing and is included in the post-service work. This difference would reasonably explain the 30 minute difference in survey time.

    - To value CPT code 26357, CMS used the crosswalk code 27654 *Repair, secondary, Achilles tendon, with or without graft,* which has less total time and results in an inappropriately lower intensity for 26357 compared to 26356. In contrast, the RUC recommended the survey median value which is supported by the top key reference code 23410 *Repair of rotator cuff; acute* (work RVU= 11.39) and seven additional reference codes with similar intra-service time and work RVUs.

    - Finally, the RUC agrees with the Agency's assertion that 1.60 work RVUs is an appropriate work value increment between 26357 and 26358. However, this increment should be applied to the RUC recommended base RVU of 11.50 for 26357.

- **The RUC urges CMS to accept the RUC recommendations work RVUs of 10.03 for 26356, 11.50 for CPT code 26357 and 13.10 for CPT code 26358.**

C. Esophagogastric Fundoplasty Trans-Oral Approach (CPT Code 43210)

CPT code	Descriptor	RUC Rec RVU	CMS Proposed Interim RVU	CMS Work RVU Decision
43210	Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed	9.00	7.75	Disagree

Summary of CMS Actions:

- CMS disagreed with the RUC recommended median survey work RVU of 9.00, noting that they were unable to identify other CPT codes with identical intra-service time and a work RVU of 9.00 or above. Furthermore, the Agency stated that there were no other approved Esophagogastroduodenoscopy (EGD) codes that were valued as high as 9.00 work RVUs.

RUC Comments:

- The RUC disagrees with the CMS decision for the following reasons:
    - While it is true that no other EGD procedures are valued as high as 9.00, it is also true that only one EGD procedure, 43240, has greater intra-service time. Therefore, it is reasonable that 43210, with greater total time than any procedure in the recently reviewed EGD family should be valued the highest. Furthermore, there are numerous other recently valued endoscopic retrograde cholangiopancreatography (ERCP) endoscopy services which compare favorably to the RUC recommended values.
    - The RUC recommendation compares extremely well with the Key Reference Service 43276 *ERCP; with removal and exchange of stent(s), biliary or pancreatic duct, including pre- and post-dilation and guide wire passage, when performed, including sphincterotomy, when performed, each stent exchanged* (work RVU= 8.94, intra= 60 minutes). These services have identical intra-service time and intensity and should be valued nearly identically.
    - **Given that the RUC recommendation for CPT code 43210 has several comparators within the lower GI endoscopy family as well as strong survey data, with key reference services that are nearly identical in physician work, CMS should accept the RUC recommended work RVU of 9.00. The RUC also requests Refinement Panel consideration for this service.**

D. Percutaneous Biliary Procedures (CPT Codes 47531, 47532, 47533, 47534, 47535, 47536, 47537, 47538, 47539, 47540, 47541, 47542, 47543, and 47544)

Summary of CMS Actions:

- CMS reviewed the RUC submitted interim recommendations for the percutaneous biliary procedures from the April 2015 RUC meeting and rejected four of the interim RUC recommendations (47540, 47542, 47543 and 47544) and accepted the interim recommendations for the rest of the family.

RUC Comments:

- The RUC notes that CMS rejected the interim RUC recommendations for four codes. However, the RUC submitted revised recommendations for the entire family to CMS following the October 2015 RUC meeting.
    - While we understand that CMS did not have a large amount of time to review these recommendations prior to finalizing the Final Rule, the RUC requests that CMS consider the updated recommendations from the October 2015 submission in the 2017 MPFS and not finalize these outdated interim final recommendations. This is critical because the RUC and specialty societies agreed that the initial survey data from the April 2015 RUC meeting for this family of services was problematic. These services were resurveyed for the October 2015 RUC meeting. Leaving in physician time and work values for services that are known to be flawed is not appropriate, especially in a payment system that is based on relativity.
    - **Therefore, CMS should review the 2015 RUC recommendations for these percutaneous biliary procedures for the 2017 NPRM.** The full recommendations are attached to this comment letter (*see 03 Addendum - Percutaneous Biliary Procedures Bundling*).

E. Percutaneous Image Guided Sclerotherapy (CPT Code 49185)

CPT code	Descriptor	RUC Rec RVU	CMS Proposed Interim RVU	CMS Work RVU Decision
49185	Sclerotherapy of a fluid collection (e.g., lymphocele, cyst, or seroma), percutaneous, including contrast injection(s), sclerosant injection(s), diagnostic study, imaging guidance (e.g., ultrasound, fluoroscopy) and radiological supervision and interpretation when performed	2.78	2.35	Disagree

Summary of CMS Actions:

- CMS did not agree with the RUC recommended direct crosswalk for CPT code 49185. Instead the Agency chose CPT code 62305 *Myelography via lumbar injection, including radiological supervision and interpretation; 2 or more regions (e.g., lumbar/thoracic, cervical/thoracic, lumbar/cervical, lumbar/thoracic/cervical).*

- CMS cites that this procedure is more similar in its complexity to the surveyed code.

RUC Comments:

- The RUC does not agree with the Agency's assertion that 62305 is a better crosswalk than the RUC recommended crosswalk to 31622 *Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with cell washing, when performed*. CPT code 31622 was used as the crosswalk for three reasons:

    - The clinical nature of 31622 is analogous to the surveyed code because both are diagnostic studies with imaging included

    - Both services involve performing an analogous procedure (e.g. cell washing compared with sclerosant injection)

    - Both procedures involve the injection procedure repeated at least three separate times

- In contrast, the CMS crosswalk code, 62305, is inappropriate for the following reasons:

    - 62305 involves only a needle, whereas 49185 involves a needle plus placement of a wire, fascial dilator and a catheter

    - 62305 involves a single injection of solution (contrast) whereas 49185 involves the injection of contrast PLUS multiple injections of sclerosant, requiring a greater amount of physician work

    - 62305 is purely a diagnostic procedure, whereas 49185 is both diagnostic and therapeutic, involving greater work, mental effort, technical skill and stress.

- **Given these arguments, CMS should accept the RUC recommended work RVU of 2.78 for CPT code 49185. The RUC also requests Refinement Panel consideration for this service.**

F. Genitourinary Catheter Procedures (CPT Codes 50606, 50705, and 50706)

Summary of CMS Actions:

- The RUC recommended the inclusion of *room, angiography,* (EL011) for this family of Genitourinary Catheter Procedures (GU) codes. CMS states that:

- Since the predecessor procedure codes generally did not include an angiography room and we do not have a reason to believe that the procedure would have shifted to an angiography room in the course of this coding change, we do not believe that the use of an angiography room would be typical for these procedures.

RUC Comments:

- The RUC is not sure what codes CMS is referring to as the predecessor procedure codes in the excerpt above. If CMS is referring to the previously reported codes, than all three CPT code were previously reported using 53899 *Unlisted procedure, urinary system.* This unlisted procedure does not have any PE inputs. The reference code provided is 50387 *Removal and replacement of externally accessible transnephric ureteral stent (e.g., external/internal stent) requiring fluoroscopic guidance, including radiological supervision and interpretation* which includes a *room, angiography,* (EL011) and other codes that are being bundled together to create these new GU codes do include a *room, angiography,* (EL011) as well.

- The RUC disagrees with CMS' refinement to assign this new GU family of procedures to a radiographic-fluoroscopic (R/F) room instead of an angiography room.

  - It is important to note that an R/F device is incapable of 3-axis rotational imaging. An R/F room (fixed imaging plane) is not conducive to performance of these procedures because it cannot image the target surgical field in multiple obliquities except by moving the patient (rolling from side to side). However, rolling the patient is impractical and dangerous while the patient is sedated.

  - Just as importantly, while performing these procedures, the patient must not physically move to avoid physical injury from the needles and other tools used during the procedure.

  - Sterility is also a major concern in an R/F room where the fixed imaging chain is not amenable to standard surgical sterile preparation. Additionally, an R/F room would create unacceptable radiation exposure to the physicians, their staff, and their patients, which would be contrary to ALARA principles of minimized patient radiation dose.

- The typical imaging equipment utilized for this family of GU procedures are the items included in CMS' angiographic room. The only piece of equipment listed in the angiography room that is not typically utilized for these procedures is the *Injector*, *Provis*. All of the other items are used for these GU procedures.

- **The RUC urges CMS to include *room, angiography,* (EL011) for this family of Genitourinary Catheter Procedures (GU) codes. The RUC also requests Refinement Panel consideration for this service.**

G. Laparoscopic Radical Prostatectomy (CPT Code 55866)

CPT code	Descriptor	RUC Rec RVU	CMS Proposed RVU	CMS Work RVU Decision
55866	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed	26.80	21.36	Disagree

Summary of CMS Actions:

- CMS disagreed with the survey 25th percentile work RVU of 26.80 for CPT code 55866 and recommended a crosswalk to the key reference service 55840 *Prostatectomy, retropubic radical, with or without nerve sparing* (work RVU = 21.36).

RUC Comments:

- In the Final Rule for 2014, CMS noted that the majority of commenters indicated that it was appropriate that the work RVUs be higher for CPT code 55866 than for CPT code 55845 *Prostatectomy, retropubic radical, with or without nerve sparing; with bilateral pelvic lymphadenectomy, including external iliac, hypogastric, and obturator nodes* (work RVU = 25.18). The CMS interim-final work RVU for 2016 is much lower than 25.18 and may cause a rank order anomaly.
    - Crosswalk code 55840 is not a laparoscopic procedure and includes nerve sparing when performed and does not include robotic assistance, therefore should not be valued exactly the same as 55866.
    - CPT Code 55866 requires more skill and competency even though it requires similar time as 55840. The intensity scoring by the survey respondents determined that the 55866 was more complex than the 55840. The respondents chose code 55840 as the key reference service because this was the closest procedure to "removing a prostate", however the physician work of the two procedures is totally different. The RUC instructions advise respondents to choose the code that is closest in work to the surveyed code and then determine the work RVU based on the key reference code. There was no laparoscopic/robotic code on the reference list so by default the survey respondents chose 55840 because the outcome was the same.
    - CMS should not discount the survey intensity and complexity comparison gauged by the respondents by choosing to crosswalk to a lower value without providing clinical evidence to support that the physician work is exactly the same.

- The RUC provided five additional reference codes to support the survey recommended value. 50543 *Laparoscopy, surgical; partial nephrectomy* (work RVU = 27.41 and 240 minutes intra-service time), 23473 *Revision of total shoulder arthroplasty, including allograft when performed; humeral or glenoid component* (work RVU = 25.00), 32670 *Thoracoscopy, surgical; with removal of two lobes (bilobectomy)* (work RVU = 28.52) and 43281 *Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; without implantation of mesh* (work RVU = 26.60).

- **The RUC urges CMS to accept the survey 25th percentile work RVU of 26.80 for CPT code 55866. The RUC also requests Refinement Panel consideration for this service.**

H. Intracranial Endovascular Intervention (CPT Codes 61645, 61650 and 61651)

CPT code	Descriptor	RUC Rec RVU	CMS Proposed RVU	CMS Work RVU Decision
61645	Percutaneous arterial transluminal mechanical thrombectomy and/or infusion for thrombolysis, intracranial, any method, including diagnostic angiography, fluoroscopic guidance, catheter placement, and intraprocedural pharmacological thrombolytic injection(s)	17.00	15.00	Disagree
61650	Endovascular intracranial prolonged administration of pharmacologic agent(s) other than for thrombolysis, arterial, including catheter placement, diagnostic angiography, and imaging guidance; initial vascular territory	12.00	10.00	Disagree
61651	Endovascular intracranial prolonged administration of pharmacologic agent(s) other than for thrombolysis, arterial, including catheter placement, diagnostic angiography, and imaging guidance; each additional vascular territory (List separately in addition to the primary code)	5.50	4.25	Disagree

Summary of CMS Actions:

- CMS refined the physician times for certain codes based on the Agency's policy related to 23-hr outpatient surgical codes with post-operative visits (first implemented for CY 2011). For codes the Agency classified as 23-hour stay outpatient services, they removed a subsequent hospital visit and instead added the hospital visit's intra-service time to the immediate post-service time of the procedure. The Agency applied these physician time refinements to codes 61645 and 61650.

- CMS states that it believes that CPT codes 61645, 61650 and 61651 would be considered outpatient hospital services and therefore refined the work time for 61645 and 61650 and value for all three codes.

RUC Comments:

- CMS's assumption is flawed as CPT codes 61645, 61650 and 61651 were previously reported with inpatient services 37184 (66% Inpatient Hospital), 36224 (58% Inpatient Hospital) and 36228 (84% Inpatient Hospital), all based on 2014 Medicare claims data, as indicated in the summary of recommendation forms previously submitted.

    - The new intracranial endovascular intervention codes (61645, 61650 and 61651) are typically performed on acute stroke patients and **are performed in the inpatient hospital**. Therefore, the Agency's 23-hour outpatient policy was inappropriately applied to these services and the physician times for 61645 and 61650 were inappropriately revised. Additionally, 100% of the RUC survey respondents indicated that this service is performed in an inpatient setting.

    - The codes CMS used as crosswalks are inappropriate because they are outpatient codes. If fact, CPT Code 37231, which CMS used to lower the value of 61645, is predominately an office code (52%).

    - The RUC practice expense recommendation further confirms "CPT codes 61645-61651 are facility-only codes therefore the RUC does not have any direct practice input recommendations".

- Due to CMS' flawed assumption regarding the site of service, the reduction in physician time and work associated with the 99233 is inappropriate. This underestimates the time and intensity of the follow up visit which requires the physician to assess the patient's neurologic condition and review interval chart notes, record patient progress, write orders for imaging and labs, answer family questions, and discuss ongoing care with the ICU/stroke unit team.

- CMS should use the data surveyed by over 50 physicians and supported by the extensive review of the RUC. **The RUC urges CMS to accept the survey 25th percentile work RVUs of 17.00 for 61645, 12.00 for 61650 and 5.50 for 61651.**

PLI Crosswalks

Summary of CMS Actions:

- CMS refined the RUC-recommended malpractice crosswalks for this family of codes to align with the specialty mix that furnish the services in this family.

- CMS established the following interim final malpractice crosswalks in place of the RUC-recommended malpractice crosswalks: CPT code 37218 to CPT code 61645; and CPT code 37202 to CPT codes 61650 and 61651.

RUC Comments:

- **The CMS recommended malpractice crosswalks do not represent the specialty mix that will perform these services.**
    - The specialty mix for new services 61645, 61650 and 61651 will be approximately 75% neurosurgery and 25% diagnostic radiology. The RUC recommended PLI crosswalk for all three services was 61791 (80% neurosurgery and 18% diagnostic radiology), which is in line with the specialty mix for the three new services.
    - CMS's recommended malpractice crosswalk of 37218 for 61645 is not appropriate because 37218 was new for 2015 and the specialty mix is not yet known, but was predicted to be 25% diagnostic radiology, 20 % neurosurgery and 20% vascular surgery. This specialty mix is not comparable to who will be performing 61645.
    - CMS's recommended malpractice crosswalk of 37202 for 61650 and 61651 is not appropriate because the specialty mix is 34% cardiology, 21% vascular surgery and 12% general surgery. Neurosurgery will be the dominant specialty performing 61650 and 61651 and only perform about 5% of the CMS recommended crosswalk 37202.
- **The RUC urges CMS to accept the malpractice crosswalk of 61791 for codes 61645, 61650 and 61651 which accounts for the appropriate specialty mix. The RUC also requests Refinement Panel consideration for this service.**

I. Paravertebral Block Injection (CPT Codes 64461, 64462 and 64463)

CPT code	Descriptor	RUC Rec RVU	CMS Proposed RVU	CMS Work RVU Decision
64461	Paravertebral block (PVB) (paraspinous block), thoracic; single injection site (includes imaging guidance, when performed)	1.75	1.75	Agree
64462	Paravertebral block (PVB) (paraspinous block), thoracic; second and any additional injection site(s), (includes imaging guidance, when performed)	1.10	1.10	Agree
64463	Paravertebral block (PVB) (paraspinous block), thoracic; continuous infusion by catheter (includes imaging guidance, when performed)	1.90	1.81	Disagree

Summary of CMS Actions:

- CMS' interim final crosswalk for CPT 64463 is flawed as CPT code 64463 includes imaging guidance when performed and those referenced continuous injection of anesthetic agent codes (64416, 64446 and 64449) do not account for this.

RUC Comments:

- A physician work RVU of 0.09 more for 64443 appropriately reflects the physician work and intensity associated with the paravertebral block and possible imaging guidance.
    - The RUC argues that 64443 is more comparable to the key reference service 64483 *Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, single level* (work RVU = 1.90), which requires the same physician work and time to perform.
- CMS should use the valid survey data and supported by the extensive review of the RUC. **The RUC urges CMS to accept the survey 25th percentile work RVU of 1.90 for CPT code 64463. The RUC also requests Refinement Panel consideration for this service.**
- Additionally, there is a **typo** in the Federal Register/Vol. 80, No. 220/ page 71055. "We believe a direct crosswalk from three other injection codes which all have a work RVU of 1.81 (CPT codes ~~64461~~ 64416, 64446, and 64449) more accurately reflects the work involved in furnishing this service." **The numbers were transposed and should be 64416 not 64461.**

J. Ocular Reconstruction Transplant (CPT Code 65780)

CPT code	Descriptor	RUC Rec RVU	CMS Proposed RVU	CMS Work RVU Decision
65780	Ocular surface reconstruction; amniotic membrane transplantation, multiple layers	8.80	8.00	Disagree

Summary of CMS Actions:

- CMS derived the interim-final work RVU for CPT code 65780 by simply multiplying the current work RVU by the ratio between the RUC recommended total time and the existing total time from 2003 (8.00 RVUs= 10.73 RVUs X (230 minutes /316 minutes).

RUC Comments:

- The Agency's rough calculation distills the valuation of this service into a basic formula with the only variable being the new total physician time. This methodology is based on the incorrect assumption that the per minute physician work intensity established is permanent regardless of when the service was last valued (2003 in this case).

    - The RUC would like to reiterate that different components of a physician service have vastly different intensities of physician work. The RUC recommended IWPUT for the intra-service time component of this service is 0.062, whereas other components of the physician time have established IWPUTs that are up to 7.5 times lower, as displayed in the above graph (*see Section III, A. CMS' Inappropriate Ratio Calculatio*n) in this letter.

    - The proportion of the physician time components with an IWPUT of greater than 0.05 increased from 19% of the current physician time to 42% of the new physician time. In addition, the proportion of physician time components with an intensity of 0.0224 or lower went from 75% of the current physician time to 50% of the new physician time. A full breakdown of the change in physician time is provided in the included charts *(see 02 Addendum - Ocular Reconstruction Transplant).*

- With a higher proportion of physician time shifting to the more intense skin-to-skin time and a higher office visit level (99212 to 99213), using a total time ratio to reduce the work RVU is inappropriate.

- Treating all components of physician time (pre-service, intra-service, post-service and post-operative visits) as having identical intensity is incorrect and inconsistently applying it to only certain services under review creates inherent payment disparities in a payment system which is based on relative valuation.

- **The RUC recommends for CMS to reconsider its decision to not accept the RUC recommendation for CPT code 65780 listed in the table above. The RUC also requests Refinement Panel consideration for this service.**

K. Trabeculoplasty by Laser Surgery (CPT code 65855)

CPT code	Descriptor	RUC Rec RVU	CMS Proposed RVU	CMS Work RVU Decision
65855	Trabeculoplasty by laser surgery	3.00	2.66	Disagree

Summary of CMS Actions:

- CMS selected ratio calculation discounts the relative resources incorporating physician time and intensity required in furnishing the service.

RUC Comments:

- CMS cannot take one element that changed and apply an overall ratio reduction based on changes to intra-service time; this renders the value no longer resource-based.

- The RUC recommendation already accounted for the reduction in physician intra-service time and post-operative visit.

- CMS' recommended work RVU lacks relativity to other similar services.

- **The RUC urges CMS to accept the survey 25th percentile work RVU of 3.00 for 65855**, which correlates accurately to the key reference service 66761, with the same work RVU, intra-service time (10 minutes) and similar total time (66 minutes for 66761 and 61 minutes for 65855). **The RUC also requests Refinement Panel consideration for this service.**

L. Glaucoma Surgery (CPT Codes 66170 and 66172)

CPT Code	Descriptor	RUC Rec RVU	CMS Proposed RVU	CMS Work RVU Decision
66170	Fistulization of sclera for glaucoma; trabeculectomy ab externo in absence of previous surgery	13.94	11.27	Disagree
66172	Fistulization of sclera for glaucoma; trabeculectomy ab externo with scarring from previous ocular surgery or trauma (includes injection of antifibrotic agents)	14.81	12.57	Disagree

Summary of CMS Actions:

- CMS selected ratio calculation discounts the relative resources incorporating physician time and intensity required in furnishing the service.

RUC Comments:

- CMS cannot take one element that changed and apply an overall ration reduction based on changes to intra-service time; this renders the value no longer resource-based.

- CMS' recommended work RVU lacks relativity to other similar services. The two services referenced (44900 and 59100) are not comparable to 66170 and 66172. The referenced services do not require the same intensity and complexity and only account for half of the post-operative services required with 66170 and 66172 to avoid permanent vision loss for the patient.

- CMS referenced codes 44900 and 59100 are not services identified by the RUC on the Multi-Specialty Points of Comparison List.

- The RUC provided five reference codes for both 66170 and 66172, including MPC codes, to support the survey 25th percentile results. Codes 66180 (work RVU = 15.00), 66183 (work RVU = 13.20), 53445 (work RVU = 13.00), 52649 (work RVU = 14.560 and 52601 (work RVU = 15.26).

- CMS should use the data surveyed by 74-88 physicians and supported by the extensive review of the RUC. **The RUC urges CMS to accept the survey 25th percentile work RVU of 13.94 for 66170 and 14.81 for 66172**. **The RUC also requests Refinement Panel consideration for this service.**

M. Retinal Detachment Repair (CPT Codes 67107, 67108, 67110, and 67113)

CPT code	Descriptor	RUC Rec RVU	CMS Proposed RVU	CMS Work RVU Decision
67107	Repair of retinal detachment; scleral buckling (such as lamellar scleral dissection, imbrication or encircling procedure), including, when performed, implant, including, when performed, cryotherapy, photocoagulation, and drainage of subretinal fluid	16.00	14.06	Disagree
67108	Repair of retinal detachment; with vitrectomy, any method, including, when performed, air or gas tamponade, focal endolaser photocoagulation, cryotherapy, drainage of subretinal fluid, scleral buckling, and/or removal of lens by same technique	17.13	15.19	Disagree
67110	Repair of retinal detachment; by injection of air or other gas (e.g., pneumatic retinopexy)	10.25	8.31	Disagree
67113	Repair of complex retinal detachment (e.g., proliferative vitreoretinopathy, stage C-1 or greater, diabetic traction retinal detachment, retinopathy of prematurity, retinal tear of greater than 90 degrees), with vitrectomy and membrane peeling, including, when performed, air, gas, or silicone oil tamponade, cryotherapy, endolaser photocoagulation, drainage of subretinal fluid, scleral buckling, and/or removal of lens	19.00	19.00	Agree

Summary of CMS Actions:

- *67107:* Multiplying the current work RVU by the ratio between the RUC recommended intra-service time and the existing intra-service time (14.06 RVUs= 16.71 RVUs X (90 minutes /107 minutes).

- *67108:* Adding the 1.13 RVU increment, between the RUC recommendations for 67108 and 67107, to the CMS derived work RVU for 67107, resulting in a new RVU of 15.09.

- *67110:* Subtracting the 5.75 RVU increment, between CPT code 67107 and 67110, from the CMS derived work RVU for 67107, resulting in a new RVU of 8.31.

RUC Comments:

- CMS' reliance on existing time to derive new proposed work values for these potentially misvalued service is misguided, as the existing physician times were last determined by the Harvard study over 20 years ago. These reductions appear arbitrary and punitive. By accepting some increments and rejecting others, CMS has not only established inconsistencies within the family of codes, but potentially opened up anomalies across a wide range of services.

- In addition, the new IWPUT values for these three services are inappropriately low with the most egregious being 0.064 for CPT code 67110, putting the physician work intensity of that service in the same range as mid-level office visits. Furthermore, if the RVUs for the CMS-accepted post-operative visits were backed out of the interim-final work RVU for 67110, that would only leave 2.49 RVUs for the 58 minutes of very intense surgical work.

- **The RUC recommends for CMS to reconsider its decision and accept the RUC recommendation for CPT code 67107, 67108 and 67110 listed in the table above.**

- The RUC does not agree with CMS using work RVU increments added to or subtracted from the calculated work RVU for 67107, as it is no longer the appropriate magnitude estimation when the work RVU of 67107 is adjusted to an inappropriate value.

- **The RUC recommends that CMS use magnitude estimation, instead of inappropriate calculations to arrive at work RVUs for CPT codes 67107, 67108 and 67110. The RUC urges CMS to accept work RVUs of 16.00 for code 67107, 17.13 for 67108 and 10.25 for CPT code 67110. The RUC also requests Refinement Panel consideration for this service.**

N. Fetal MRI (CPT Codes 74712 and 74713)

CPT code	Descriptor	RUC Rec RVU	CMS Proposed RVU	CMS Work RVU Decision
74712	Magnetic resonance (e.g., proton) imaging, fetal, including placental and maternal pelvic imaging when performed; single or first gestation	3.00	3.00	Agree
74713	Magnetic resonance (e.g., proton) imaging, fetal, including placental and maternal pelvic imaging when performed; each additional gestation (List separately in addition to code for primary procedure)	1.85	1.78	Disagree

Summary of CMS Actions:

- CMS rejected the RUC's recommendation for the median work RVU and instead proposed the 25th percentile work RVU for 74713. The Agency stated their belief that "the ratio of work to time for these codes" should be similar to these services.

RUC Comments:

- By changing its evaluation process to focusing primarily on the relationship between work and total time for certain services, the Agency has overlooked important clinical information, as is the case for this code family.
    - The typical patient for this service is a woman pregnant with monochorionic diamniotic twins, as 93% of the RUC survey respondents agreed.
    - When comparing CPT codes 74712 and 74713, the intensity of an additional fetus would be greater as twin gestations have a higher incidence of congenital anomalies and propensity for ischemic brain injury, especially in the presence of twin-to-twin transfusion.
    - Twin gestations are more difficult to image, given increased motion artifact of two fetuses versus one.
- **The RUC urges CMS to accept work RVUs of 1.85 for code 74713. The RUC also requests Refinement Panel consideration for this service.**

O. Interstitial Radiation Source Codes (CPT Codes 77778 and 77790)

CPT code	Descriptor	RUC Rec RVU	CMS Proposed RVU	CMS Work RVU Decision
77778	Interstitial radiation source application, complex, includes supervision, handling, loading of radiation source, when performed	8.78	8.00	Disagree
77790	Supervision, handling, loading of radiation source	0.00	0.00	Agree

Summary of CMS Actions:

- CMS questioned the difference between the physician times from the raw survey data relative to the RUC recommended physician times, noting that the times were reduced whereas the median work RVU from the survey was recommended. Therefore, CMS proposed a work RVU of 8.00 which was the survey 25th percentile.

RUC Comments:

- The RUC and CMS have used standardized pre-service time packages for several years now. Virtually all 000-day, 010-day and 090-day services have a difference between the raw survey pre-service time and the standardized pre-service time package; identifying this for an individual service while at the same time accepting it for the vast majority of other services over the past several years is inconsistent with the vast majority CMS decisions in current and past rulemaking.

    - The work for 77790 was unbundled from CPT code 77778. The reduction in work RVUs from 11.32 to 8.78 already fully accounts for this unbundling.

    - RUC recommendations are based on magnitude estimation and detailed review of the clinical work involved in performing a service. In this instance, the RUC determined that the survey respondents accurately estimated the work RVU based on magnitude estimation while overestimating the relatively low intensity pre-service time involved in performing this service.

    - The RUC compared the survey code to the second key reference service 41019 *Placement of needles, catheters, or other device(s) into the head and/or neck region (percutaneous, transoral, or transnasal) for subsequent interstitial radioelement application* (work RVU of 8.84, intra-service time of 90 minutes) and noted that both services have identical intra-service time and post-service time and should be valued similarly. To further justify a work RVU of 8.78 for the survey code, the RUC reviewed CPT code 52355 *Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with resection of ureteral or renal pelvic tumor* (work RVU of 9.00, intra-service time of 90 minutes) and noted that both services have identical intra-service time and similar intensities and therefore should be valued similarly.

- **The RUC recommends for CMS to reconsider its decision to not accept the RUC recommendation for CPT code 77778 and to accept work RVUs of 8.78. The RUC also requests Refinement Panel consideration for this service.**

P. Colon Transit Imaging (CPT Codes 78264, 78265, and 78266)

CPT code	Descriptor	RUC Rec RVU	CMS Proposed RVU	CMS Work RVU Decision
78264	Gastric emptying imaging study (e.g., solid, liquid, or both);	0.80	0.74	Disagree
78265	Gastric emptying imaging study (e.g., solid, liquid, or both); with small bowel transit, up to 24 hours	0.98	0.98	Agree
78266	Gastric emptying imaging study (e.g., solid, liquid, or both); with small bowel and colon transit, multiple days	1.08	1.08	Agree

Summary of CMS Actions:

- CMS mistakenly observed that "CPT code 78264 has a higher recommended work RVU and a shorter intraservice time relative to the other codes in the family." CMS also highlighted the reduction in intra-service time from 12 minutes to 10 minutes.

- CMS proposed a work RVU of 0.74 by directly crosswalking to CPT code 78226 (Hepatobiliary system imaging, including gallbladder when present), noting that both codes have intraservice time of 10 minutes and their belief that both services have similar intensity.

RUC Comments:

- CMS' rationale is primarily based on the incorrect observation that "CPT code 78264 has a higher recommended work RVU and a shorter intraservice time relative to the other codes in the family." The RUC recommended work RVUs for these services were 0.80 for 78264, 0.98 for 78265 and 1.08 for 78266.

- When working with estimates of time, a change in the median intra-service time of only 2 minutes should not be used as the remaining sole rationale for rejecting a RUC recommendation.

- **The RUC urges CMS to accept the RUC recommendation for CPT code 78264 and urges CMS to accept work RVUs of 0.80. The RUC also requests Refinement Panel consideration for this service.**

Q. Reflectance Confocal Microscopy (CPT Codes 96931-96936)

Summary of CMS Actions:

- In the CY 2016 Final Rule, CMS proposed for reflectance confocal microscopy codes 96931-96936 to be carrier priced for CY 2016 as the Agency did not yet have the opportunity to review the RUC recommendations submitted for this new family of services in October 2015.

RUC Comments:

- The RUC resubmitted the recommendation attached to this comment letter (*see 04 Addendum – Reflectance Confocal Microscopy*). The RUC would appreciate the Agency's consideration as soon as possible

IV. CY 2016 Identification and Review of Potentially Misvalued Services

The RUC continues to ensure that potentially misvalued services are fairly identified and reviewed. Since 2006, the RUC's efforts have led to the identification of more than 1,900 codes and resulted in nearly $4 billion in redistribution within the Medicare Physician Payment Schedule. A report of the RUC's progress in this project is attached to this letter (*see 05 Addendum - Progress of Relativity Assessment Workgroup November 2015*).

- In the Final Rule, CMS revised the list of codes identified as potentially misvalued in a proposed rulemaking "High Expenditure" screen based on comments received. The RUC is prepared to start reviewing these services at the January 2016 RUC meeting.

- The RUC will also review other potentially misvalued services in which CMS is seeking public comment.

V. Resource-Based Practice Expense (PE) Relative Value Units (RVUs)

A. Practice Expense Inputs for Digital Imaging Services

- The RUC agrees with CMS' decision to update the price for the PACS workstation to $5,557 from the current price of $2,501 since the latter price was based on the proxy item and the former based on submitted invoices.

- We appreciate that CMS acknowledges that the professional workstations for interpretation of digital images are similar in principle to some of the previous direct film inputs incorporated into the global and technical components of the codes, and that it may be appropriate to include these costs as direct inputs for the associated CPT codes.

- The RUC defers to the radiology specialties to determine the services that require this equipment.

B. Clinical Labor Tasks associated with Digital Imaging

- The RUC appreciates that CMS accepted our recommendation to maintain line item, *Technologist QC's images in PACS, checking for all images, reformats, and dose page*, as a nonstandard clinical staff activity.

- CMS has requested comment on establishing several different standard times for this clinical labor task for a low/medium/high quantity of images to be reviewed, in future rulemaking. Although, The RUC agrees that defining standards for specific clinical labor activities has value in maintaining the relativity of direct PE inputs, we maintain that for *Technologist QC's images in PACS, checking for all images, reformats, and dose page,* the number of minutes varies significantly for different modalities and the time is not simple based on the quantity of images to be reviewed.

- If there were a standard, the appropriate time would need to be defined for each modality, recognizing that even within the same modality, QC times could vary based on the complexity of the examination. This would be confusing and add unnecessary complexity.

- **The RUC recommends that this line item remain nonstandard and that the specialty continues to have the opportunity to use their clinical judgment and expertise to make a recommendation of the appropriate number of minutes.**

C. Pathology Clinical Labor Tasks

- The RUC appreciates CMS' acknowledgment that batch size and number of blocks play an important role in the labor time of clinical staff. We support submission of detailed information regarding batch size and number of blocks as part of the RUC's PE submission for Pathology services.

- The RUC will work with the Pathology specialties to be able to include that information moving forward. As stated in our comments in response to the proposed rule, the RUC does not support the standardization of clinical labor activities across all pathology services, as each pathology service encompasses distinct and unique clinical labor tasks. We recognize that it may be possible to establish some clinical labor standards for pathology services on a "per block" or "per batch size" basis, however we defer comment on how best to do this to the Pathology specialties.

- The RUC understands CMS' concern about consistencies across the codes that the specialty performs.

- The RUC agrees that some of the clinical labor times that CMS has standardized may be appropriate for some pathology services; however the RUC maintains that it is not appropriate to standardize all clinical labor activities across Pathology and **urges CMS to limit standardization to the PE direct inputs listed in this final rule.**

D. Methodology for Establishing the Direct PE Inputs Used to Develop PE RVUs

1. New Supply and Equipment Items

- The RUC appreciates CMS' acceptance of the recommendation to create a new equipment code, *radiofrequency generator (Gyrus ENT G3 workstation)* (EQ374), for the radiofrequency generator used in otolaryngology CPT codes 41530, 43228, 43229, and 43270 and maintenance of the current pricing for *radiofrequency generator (NEURO)* (EQ214) impacting CPT codes 64633, 64634, 64635, and 64636.

2. Refinement Table

- The RUC appreciates CMS' effort to maintain appropriate relativity among PE and work components of PFS payment and in some cases we agree with the refinement of direct PE inputs listed in Table 16, however there are many instances where the RUC disagrees with the refinements. Please see a complete list of the *CY 2016 Interim Final Codes with Direct PE Input Recommendations Accepted With Refinements* with specialty society comments in the attached table (*see 06 Addendum - CY2016 - CMS FR PE Refinements w-spec comment*).

Thank you for your careful consideration of the RUC's comments on the CMS Final Rule on the revisions to Medicare payment policies under the Physician Payment Schedule for calendar year 2016, published in the November 16, 2015 *Federal Register (Vol. 80, No. 220 FR, pages 70886-71386, November 16, 2015)*. Please do not hesitate to contact the RUC with questions about our recommendations and comments. We appreciate the continued opportunities to offer recommendations to improve the RBRVS.

Sincerely,

Peter K. Smith, MD

cc: RUC Participants
Edith Hambrick, MD
Ryan Howe
Steve Phurrough, MD
Chava Sheffield
Marge Watchorn
Michael Soracoe

Action Plan for Review of Potentially Misvalued Services
September 2014

CPT Code	Descriptor	Work RVU	Global
15002	Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, trunk, arms, legs; first 100 sq cm or 1% of body area of infants and children	3.65	000

Screen: *Pre-Time Analysis*

Include codes from family (please list all): N/A

Please check all recommended actions that apply:
(If necessary, please clearly mark and attach all supplemental information)

- ❑ **Survey**
- ❑ **Refer to CPT/CPT Assistant**
- ☒ **Maintain work RVU**
- ☒ **Other Action (please describe): Update pre-service time to be consistent with pre-time packages.**

Rationale for Recommended Action:

1. **Current total pre-service time:** 75

2. **Median times for pre-service components from the most recent survey:**

RUC Year	CPT Code	Median Survey Times		
		EVAL	POSIT	SDW
2006	15002	45	15	15

3. **Specialty recommendation for pre-service package to be applied to the code, with any recommended adjustments to the package:**

   Recommended Pre-time Package: 4 - Difficult Patient/Difficult Procedure

	EVAL	POSIT	SDW
Recommended Pre-Time Package 4	40	3	20
+ /- Adjustments to Pre-Time Package	0	+12	-5
Specialty Recommended Pre-Service Time	40	15	15

4. **Specialty recommendation for a crosswalk code to support the recommended pre-service time changes:**

   Evaluation: No change to pre-time package.

   Positioning: Add 12 minutes (total = 15 minutes). Burn patients typically encounter burns on multiple surfaces that will require re-positioning throughout the procedure. For example, a burn of the shoulder, chest, and arm (typical for 15002) will involve separate supine and lateral positioning to allow access to all burn sites. In addition, patients do not typically arrive in the OR with their prior dressings removed, resulting in a more extensive procedure prep. After transfer to the OR table, the patients will be sedated &/or anesthetized prior to removal of previous dressings. This is followed by surgical prepping and draping prior to the procedure. A total of 15 minutes for positioning is supported by CPT code 15277 *Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children* (reviewed by the RUC in 2011).

   Scrub, dress, wait: Subtract 5 minutes to be consistent with the survey median.

5. **Summary of the RUC rationale for code valuation, to indicate whether the code was valued based on magnitude estimation or other methodology:**

   The RUC accepted the median survey work RVU using magnitude estimation. This value was then adjusted (reduced) for family work neutrality.

Timeline (please list expected CPT/RUC meetings as applicable):

September 2014 RUC meeting.

Action Plan for Review of Potentially Misvalued Services
September 2014

CPT Code	Descriptor	Work RVU	Global
15004	Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet and/or multiple digits; first 100 sq cm or 1% of body area of infants and children	4.58	000

Screen: *Pre-Time Analysis*

Include codes from family (please list all): N/A

Please check all recommended actions that apply:
(If necessary, please clearly mark and attach all supplemental information)
❑ **Survey**
❑ **Refer to CPT/CPT Assistant**
☒ **Maintain work RVU**
☒ **Other Action (please describe): Update pre-service time to be consistent with pre-time packages.**

Rationale for Recommended Action:

1. **Current total pre-service time:** 75

2. **Median times for pre-service components from the most recent survey:**

RUC Year	CPT Code	Median Survey Times		
		EVAL	POSIT	SDW
2006	15004	45	15	15

3. **Specialty recommendation for pre-service package to be applied to the code, with any recommended adjustments to the package:**

   Recommended Pre-time Package: 4 - Difficult Patient/Difficult Procedure

	EVAL	POSIT	SDW
Recommended Pre-Time Package 4	40	3	20
+ /- Adjustments to Pre-Time Package	0	+12	-5
Specialty Recommended Pre-Service Time	40	15	15

4. **Specialty recommendation for a crosswalk code to support the recommended pre-service time changes:**

   Evaluation: No change to pre-time package.

   Positioning: Add 12 minutes (total = 15 minutes). Burn patients typically encounter burns on multiple surfaces that will require re-positioning throughout the procedure. For example, a burn of the face, scalp, and neck (typical for 15004) will involve separate supine and lateral positioning to allow access to all burn sites. In addition, patients do not typically arrive in the OR with their prior dressings removed, resulting in a more extensive procedure prep. After transfer to the OR table, the patients will be sedated &/or anesthetized prior to removal of previous dressings. This is followed by surgical prepping and draping prior to the procedure. A total of 15 minutes for positioning is supported by CPT code 15277 *Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children* (reviewed by the RUC in 2011).

   Scrub, dress, wait: Subtract 5 minutes to be consistent with the survey median.

5. **Summary of the RUC rationale for code valuation, to indicate whether the code was valued based on magnitude estimation or other methodology:**

   The RUC accepted the median survey work RVU using magnitude estimation. This value was then adjusted (reduced) for family work neutrality.

Timeline (please list expected CPT/RUC meetings as applicable):

September 2014 RUC meeting.

Action Plan for Review of Potentially Misvalued Services
September 2014

CPT Code	Descriptor	Work RVU	Global
15100	Split-thickness autograft, trunk, arms, legs; first 100 sq cm or less, or 1% of body area of infants and children (except 15050)	9.90	090

Screen: *Pre-Time Analysis*

Include codes from family (please list all): N/A

Please check all recommended actions that apply:
(If necessary, please clearly mark and attach all supplemental information)

❑ **Survey**
❑ **Refer to CPT/CPT Assistant**
☒ **Maintain work RVU**
☒ **Other Action (please describe): Update pre-service time to be consistent with pre-time packages.**

Rationale for Recommended Action:

1. **Current total pre-service time:** 65

2. **Median times for pre-service components from the most recent survey:**

RUC Year	CPT Code	Median Survey Times		
		EVAL	POSIT	SDW
2005	15100	45	10	10

3. **Specialty recommendation for pre-service package to be applied to the code, with any recommended adjustments to the package:**

   Recommended Pre-time Package: 4 - Difficult Patient/Difficult Procedure

	EVAL	POSIT	SDW
Recommended Pre-Time Package 4	40	3	20
+ /- Adjustments to Pre-Time Package	0	+7	-10
Specialty Recommended Pre-Service Time	40	10	10

4. **Specialty recommendation for a crosswalk code to support the recommended pre-service time changes:**

   Evaluation: No change to pre-time package.

Positioning: Add 7 minutes (total = 10 minutes). Split thickness grafts will involve several separate operative sites. For example, a graft may be taken from the lower extremity and applied to the upper extremity. The involved sites may require supine, lateral, and / or prone positioning / repositioning. A total of 10 minutes for positioning is supported by CPT code 15273 *Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children* (reviewed by the RUC in 2011).

Scrub, dress, wait: Subtract 10 minutes to be consistent with the survey median.

5. **Summary of the RUC rationale for code valuation, to indicate whether the code was valued based on magnitude estimation or other methodology:**

   The RUC determined the survey 25th percentile work RVU was almost identical to the current work RVU and recommended maintaining the current RVU.

Timeline (please list expected CPT/RUC meetings as applicable):

September 2014 RUC meeting.

Action Plan for Review of Potentially Misvalued Services
September 2014

CPT Code	Descriptor	Work RVU	Global
15240	Full thickness graft, free, including direct closure of donor site, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands, and/or feet; 20 sq cm or less	10.41	090

Screen: *Pre-Time Analysis*

Include codes from family (please list all): N/A

Please check all recommended actions that apply:
(If necessary, please clearly mark and attach all supplemental information)

❑ **Survey**
❑ **Refer to CPT/CPT Assistant**
☒ **Maintain work RVU**
☒ **Other Action (please describe): Update pre-service time to be consistent with pre-time packages.**

Rationale for Recommended Action:

1. **Current total pre-service time:** 65

2. **Median times for pre-service components from the most recent survey:**

RUC Year	CPT Code	Median Survey Times		
		EVAL	POSIT	SDW
2005	15240	45	10	10

3. **Specialty recommendation for pre-service package to be applied to the code, with any recommended adjustments to the package:**

Recommended Pre-time Package: 4 - Difficult Patient/Difficult Procedure, Facility

	EVAL	POSIT	SDW
Recommended Pre-Time Package Time	40	3	20
+ /- Adjustments to Pre-Time Package	0	0	0
Specialty Recommended Pre-Service Time	40	3	20

4. **Specialty recommendation for a crosswalk code to support the recommended pre-service time changes:**

   Evaluation: No change from the pre-time package of 40 minutes. 5 minute reduction from current RUC time.

   Positioning: No change from pre-time package of 3 minutes. 7 minute reduction from current RUC time.

   Scrub, dress, wait: Use standard package. Add 10 minutes to current RUC time.

5. **Summary of the RUC rationale for code valuation, to indicate whether the code was valued based on magnitude estimation or other methodology:**

   Changed current RUC pre-time to match standard package 4. This is a reduction of 2 minutes from the current RUC times.

Timeline (please list expected CPT/RUC meetings as applicable):

N/A

Action Plan for Review of Potentially Misvalued Services
September 2014

CPT Code	Descriptor	Work RVU	Global
20680	Removal of implant; deep (eg, buried wire, pin, screw, metal band, nail, rod or plate)	5.96	090

Screen: *Pre-Time Analysis*

Include codes from family (please list all):

Please check all recommended actions that apply:
(If necessary, please clearly mark and attach all supplemental information)

❑ **Survey**
❑ **Refer to CPT/CPT Assistant**
☒ **Maintain work RVU**
☒ **Other Action (please describe): Update pre-service time to be consistent with pre-time packages.**

Rationale for Recommended Action:

1. **Current total pre-service time:** 65 minutes

2. **Median times for pre-service components from the most recent survey**

RUC Year	CPT Code	Median Survey Times		
		EVAL	POSIT	SDW
2005	20680	35	15	15

3. **Specialty recommendation for pre-service package to be applied to the code, with any recommended adjustments to the package;**

Recommended Pre-time Package: 3-Straightforward Procedure/Difficult Patient

	EVAL	POSIT	SDW
Recommended Pre-Time Package Time	33	3	15
+ /- Adjustments to Pre-Time Package	0	12	0
Specialty Recommended Pre-Service Time	33	15	15

Evaluation: No change to pre-time package.

Positioning: Add 12 minutes (total = 15 minutes) for positioning. A total of 15 minutes for positioning is supported by CPT codes 23334 *Removal of prosthesis, includes debridement and synovectomy when performed; humeral or glenoid component* (reviewed by the RUC in 2013).

Scrub, dress, wait: No change to pre-time package.

4. **Specialty recommendation for a crosswalk code to support the recommended pre-service time changes**
   CPT code 23334, Removal of prosthesis, includes debridement and synovectomy when performed; humeral or glenoid component which was RUC surveyed in 2013.

RUC Year	CPT Code	Median Survey Times		
		EVAL	POSIT	SDW
2013	23334	40	15	20

5. **Summary of the RUC rationale for code valuation, to indicate whether the code was valued based on magnitude estimation or other methodology**

   The RUC used magnitude estimation as part of the review of 20680 in 2005 which accepted a value near the 25th percentile survey RVW while accounting for a change in site-of-service.

Timeline (please list expected CPT/RUC meetings as applicable):

September 2014 RUC meeting.

Action Plan for Review of Potentially Misvalued Services
September 2014

CPT Code	Descriptor	Work RVU	Global
22612	Arthrodesis, posterior or posterolateral technique, single level; lumbar (with lateral transverse technique, when performed)	23.53	090

Screen: *Pre-Time Analysis*

Include codes from family (please list all):

Please check all recommended actions that apply:
(If necessary, please clearly mark and attach all supplemental information)

❑ **Survey**
❑ **Refer to CPT/CPT Assistant**
☒ **Maintain work RVU**
☒ **Other Action (please describe): Update pre-service time to be consistent with pre-time packages.**

Rationale for Recommended Action:

1. **Current total pre-service time:** 95 minutes

2. **Median times for pre-service components from the most recent survey**

RUC Year	CPT Code	Median Survey Times		
		EVAL	POSIT	SDW
2005	22612	60	20	15

3. **Specialty recommendation for pre-service package to be applied to the code, with any recommended adjustments to the package;**

   Recommended Pre-time Package: 4-Difficult Procedure/Difficult Patient

	EVAL	POSIT	SDW
Recommended Pre-Time Package Time	40	3	20
+ /- Adjustments to Pre-Time Package	0	15	-5
Specialty Recommended Pre-Service Time	40	18	15

4. **Specialty recommendation for a crosswalk code to support the recommended pre-service time changes**

   Evaluation: No change to pre-time package.

   Positioning: Add 15 minutes (total = 18 minutes) for SS3 positioning [Posterior Thoracic/Lumbar (Prone) (eg laminectomy)] which occurs after patient is placed supine and lines /anesthesia are placed. A total of 18 minutes for positioning is supported by CPT codes 22633 *Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar* (reviewed by the RUC in 2011).

   Scrub, dress, wait: Subtract 5 minutes from package time to be consistent with survey median of 15 minutes.

5. **Summary of the RUC rationale for code valuation, to indicate whether the code was valued based on magnitude estimation or other methodology**

   The RUC used magnitude estimation and recommended the survey 25th percentile work RVU.

Timeline (please list expected CPT/RUC meetings as applicable):

September 2014 RUC meeting.

Action Plan for Review of Potentially Misvalued Services
September 2014

CPT Code	Descriptor	Work RVU	Global
23412	Repair of ruptured musculotendinous cuff (eg, rotator cuff) open; chronic	11.93	090

Screen: *Pre-Time Analysis*

Include codes from family (please list all):

Please check all recommended actions that apply:
(If necessary, please clearly mark and attach all supplemental information)

❑ **Survey**
❑ **Refer to CPT/CPT Assistant**
☒ **Maintain work RVU**
☒ **Other Action (please describe): Update pre-service time to be consistent with pre-time packages.**

Rationale for Recommended Action:

1. **Current total pre-service time:** 70 minutes

2. **Median times for pre-service components from the most recent survey**

RUC Year	CPT Code	Median Survey Times		
		EVAL	POSIT	SDW
2008	23412	40	15	15

3. **Specialty recommendation for pre-service package to be applied to the code, with any recommended adjustments to the package;**

Recommended Pre-time Package: 4-Difficult Procedure/Difficult Patient

	EVAL	POSIT	SDW
Recommended Pre-Time Package Time	40	3	20
+ /- Adjustments to Pre-Time Package	0	12	-5
Specialty Recommended Pre-Service Time	40	15	15

Evaluation: No change to pre-time package.

Positioning: Add 12 minutes (total = 15 minutes) for positioning. A total of 15 minutes for positioning is supported by CPT codes 23472 *Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (eg, total shoulder))* (reviewed by the RUC in 2012).

Scrub, dress, wait: Subtract 5 minutes from pre-time package 4 to match survey SDW time.

4. **Specialty recommendation for a crosswalk code to support the recommended pre-service time changes**
   CPT code 23472, Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (eg, total shoulder)) which was RUC surveyed in 2012.

RUC Year	CPT Code	Median Survey Times		
		EVAL	POSIT	SDW
2012	23472	40	15	20

5. **Summary of the RUC rationale for code valuation, to indicate whether the code was valued based on magnitude estimation or other methodology**

   The RUC used a combination of magnitude estimation and reverse building block methodology as part of the review of 23412 in 2008. However, our recommended pre-service times result in no change in total pre-service time.

Timeline (please list expected CPT/RUC meetings as applicable):

September 2014 RUC meeting.

Action Plan for Review of Potentially Misvalued Services
September 2014

CPT Code	Descriptor	Work RVU	Global
25609	Open treatment of distal radial intra-articular fracture or epiphyseal separation; with internal fixation of 3 or more fragments	14.38	090

Screen: *Pre-Time Analysis*

Include codes from family (please list all):

25606	Percutaneous skeletal fixation of distal radial fracture or epiphyseal separation	8.31	090
25607	Open treatment of distal radial extra-articular fracture or epiphyseal separation, with internal fixation	9.56	090
25608	Open treatment of distal radial intra-articular fracture or epiphyseal separation; with internal fixation of 2 fragments	11.07	090

Please check all recommended actions that apply:
(If necessary, please clearly mark and attach all supplemental information)

❑ **Survey**
❑ **Refer to CPT/CPT Assistant**
☒ **Maintain: work RVU**
☒ **Other Action (please describe): Update pre-service time to be consistent with pre-time packages.**

Rationale for Recommended Action:

1. **Current total pre-service time:** 65 for all four codes

2. **Median times for pre-service components from the most recent survey:**

RUC Year	CPT Code	Median Survey Times		
		EVAL	POSIT	SDW
2006	25606	40	10	15
2006	25607	40	10	15
2006	25608	40	10	15
2006	25609	40	10	15

3. **Specialty recommendation for pre-service package to be applied to the code, with any recommended adjustments to the package:**

   Recommendation applies to all four codes.

Recommended Pre-time Package: 3 - FAC Straightforward Patient/Difficult Procedure

	EVAL	POSIT	SDW
Recommended Pre-Time Package 3	33	3	15
+ /- Adjustments to Pre-Time Package	0	+7	0
Specialty Recommended Pre-Service Time	33	10	15

4. Specialty recommendation for a crosswalk code to support the recommended pre-service time changes:

Evaluation: No change to pre-time package.

Positioning: Add 7 minutes (total = 10 minutes) for application of a tourniquet, rotating patient onto a hand table, setting up fluoroscopy for guidance during procedure, and shoulder bump padding. This is less than additional positioning time that has been approved for many similar hand operations, but is consistent with the survey median time. A total of 10 minutes for positioning is supported by CPT codes 27792 *Open treatment of distal fibular fracture (lateral malleolus), includes internal fixation, when performed* (reviewed by the RUC in 2011) and 14301 *Adjacent tissue transfer or rearrangement, any area; defect 30.1 sq cm to 60.0 sq cm* (reviewed by the RUC in 2009)

Scrub, dress, wait: No change to pre-time package.

5. Summary of the RUC rationale for code valuation, to indicate whether the code was valued based on magnitude estimation or other methodology:

The RUC used magnitude estimation compared with other similar fracture repair services and recommended the survey 25th percentile for all four codes.

Timeline (please list expected CPT/RUC meetings as applicable):

September 2014 RUC meeting.

Action Plan for Review of Potentially Misvalued Services
September 2014

CPT Code	Descriptor	Work RVU	Global
27134	Revision of total hip arthroplasty; both components, with or without autograft or allograft	30.28	090

Screen: *Pre-Time Analysis*

Include codes from family (please list all):

Please check all recommended actions that apply:
(If necessary, please clearly mark and attach all supplemental information)

❑ **Survey**
❑ **Refer to CPT/CPT Assistant**
☒ **Maintain work RVU**
☒ **Other Action (please describe): Update pre-service time to be consistent with pre-time packages.**

Rationale for Recommended Action:

1. **Current total pre-service time:** 90 minutes

2. **Median times for pre-service components from the most recent survey**

RUC Year	CPT Code	Median Survey Times		
		EVAL	POSIT	SDW
1995	27134	90		

3. **Specialty recommendation for pre-service package to be applied to the code, with any recommended adjustments to the package;**

   Recommended Pre-time Package: 4-Difficult Procedure/Difficult Patient

	EVAL	POSIT	SDW
Recommended Pre-Time Package Time	40	3	20
+ /- Adjustments to Pre-Time Package	15	12	0
Specialty Recommended Pre-Service Time	55	15	20

Rationale for Recommended Data:

Evaluation time: Recommend the standard package time of 40 minutes plus 15 additional minutes (55 minutes total) for check/set up room, supplies and equipment which is assigned 5 minutes under package 4. For 27134, the typical procedure requires coordination with company reps making sure the appropriate implants are sterilized and available. The bone graft options have to be available, reviewed and ready for the case. The extraction devices for the implants also need to be present and reviewed and verified. In revision total joint surgery this take much more time since multiple combinations of implants have to be available especially for bone loss situations. In addition, a urinary catheter is typically inserted in revision cases and this also occurs pre-positioning of the patient.

Positioning time: Recommend additional 12 minutes (15 minutes total) for patient positioning which is consistent with positioning time for other recently surveyed hip procedures such as CPT code 27130, RUC reviewed in 2013.

Scrub, Dress, Wait time: No change from standard pre-service package.

4. **Specialty recommendation for a crosswalk code to support the recommended pre-service time changes**
   CPT code 27130, Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft which was RUC surveyed in 2013.

RUC Year	CPT Code	Median Survey Times		
		EVAL	POSIT	SDW
2013	27130	40	15	20

   Please note that 27134 represents considerably more work than 27130, including pre-service work as detailed above.

5. **Summary of the RUC rationale for code valuation, to indicate whether the code was valued based on magnitude estimation or other methodology**

   The RUC used magnitude estimation to arrive at the current RVW for 27134 as part of the 5 year review. It is also noted that our recommended pre-service time represents no change from the current pre-service time, but only redistributes the time across the three categories and accounts for the additional clinical pre-service physician work time typical for 27134.

Timeline (please list expected CPT/RUC meetings as applicable):

September 2014 RUC meeting.

Action Plan for Review of Potentially Misvalued Services
September 2014

CPT Code	Descriptor	Work RVU	Global
27814	Open treatment of bimalleolar ankle fracture (eg, lateral and medial malleoli, or lateral and posterior malleoli, or medial and posterior malleoli), includes internal fixation, when performed	10.62	090

Screen: *Pre-Time Analysis*

Include codes from family (please list all):

Please check all recommended actions that apply:
(If necessary, please clearly mark and attach all supplemental information)

- ❑ **Survey**
- ❑ **Refer to CPT/CPT Assistant**
- ☒ **Maintain work RVU**
- ☒ **Other Action (please describe): Update pre-service time to be consistent with pre-time packages.**

Rationale for Recommended Action:

1. **Current total pre-service time:** 70 minutes

2. **Median times for pre-service components from the most recent survey**

RUC Year	CPT Code	Median Survey Times		
		EVAL	POSIT	SDW
2007	27814	45	10	15

3. **Specialty recommendation for pre-service package to be applied to the code, with any recommended adjustments to the package;**

   Recommended Pre-time Package: 3-Straightforward Procedure/Difficult Patient

	EVAL	POSIT	SDW
Recommended Pre-Time Package Time	33	3	15
+ /- Adjustments to Pre-Time Package	0	7	0
Specialty Recommended Pre-Service Time	33	10	15

   Evaluation: No change to pre-time package.

Positioning: Add 7 minutes (total = 10 minutes) for positioning. A total of 10 minutes for positioning is supported by CPT codes 27691 *Transfer or transplant of single tendon (with muscle redirection or rerouting); deep (eg, anterior tibial or posterior tibial through interosseous space, flexor digitorum longus, flexor hallucis longus, or peroneal tendon to midfoot or hindfoot)* (reviewed by the RUC in 2008). For bimalleolar fractures, during positioning the physician will apply padding and tourniquet to the patient's limb, set tourniquet pressure and duration alarms; confirm control unit is function, place bump under buttock, support ipsilateral upper extremity (eg, pillow/blankets under shoulder/arm), support opposite lower extremity so it does not fall off the table (tape, bolsters, etc) and position the c-arm or fluoroscopy equipment and monitor and confirm ability to image the operative area and in the case of fluoroscopy, take and wait for images as part of positioning.

Scrub, dress, wait: No change to pre-time package.

4. **Specialty recommendation for a crosswalk code to support the recommended pre-service time changes**

   CPT code 27691, Transfer or transplant of single tendon (with muscle redirection or rerouting); deep (eg, anterior tibial or posterior tibial through interosseous space, flexor digitorum longus, flexor hallucis longus, or peroneal tendon to midfoot or hindfoot) which was RUC surveyed in 2008.

RUC Year	CPT Code	Median Survey Times		
		EVAL	POSIT	SDW
2008	27691	33	10	15

5. **Summary of the RUC rationale for code valuation, to indicate whether the code was valued based on magnitude estimation or other methodology**

   The RUC used a magnitude estimation to arrive at the current RVW for 27814 in 2008 as part of the review of all fracture repair with internal fixation codes.

Timeline (please list expected CPT/RUC meetings as applicable):

September 2014 RUC meeting.

Action Plan for Review of Potentially Misvalued Services
September 2014

CPT Code	Descriptor	Work RVU	Global
29827	Arthroscopy, shoulder, surgical; with rotator cuff repair	15.59	090

Screen: *Pre-Time Analysis*

Include codes from family (please list all):

Please check all recommended actions that apply:
(If necessary, please clearly mark and attach all supplemental information)

❑ **Survey**
❑ **Refer to CPT/CPT Assistant**
☒ **Maintain work RVU**
☒ **Other Action (please describe): Update pre-service time to be consistent with pre-time packages.**

Rationale for Recommended Action:

1. **Current total pre-service time:** 75 minutes

2. **Median times for pre-service components from the most recent survey**

RUC Year	CPT Code	Median Survey Times		
		EVAL	POSIT	SDW
2002	29827	75		

3. **Specialty recommendation for pre-service package to be applied to the code, with any recommended adjustments to the package;**

Recommended Pre-time Package: 3-Straightforward Procedure/Difficult Patient

	EVAL	POSIT	SDW
Recommended Pre-Time Package Time	33	3	15
+ /- Adjustments to Pre-Time Package	0	12	0
Specialty Recommended Pre-Service Time	33	15	15

Evaluation: No change to pre-time package.

Positioning: Add 12 minutes (total = 15 minutes) for positioning. A total of 15 minutes for positioning is supported by CPT codes 29828 *Arthroscopy, shoulder, surgical; biceps tenodesis* (reviewed by the RUC in 2012).

Scrub, dress, wait: No change to pre-time package.

4. **Specialty recommendation for a crosswalk code to support the recommended pre-service time changes**
   CPT code 29828, Arthroscopy, shoulder, surgical; biceps tenodesis which was RUC surveyed in 2012.

RUC Year	CPT Code	Median Survey Times		
		EVAL	POSIT	SDW
2012	29828	33	15	15

5. **Summary of the RUC rationale for code valuation, to indicate whether the code was valued based on magnitude estimation or other methodology**

   The RUC used magnitude estimation to arrive at the current RVW for 29827 in 2002. Specifically the RUC compared the survey RVW for 29827 to 29806 for the overall RVW recommendation.

Timeline (please list expected CPT/RUC meetings as applicable):

September 2014 RUC meeting.

Action Plan for Review of Potentially Misvalued Services
September 2014

CPT Code	Descriptor	Work RVU	Global
47562	Laparoscopy, surgical; cholecystectomy	10.47	090

Screen: *Pre-Time Analysis*

Include codes from family (please list all): N/A

Please check all recommended actions that apply:
(If necessary, please clearly mark and attach all supplemental information)

❑ **Survey**
❑ **Refer to CPT/CPT Assistant**
☒ **Maintain: work RVU**
☒ **Other Action (please describe): Update pre-service time to be consistent with pre-time packages.**

Rationale for Recommended Action:

1. **Current total pre-service time:** 65

2. **Median times for pre-service components from the most recent survey:**

RUC Year	CPT Code	Median Survey Times		
		EVAL	POSIT	SDW
2005	47562	40	10	15

3. **Specialty recommendation for pre-service package to be applied to the code, with any recommended adjustments to the package:**

   Recommended Pre-time Package: 3 - FAC Straightforward Patient/Difficult Procedure

	EVAL	POSIT	SDW
Recommended Pre-Time Package 3	33	3	15
+ /- Adjustments to Pre-Time Package	0	+7	0
Specialty Recommended Pre-Service Time	33	10	15

4. **Specialty recommendation for a crosswalk code to support the recommended pre-service time changes:**

   Evaluation: No change to pre-time package.

Positioning: Add 7 minutes (total = 10 minutes). Additional time is required for patient positioning, with special attention to padding arms, legs, and pressure points when the patient is secured to the table to prevent the patient movement when patient is placed in reverse Trendelenburg position or when turned from side to side. Additional time is also required for equipment positioning relative to the patient and to other equipment to insure access to the operative site, including the scope and video equipment, intra-operative imaging equipment, surgical instruments, and anesthesia lines. A total of 10 minutes for positioning is supported by CPT codes 47563 *Laparoscopy, surgical; cholecystectomy with cholangiography* (reviewed by the RUC in 2010) and 47564 *Laparoscopy, surgical; cholecystectomy with exploration of common duct* (reviewed by the RUC in 2010).

Scrub, dress, wait: No change to pre-time package.

5. **Summary of the RUC rationale for code valuation, to indicate whether the code was valued based on magnitude estimation or other methodology:**

In 2005, The RUC recommended and CMS agreed to maintain the value which was based on magnitude estimation. In the 2012 NPRM for the 2013 PFS, CMS identified codes 47562 and 47563 as potentially misvalued based on one commenter that questioned the rank order. In January 2012, the RUC Relativity Assessment Workgroup agreed that the physician work had not changed since the October 2010 review and reaffirmed the RUC's original recommendation for correctly ranked work RVUs (11.87 for 47562 and 12.11 for 47563). For 2013, CMS did not agree with the RUC and instead reduced the work RVU for 47562 to correct the rank order anomaly that CMS created when it reduced the work RVU for 47563.

Timeline (please list expected CPT/RUC meetings as applicable):

September 2014 RUC meeting.

Action Plan for Review of Potentially Misvalued Services
September 2014

CPT Code	Descriptor	Work RVU	Global
63030	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, lumbar	13.18	090

Screen: *Pre-Time Analysis*

Include codes from family (please list all):

Please check all recommended actions that apply:
(If necessary, please clearly mark and attach all supplemental information)

- ❑ **Survey**
- ❑ **Refer to CPT/CPT Assistant**
- ☒ **Maintain work RVU**
- ☒ **Other Action (please describe): Update pre-service time to be consistent with pre-time packages.**

Rationale for Recommended Action:

1. **Current total pre-service time:** 75 minutes

2. **Median times for pre-service components from the most recent survey**

RUC Year	CPT Code	Median Survey Times		
		EVAL	POSIT	SDW
1995	63030	75		

3. **Specialty recommendation for pre-service package to be applied to the code, with any recommended adjustments to the package;**

   Recommended Pre-time Package: 4-Difficult Procedure/Difficult Patient

	EVAL	POSIT	SDW
Recommended Pre-Time Package Time	40	3	20
+ /- Adjustments to Pre-Time Package	0	15	-3
Specialty Recommended Pre-Service Time	40	18	17

4. **Specialty recommendation for a crosswalk code to support the recommended pre-service time changes**

Evaluation: No change to pre-time package.

Positioning: Add 15 minutes (total = 18 minutes) for SS3 positioning [Posterior Thoracic/Lumbar (Prone) (eg laminectomy)] which occurs after patient is placed supine and lines /anesthesia are placed. A total of 18 minutes for positioning is supported by CPT codes 22633 *Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar* (reviewed by the RUC in 2011).

Scrub, dress, wait: Subtract 3 minutes from pre-time package so that total recommended time does not exceed survey median time.

5. **Summary of the RUC rationale for code valuation, to indicate whether the code was valued based on magnitude estimation or other methodology**

For the first 5YR, the AANS/CNS conducted a survey of almost 100 codes for pre, intra- and post-times (intra-time and LOS were based on operative logs). In addition, a survey ranking intensity and complexity of the codes was conducted. These data were compiled to produce a scale of total physician work that was ranked by magnitude estimation. After significant review and discussion, the RUC agreed with the relative ranking and work values for this set of codes, both within the set and compared with other non-neurosurgery procedures.

The RUC used magnitude estimation as part of the review of 63030 in 1995. This resulted in a **decrease** in the work RVU. Please also note that the recommended pre-time is the same as the current pre-time for 63030.

Timeline (please list expected CPT/RUC meetings as applicable):

September 2014 RUC meeting.

Action Plan for Review of Potentially Misvalued Services
September 2014

CPT Code	Descriptor	Work RVU	Global
63042	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; lumbar	18.76	090

Screen: *Pre-Time Analysis*

Include codes from family (please list all):

Please check all recommended actions that apply:
(If necessary, please clearly mark and attach all supplemental information)

- ❑ **Survey**
- ❑ **Refer to CPT/CPT Assistant**
- ☒ **Maintain work RVU**
- ☒ **Other Action (please describe): Update pre-service time to be consistent with pre-time packages.**

Rationale for Recommended Action:

1. **Current total pre-service time:** 83 minutes

2. **Median times for pre-service components from the most recent survey**

RUC Year	CPT Code	Median Survey Times		
		EVAL	POSIT	SDW
1995	63042	83		

3. **Specialty recommendation for pre-service package to be applied to the code, with any recommended adjustments to the package;**

Recommended Pre-time Package: 4-Difficult Procedure/Difficult Patient

	EVAL	POSIT	SDW
Recommended Pre-Time Package Time	40	3	20
+ /- Adjustments to Pre-Time Package	0	15	0
Specialty Recommended Pre-Service Time	40	18	20

4. **Specialty recommendation for a crosswalk code to support the recommended pre-service time changes**

   Evaluation: No change to pre-time package.

   Positioning: Add 15 minutes (total = 18 minutes) for SS3 positioning [Posterior Thoracic/Lumbar (Prone) (eg laminectomy)] which occurs after patient is placed supine and lines /anesthesia are placed. A total of 18 minutes for positioning is supported by CPT codes 22633 *Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar* (reviewed by the RUC in 2011).

   Scrub, dress, wait: No change to pre-time package.

5. **Summary of the RUC rationale for code valuation, to indicate whether the code was valued based on magnitude estimation or other methodology**

   For the first 5YR, the AANS/CNS conducted a survey of almost 100 codes for pre, intra- and post-times (intra-time and LOS were based on operative logs). In addition, a survey ranking intensity and complexity of the codes was conducted. These data were compiled to produce a scale of total physician work that was ranked by magnitude estimation. After significant review and discussion, the RUC agreed with the relative ranking and work values for this set of codes, both within the set and compared with other non-neurosurgery procedures.

   The RUC used magnitude estimation as part of the review of 63042 in 1995. This resulted in a **decrease** in the work RVU.

Timeline (please list expected CPT/RUC meetings as applicable):

September 2014 RUC meeting.

Specialty: __ACC, HRS____

Action Plan for Review of Potentially Misvalued Services
September 2014

CPT Code Current Global Current work RVU CPT Descriptor):

93641	000	5.92	Electrophysiologic evaluation of single or dual chamber pacing cardioverter-defibrillator leads including defibrillation threshold evaluation (induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination) at time of initial implantation or replacement; with testing of single or dual chamber pacing cardioverter-defibrillator pulse generator

Screen: The RUC identified codes reviewed prior to April 2008 with pre-time greater than pre-time package 4 *Facility - Difficult Patient/Difficult Procedure* (63 minutes) for services with 2012 Medicare Utilization over 10,000. 93641 has 75 minutes of pre-service time when the longest standardized pre-service package is 63 minutes. **The RUC requests revised action plans in which the specialty societies provide the following information:**

- **current total pre-service time;**
- **median times for pre-service components from the most recent survey;**
- **specialty recommendation for pre-service package to be applied to the code, with any recommended adjustments to the package;**
- **specialty recommendation for a crosswalk code to support the recommended pre-service time changes; and**
- **summary of the RUC rationale for code valuation, to indicate whether the code was valued based on magnitude estimation or other methodology.**

Include codes from family (please list all):

93640	000	3.51	Electrophysiologic evaluation of single or dual chamber pacing cardioverter-defibrillator leads including defibrillation threshold evaluation (induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination) at time of initial implantation or replacement;
93642	000	4.88	Electrophysiologic evaluation of single or dual chamber pacing cardioverter-defibrillator (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)

Please check all recommended actions that apply:
(If necessary, please clearly mark and attach all supplemental information)

❑ **Survey**
❑ **Refer to CPT/CPT Assistant**
☒ **Maintain**

❑ **Other Action (please describe):**

Rationale for Recommended Action: We do not find a long preservice time unusual in and of itself, since surveys often indicate more preservice time than the RUC has chosen to assign using standard packages. The current preservice times for these three codes correspond with the most recent survey median preservice times. These codes were valued before use of preservice time was standardized using packages.

Utilization is low and declining for 93640 and 93642, 3,011 and 4,639 respectively. Utilization for 93641 has declined significantly from 98,505 in 2005 to 53,053 in 2013. We recommend the work values and times for these codes be maintained by the RAW and the RUC.

Since the RAW appears interested in considering changes to preservice times in isolation from complete review of the codes, we have provided requested information in the table below. We believe the preservice times for these codes could reasonably be adjusted to package 2B. Package 2B was recently approved by the RUC for a similar code included in the group of SICD services in April. However, we think the RAW should carefully consider the possible outcomes of making changes to times in this fashion. We believe maintenance of these codes without revision and dismissal of this entire screen without further action would be appropriate.

Code	Pre	Survey Pre	Pack. Rec.	Crosswalk	Rationale for existing time
93640	70	70	2B, 39 min	9364XX	Survey
93641	75	75	2B, 39 min	9364XX	Survey
93642	30	30	2B, 39 min	9364XX	Survey

Timeline (please list expected CPT/RUC meetings as applicable):

01- Addendum – Tech Corrections to CY2016 PE Database

Below please find a list of potential technical corrections to direct PE inputs that the RUC has identified in the CMS CY 2016 direct PE input database.

37215

- Pack, minimum multi-specialty visit (SA048) – CMS decreased from 2 packs to 0 with no rationale.
- Table, exam (EF023) - CMS decreased to 0 minutes with no rationale.

72081

- Clean room/equipment by physician staff – 3 minutes erroneously allocated to "post service" instead of "service post"
- Exam documents scanned into PACs. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue– 1 minute erroneously allocated to "post service" instead of "service post"
- Review examination with interpreting MD– 2 minutes erroneously allocated to "post service" instead of "service post"
- PACS Workstation (ED050) – this should equal the (to be revised) clinical service time of 21 minutes

72082

- PACS Workstation (ED050) – this should equal the clinical service time of 36 minutes

72083

- PACS Workstation (ED050) – this should equal the clinical service time of 44 minutes

72084

- PACS Workstation (ED050) – this should equal the clinical service time of 53 minutes

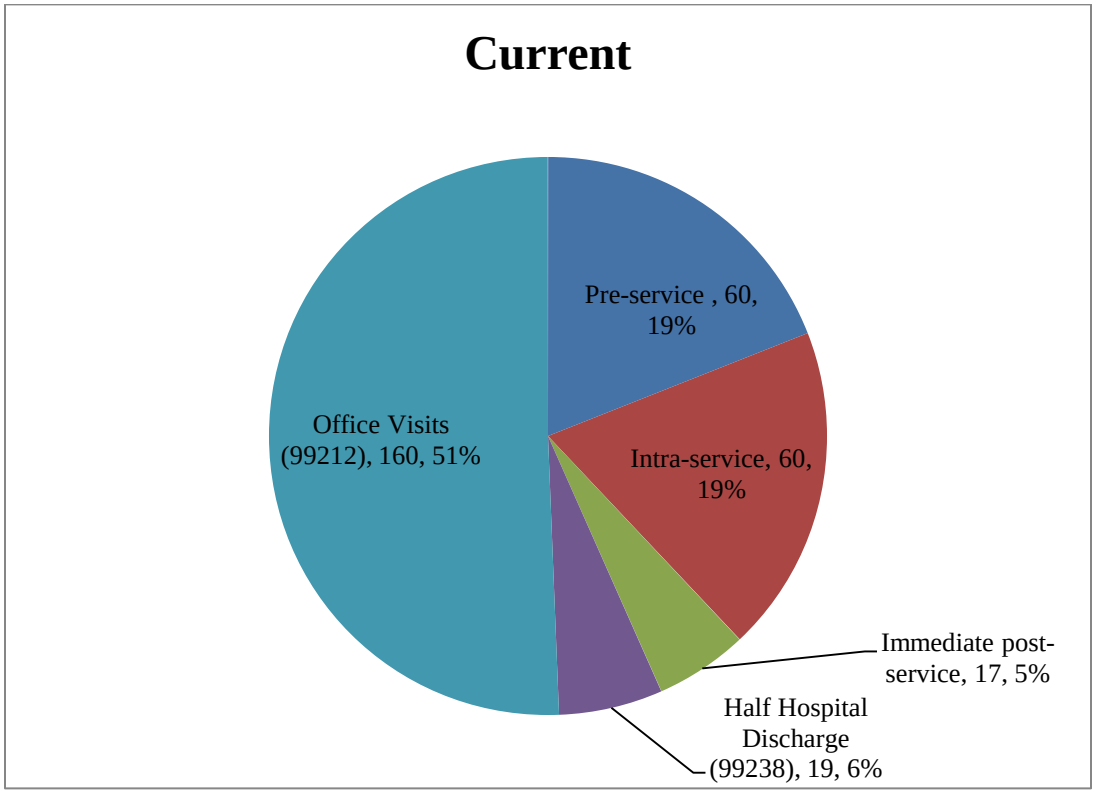
50432

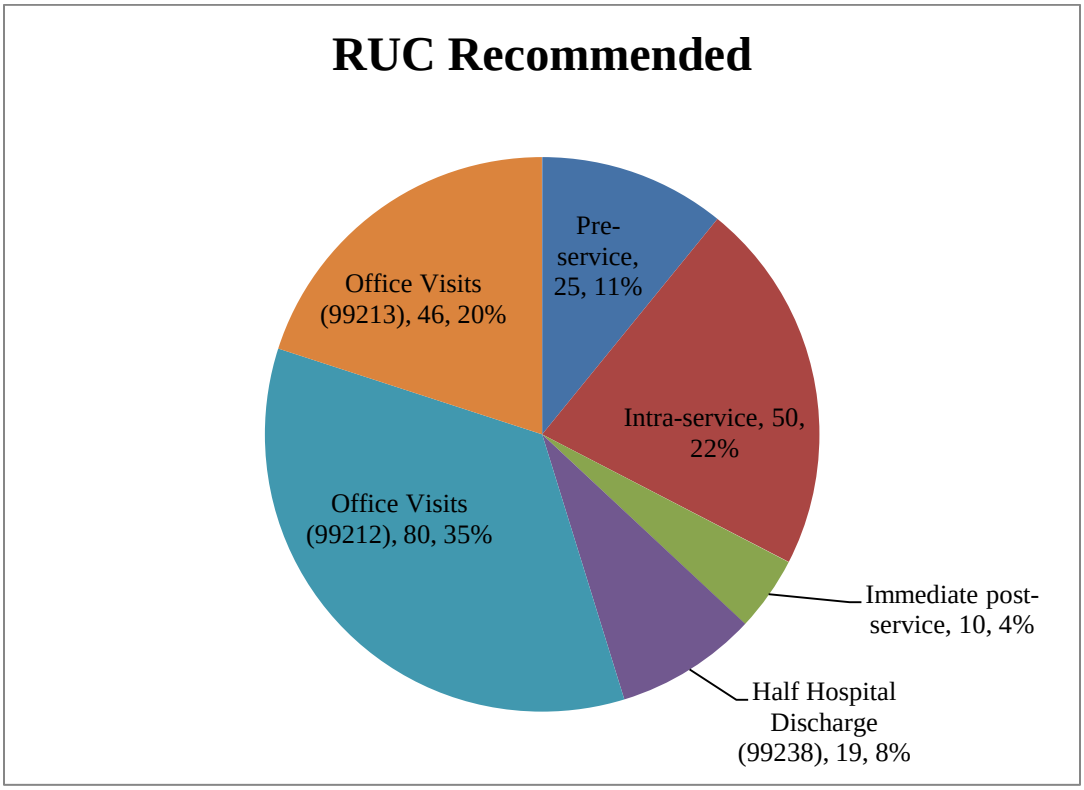
- Review examination with interpreting MD – Labor Task Detail file lists this activity in the Post-Service Period, but it should be in Service Post.
- Therefore, the Labor File incorrectly lists 2 minutes of post time for the Rad Tech. The Service period time should be updated from 94 to 96 minutes.

50694

- Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation) – Labor Task Detail file lists this activity by the RN in the Post-Service Period, but it should be in Service Post.
- Therefore, the Labor File incorrectly lists 2 minutes of post time for the Rad Tech. The Service period time should be updated from 94 to 96 minutes.

02 Addendum - Ocular Reconstruction Transplant (CPT Code 65780)





AMA/Specialty Society RVS Update Committee Summary of Recommendations
Codes Reported Together 75% or More

October 2015

Percutaneous Biliary Procedures Bundling

The Joint CPT-RUC Workgroup on codes reported together frequently identified codes that are being reported together greater than 75 percent of the time and as a result the CPT Editorial Panel deleted codes 47500, 47505, 47510, 47511, 47525, 47530, 74305, 74320, 74327, 79580 and 75982 and created 14 new bundled codes 47531-47544. At the April 2015 RUC meeting, the RUC and specialty societies agreed that the survey data for this family of services was problematic. Specifically, the RUC noted the median intra-service times for 47532, 47533 and 47534 all have identical intra-service time of 60 minutes, which made it difficult to properly interpret the survey data. CPT code 47533 includes the work of 47532 plus the work of an additional access and drain placement. Furthermore, CPT code 47534 includes the work of 47533 plus the work of crossing the occlusion and placement of an internal/external drain. Given this physician time anomaly, the RUC agreed to provide interim recommendations at the April 2015 meeting, while allowing the specialty societies to re-survey the entire family of codes for October 2015.

Compelling Evidence
The specialty societies presented compelling evidence that the physician work involved in these procedures has changed.

Technique, Knowledge and Technology
The codes currently used for this family of biliary procedures no longer reflect the techniques now used for image-guided, catheter-based biliary procedures. Virtually all the medical devices currently used in biliary catheter procedures have been developed since the current codes were adopted. The past twenty years have witnessed major advances in the knowledge base, including: 1) understanding of how to use imaging guidance such as ultrasound and preoperative planning mapping to avoid hepatic hilar structures and thus prevent bleeding and bile leaks; 2) new insights into how segmental biliary ductal anatomy can help avoid bleeding and septic complications and 3) development of much less aggressive and safer guidewire-based methods which involve more steps and more effort, skill and physician time.

Patient Population
There are three changes to the patient population which have occurred since the last valuation of the current procedures, including: 1) previously the majority of all biliary catheter procedures were used for basic relief of distal ductal biliary obstruction either acutely or chronically often related to pancreatic cancer and/or stone disease. The significant majority of all of the biliary diseases referred for interventional percutaneous treatment now have higher and more complex levels of benign and malignant biliary occlusion including hilar and segmental obstruction; 2) the widespread use of liver transplantation has introduced an entirely different patient population: the postoperative liver transplant patient with ischemic biliary strictures (intrahepatic and/or extrahepatic), which requires major investments of time, skill and effort to obtain access and drain,

stent and dilate these complex situations and 3) hepatic surgery for malignancy has also become far more sophisticated and segmental or lobar resections will frequently result in referrals for drainage of biliary leaks from non-dilated ducts.

Given these changes, the RUC accepted that there is compelling evidence that the physician work has change for this family of services.

47531 Injection procedure for cholangiography, percutaneous, complete diagnostic procedure including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; existing access
The RUC reviewed the survey results from 42 interventional radiologists and agreed with the specialty societies that the following physician times accurately account for the work of this procedure: pre-service time of 27 minutes, intra-service time of 15 minutes and immediate post-service time of 12 minutes. The RUC agreed to add two additional positioning minutes to account for positioning the patient on the angiographic table, as well as optimize patient protective lead apron placement to avoid obscuring the operative field.

The RUC reviewed the survey respondents' estimated physician work values and determined that due to the lower total time in survey data compared with the existing codes total time in the RUC database, the values are overestimated at the 25th percentile work RVU of 1.50. To determine an appropriate work value, the RUC compared 47531 to CPT code 46611 *Anoscopy; with removal of single tumor, polyp, or other lesion by snare technique* (work RVU= 1.30, intra time= 15 minutes) and noted that both services have identical intra-service time and offered a reasonable physician work comparison to the surveyed code. Therefore, the RUC agreed that a direct work value crosswalk to 46611 is appropriate. To validate a work RVU of 1.30, the committee also reviewed code 36580 *Replacement, complete, of a non-tunneled centrally inserted central venous catheter, without subcutaneous port or pump, through same venous access* (work RVU= 1.31, intra time= 15 minutes) and noted the identical intra-service times and comparable physician work between the two services. **The RUC recommends a work RVU of 1.30 for CPT code 47531.**

47532 Injection procedure for cholangiography, percutaneous, complete diagnostic procedure including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; new access (eg, percutaneous transhepatic cholangiogram)
The RUC reviewed the survey results from 42 interventional radiologists and agreed with the specialty societies that the following physician times accurately account for the work of this procedure: pre-service time of 38 minutes, intra-service time of 45 minutes and immediate post-service time of 15 minutes. The RUC agreed to add two additional positioning minutes to account for positioning the patient on the angiographic table, as well as optimize patient protective lead apron placement to avoid obscuring the operative field.

The RUC reviewed the survey respondents' estimated physician work values and agree that the survey 25th percentile work value of 4.50 is appropriate for this procedure. To justify a work value of 4.50, the RUC compared the surveyed code to the top key reference code 49407 *Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst); peritoneal or retroperitoneal, transvaginal or transrectal* (work RVU= 4.50, intra time= 45 minutes) and agreed that since both services have identical intra-service time and comparable

physician work, the work value of both codes should be the same. The RUC also reviewed reference code 49407 *Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst); peritoneal or retroperitoneal, transvaginal or transrectal* (work RVU= 4.50, intra time= 45 minutes) and noted that with identical intra-service time, the two services should be valued identically. **The RUC recommends a work RVU of 4.50 for CPT code 47532.**

47533 Placement of biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; external
The RUC reviewed the survey results from 42 interventional radiologists and agreed with the specialty societies that the following physician times accurately account for the work of this procedure: pre-service time of 41 minutes, intra-service time of 60 minutes and immediate post-service time of 20 minutes. The RUC agreed to add two additional positioning minutes to account for positioning the patient on the angiographic table, as well as optimize patient protective lead apron placement to avoid obscuring the operative field.

The RUC reviewed the survey respondents' estimated physician work values and agreed that the survey 25th percentile work value of 5.63 is appropriate. To justify a work RVU of 5.63, the RUC compared the surveyed code to reference codes 32601 *Thoracoscopy, diagnostic (separate procedure); lungs, pericardial sac, mediastinal or pleural space, without* biopsy (work RVU= 5.50, intra time= 60 minutes) and code 32998 *Ablation therapy for reduction or eradication of 1 or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension, percutaneous, radiofrequency, unilateral* (work RVU= 5.68, intra time= 60 minutes) and agreed that with identical intra-service times, these reference codes offer appropriate brackets around the recommended work value for 47533. **The RUC recommends a work RVU of 5.63 for CPT code 47533.**

47534 Placement of biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; internal-external
The RUC reviewed the survey results from 42 interventional radiologists and agreed with the specialty societies that the following physician times accurately account for the work of this procedure: pre-service time of 41 minutes, intra-service time of 68 minutes and immediate post-service time of 20 minutes. The RUC agreed to add two additional positioning minutes to account for positioning the patient on the angiographic table, as well as optimize patient protective lead apron placement to avoid obscuring the operative field.

The RUC reviewed the survey respondents' estimated physician work values and agreed that the 25th percentile work RVU of 7.85 is appropriate for this procedure. To justify a work RVU of 7.85 for CPT code 47534, the RUC compared the surveyed code to the second highest key reference code 37211 *Transcatheter therapy, arterial infusion for thrombolysis other than coronary, any method, including radiological supervision and interpretation, initial treatment day* (work RVU= 8.00, intra time= 60 minutes) and agreed that since the reference code has slightly greater total time than 47534, 138 minutes and 129 minutes, respectively, it is appropriately valued higher. The RUC also reviewed MPC code 52353 *Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy (ureteral catheterization is included)* (work RVU= 7.50, intra time= 60

minutes) and noted similar intra-service times and comparable physician work to 47534. **The RUC recommends a work RVU of 7.85 for CPT code 47534.**

47535 Conversion of external biliary drainage catheter to internal-external biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation
The RUC reviewed the survey results from 42 interventional radiologists and agreed with the specialty societies that the following physician times accurately account for the work of this procedure: pre-service time of 33 minutes, intra-service time of 45 minutes and immediate post-service time of 15 minutes. The RUC agreed to add two additional positioning minutes to account for positioning the patient on the angiographic table, as well as optimize patient protective lead apron placement to avoid obscuring the operative field.

The RUC reviewed the survey respondents' estimated physician work values and agreed that the survey 25th percentile work value of 4.20 is appropriate. To justify a work RVU of 4.20, the RUC compared the surveyed code to the top key reference code 36247 *Selective catheter placement, arterial system; initial third order or more selective abdominal, pelvic, or lower extremity artery branch, within a vascular family* (work RVU= 6.29, intra time= 60 minutes) and agreed that with 15 additional minutes of intra-service time, the reference code is appropriately valued higher. The RUC also reviewed codes 31634 *Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, with assessment of air leak, with administration of occlusive substance (eg, fibrin glue), if performed* (work RVU= 4.00, intra time= 45 minutes) and 49407 *Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst); peritoneal or retroperitoneal, transvaginal or transrectal* (work RVU= 4.50, intra time= 45 minutes) and agreed that both these comparable services offer appropriate brackets above and below the recommended value for the surveyed code. **The RUC recommends a work RVU of 4.20 for CPT code 47535.**

47536 Exchange of biliary drainage catheter (eg. external, internal-external , or conversion of internal-external to external only), percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation
The RUC reviewed the survey results from 42 interventional radiologists and agreed with the specialty societies that the following physician times accurately account for the work of this procedure: pre-service time of 28 minutes, intra-service time of 20 minutes and immediate post-service time of 13 minutes. The RUC agreed to add two additional positioning minutes to account for positioning the patient on the angiographic table, as well as optimize patient protective lead apron placement to avoid obscuring the operative field.

The RUC reviewed the survey respondents' estimated physician work values and agreed that the survey 25th percentile work value of 2.86 is appropriate. To justify a work RVU of 2.86, the RUC compared the surveyed code to the top key reference service 49452 *Replacement of gastro-jejunostomy tube, percutaneous, under fluoroscopic guidance including contrast injection(s), image documentation and report* (work RVU= 2.86, intra time= 20 minutes) and agreed that both services have identical intra-service time and should be valued identically. The RUC also reviewed the MPC code 31622 *Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with cell washing, when*

performed (separate procedure) (work RVU= 2.78, intra time= 30 minutes) and noted that while the reference code has more intra-service time than 47536, both services have nearly identical total time. Therefore, the surveyed code is appropriately valued slightly higher than this MPC code. **The RUC recommends a work RVU of 2.86 for CPT code 47536.**

47537 Removal of biliary drainage catheter, percutaneous, requiring fluoroscopic guidance (eg, with concurrent indwelling biliary stents), including diagnostic cholangiography when performed, imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation

The RUC reviewed the survey results from 42 interventional radiologists and agreed with the specialty societies that the following physician times accurately account for the work of this procedure: pre-service time of 27 minutes, intra-service time of 15 minutes and immediate post-service time of 10 minutes. The RUC agreed to add two additional positioning minutes to account for positioning the patient on the angiographic table, as well as optimize patient protective lead apron placement to avoid obscuring the operative field.

The RUC reviewed the survey respondents' estimated physician work values and agreed that the survey 25th percentile work value of 1.84 is appropriate. To justify a work RVU of 1.84, the RUC compared the surveyed code to the top key reference service 49083 *Abdominal paracentesis (diagnostic or therapeutic); with imaging guidance* (work RVU= 2.00, intra time= 25 minutes) and noted that since this reference code has more intra-service time than 47537, it is appropriately valued higher. The RUC reviewed reference code 45309 *Proctosigmoidoscopy, rigid; with removal of single tumor, polyp, or other lesion by snare technique* (work RVU= 1.50, intra time= 15 minutes) and MPC code 54150 *Circumcision, using clamp or other device with regional dorsal penile or ring block* (work RVU= 1.90, intra time= 15 minutes) and noted that both these services, with identical intra-service time, offer appropriate brackets above and below the recommended value. **The RUC recommends a work RVU of 1.84 for CPT code 47537.**

47538 Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (eg, fluoroscopy and/or ultrasound), balloon dilation, catheter exchange or removal when performed, and all associated radiological supervision and interpretation, each stent; existing access

The RUC reviewed the survey results from 42 interventional radiologists and agreed with the specialty societies that the following physician times accurately account for the work of this procedure: pre-service time of 38 minutes, intra-service time of 53 minutes and immediate post-service time of 15 minutes. The RUC agreed to add two additional positioning minutes to account for positioning the patient on the angiographic table, as well as optimize patient protective lead apron placement to avoid obscuring the operative field.

The RUC reviewed the survey respondents' estimated physician work values and agreed that the survey 25th percentile work value of 5.00 is appropriate. To justify a work RVU of 5.00, the RUC compared the surveyed code to CPT codes 43242 *Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s) (includes endoscopic ultrasound examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)* (work RVU= 4.83, intra time= 50 minutes) and 50384 *Removal (via snare/capture) of internally dwelling ureteral stent via*

percutaneous approach, including radiological supervision and interpretation (work RVU= 5.00, intra time= 55 minutes) and agreed that since both these services have similar intra-service time and comparable physician work, the recommended value appropriately aligns with these services. **The RUC recommends a work RVU of 5.00 for CPT code 47538.**

47539 Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (eg, fluoroscopy and/or ultrasound), balloon dilation, catheter exchange or removal when performed, and all associated radiological supervision and interpretation, each stent; new access, without placement of separate biliary drainage catheter
The RUC reviewed the survey results from 41 interventional radiologists and agreed with the specialty societies that the following physician times accurately account for the work of this procedure: pre-service time of 41 minutes, intra-service time of 75 minutes and immediate post-service time of 20 minutes. The RUC agreed to add two additional positioning minutes to account for positioning the patient on the angiographic table, as well as optimize patient protective lead apron placement to avoid obscuring the operative field.

The RUC reviewed the survey respondents' estimated physician work values and agreed that the survey 25th percentile work value of 9.00 is appropriate. To justify a work RVU of 9.00, the RUC compared the surveyed code to the top key reference service 37226 *Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed* (work RVU= 10.49, intra time= 90 minutes) and noted that since the reference code has more intra-service time, it is appropriately valued higher. The RUC also reviewed code 37224 *Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal angioplasty* (work RVU= 9.00, intra time= 80 minutes) and agreed that this comparable service, with similar time components, should be valued identically to the surveyed code. **The RUC recommends a work RVU of 9.00 for CPT code 47539.**

47540 Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (eg, fluoroscopy and/or ultrasound), balloon dilation, catheter exchange or removal when performed, and all associated radiological supervision and interpretation, each stent; new access, with placement of separate biliary drainage catheter (eg, external or internal-external)
The RUC reviewed the survey results from 42 interventional radiologists and agreed with the specialty societies that the following physician times accurately account for the work of this procedure: pre-service time of 41 minutes, intra-service time of 85 minutes and immediate post-service time of 20 minutes. The RUC agreed to add two additional positioning minutes to account for positioning the patient on the angiographic table, as well as optimize patient protective lead apron placement to avoid obscuring the operative field.

The RUC reviewed the survey respondents' estimated physician work values and agreed that the survey 25th percentile work value of 9.28 is appropriate. To justify a work RVU of 9.28, the RUC compared the surveyed code to the second highest key reference service 37228 *Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal angioplasty* (work RVU= 11.00, intra time= 90 minutes) and agreed that since this code has more total time than 47540, 168 minutes compared to 146 minutes, it is appropriately valued higher than the recommended value. The RUC also reviewed codes 52355 *Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with resection of ureteral or renal pelvic* tumor (work RVU= 9.00, intra time= 90 minutes) and 37221 *Revascularization,*

endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed (work RVU= 10.00, intra time= 90 minutes) and agreed that with similar time components and comparable physician work, these two codes provide appropriate brackets above and below the recommended value. **The RUC recommends a work RVU of 9.28 for CPT code.**

47541 Placement of access through the biliary tree and into small bowel to assist with an endoscopic biliary procedure (eg, rendezvous procedure), percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; new access
The RUC reviewed the survey results from 42 interventional radiologists and agreed with the specialty societies that the following physician times accurately account for the work of this procedure: pre-service time of 41 minutes, intra-service time of 60 minutes and immediate post-service time of 20 minutes. The RUC agreed to add two additional positioning minutes to account for positioning the patient on the angiographic table, as well as optimize patient protective lead apron placement to avoid obscuring the operative field.

The RUC reviewed the survey respondents' estimated physician work values and agreed that the survey 25th percentile work value of 7.00 is appropriate. To justify a work RVU of 7.00, the RUC compared the surveyed code to MPC code 52353 *Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy (ureteral catheterization is included)* (work RVU= 7.50, intra time= 60 minutes) and agreed that since both these procedures have identical intra-service time, they should be valued similarly. The RUC also reviewed CPT codes 32608 *Thoracoscopy; with diagnostic biopsy(ies) of lung nodule(s) or mass(es) (eg, wedge, incisional), unilateral* (work RVU= 6.84, intra time= 60 minutes) and 37212 *Transcatheter therapy, venous infusion for thrombolysis, any method, including radiological supervision and interpretation, initial treatment day* (work RVU= 7.06, intra time= 60 minutes) and agreed that these codes, with similar time components, offer appropriate brackets above and below the recommended value. **The RUC recommends a work RVU of 7.00 for CPT code 47541.**

47542 Balloon dilation of biliary duct(s) or of ampulla (sphincteroplasty), percutaneous, including imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation, each duct (List separately in addition to code for primary procedure)
The RUC reviewed the survey results from 42 interventional radiologists and agreed with the specialty societies that an intra-service time of 30 minutes for this add-on procedure is appropriate. To determine an appropriate work value for 47542, the RUC reviewed the survey respondents' estimated physician work values and agreed that the survey 25th percentile work RVU of 2.85 is appropriate. To justify this work value, the RUC compared the surveyed code to the top reference service 37222 *Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal angioplasty* (work RVU= 3.73, intra time= 40 minutes) and agreed that with 10 additional minutes above 47542, the reference code is appropriately valued higher. The RUC also reviewed CPT codes 36476 *Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; second and subsequent veins treated in a single extremity, each through separate access sites* (work RVU= 2.65, intra time= 30 minutes) and 32507 *Thoracotomy; with diagnostic wedge resection followed by anatomic lung* resection (work RVU= 3.00, intra time= 30 minutes) and agreed that these services, with

identical time, represent appropriate brackets above and below the recommended value. **The RUC recommends a work RVU of 2.85 for CPT code 47542.**

47543 Endoluminal biopsy(ies) of biliary tree, percutaneous, any method(s) (eg, brush, forceps and/or needle), including imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation, single or multiple (List separately in addition to code for primary procedure)

The RUC reviewed the survey results from 42 interventional radiologists and agreed with the specialty societies that an intra-service time of 30 minutes for this add-on procedure is appropriate. To determine an appropriate work value for 47543, the RUC reviewed the survey respondents' estimated physician work values and agreed with the specialty societies that the survey 25th percentile work RVU of 3.00 is appropriate. To justify this work value, the RUC compared the surveyed code to the top key reference code 37185 *Primary percutaneous transluminal mechanical thrombectomy, noncoronary, arterial or arterial bypass graft, including fluoroscopic guidance and intraprocedural pharmacological thrombolytic injection(s); second and all subsequent vessel(s) within the same vascular family* (work RVU= 3.28, intra time= 40 minutes) agreed that the reference code, with 10 additional minutes of intra-service time, should be valued higher than 47543. The RUC also reviewed codes 37239 *Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; each additional vein* (work RVU= 2.97, intra time= 30 minutes) and 32668 *Thoracoscopy, surgical; with diagnostic wedge resection followed by anatomic lung resection* (work RVU= 3.00, intra time= 30 minutes) and agreed that these services, with identical time, represent appropriate brackets above and below the recommended value. **The RUC recommends a work RVU of 3.00 for CPT code 47543.**

47544 Removal of calculi/debris from biliary duct(s) and/or gallbladder, percutaneous, including destruction of calculi by any method (eg, mechanical, electrohydraulic, lithotripsy) when performed, imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation (List separately in addition to code for primary procedure)

The RUC reviewed the survey results from 32 interventional radiologists and agreed with the specialty societies that an intra-service time of 45 minutes for this add-on procedure is appropriate. To determine an appropriate work value, the RUC reviewed the survey respondents' reported physician work values and determined that they appeared overestimated at the 25th percentile (work RVUs= 3.95). Given this, the RUC considered two CPT codes 37185 *Primary percutaneous transluminal mechanical thrombectomy, noncoronary, arterial or arterial bypass graft, including fluoroscopic guidance and intraprocedural pharmacological thrombolytic injection(s); second and all subsequent vessel(s) within the same vascular family* (work RVU= 3.28, intra time= 40 minutes) and 92973 *Percutaneous transluminal coronary thrombectomy mechanical* (work RVU= 3.28, intra time= 40 minutes) and agreed that both these services have analogous work to the surveyed code and should be valued identically. Therefore, the RUC recommends a direct work value crosswalk from these two reference codes to 47544. **The RUC recommends a work RVU of 3.28 for CPT code 47544.**

Practice Expense

The RUC reviewed and approved the direct practice expense inputs with the following revisions as approved by the PE Subcommittee:

- The PE Subcommittee had extensive discussion regarding the pre-service time for these services, reminding the specialty that zero minutes of clinical staff time is standard for 000 and 010 day globals. The PE Subcommittee determined that the standard for extensive use of clinical staff time in the facility setting, of 30 minutes is not appropriate. However, the services do require more pre-service time than the standard for minimal use of clinical staff time in the facility setting of 15 minutes. The PE Subcommittee determined that 19 minutes of pre-service time in the facility setting is appropriate for the services in the family that are done in the facility outpatient setting, similar to recently reviewed gastroenterology procedures, for example esophagoscopy services (CPT codes 43211, 43213, 43214, 43212, 43229). There was additional discussion about clinical staff coming from the physician's office to the facility to consent the patient. The PE Subcommittee agreed that the time would be duplicative of the duties of the clinical staff in the facility. The specialty proposed and the PE Subcommittee agreed that services performed in the inpatient facility setting should have 14 minutes of pre-service time because the 5 minutes to provide pre-service education/obtain consent should be removed.
- Many of the interventional radiology services include three staff to assist the physicians in performing the procedure during the intra-service portion of the service period. Generally an RN assists with the moderate sedation, another staff assists the physician in performing the procedure and a third staff (two staff types, but equal to one staff) acquires the images and circulates (RT acquire images 75% of intra-service time and RN/LPN/MTA circulates 25% of intra-service time). For CPT codes 47531 and 47537 moderate sedation is not administered, however the specialty society recommended and the PE subcommittee agreed that three staff remain actively engaged in the procedure and necessary to assist the physician in performing the procedure; acquire images and circulate; as well as monitor the patient. Additionally, the PE Subcommittee recommends 4 hours of monitoring time (15 minutes of RN clinical staff time related to moderate sedation and 45 minutes not related to moderate sedation) for codes that include moderate sedation, and 1 hour (15 minutes of RN/LPN/MTA clinical staff time not related to moderate sedation) for 47531 and 47537 which do not include moderate sedation. The moderate sedation monitoring equipment is used for all the monitoring time, both following moderate sedation and following the procedure.
- The PE Subcommittee recommends 6 minutes of clinical staff time to clean room/equipment rather than the standard 3 minutes due to the bodily fluids involved and the large amount of equipment.
- The specialty societies clarified that there are no balloon dilation catheters specifically for the biliary tree. The supply item, catheter, balloon, PTA (SD152) used in some of these services is not only an angioplasty balloon; it is appropriately used in these services as a dilation device. The supply item, tray, shave prep (SA067) is used to prepare the area and is needed for all the services except for 47531 and 47537.
- The supply item, pack, cleaning and disinfecting, endoscope (SA042) which was used a proxy for the necessary cleaning supplies for the room was removed and replaced with 1 supply item, gloves, non-sterile (SB022) and 3 supply items, sanitizing cloth-wipe (surface, instruments, equipment) (SM022), the correct supplies necessary to clean the room for these services.

CPT Code (•New)	Tracking Number	CPT Descriptor	Global Period	Work RVU Recommendation
Digestive System **Esophagus** **Endoscopy** **Endoscopic Retrograde Cholangiopancreatography (ERCP)**				
Report the appropriate code(s) for each service performed. Therapeutic ERCP……...To report ERCP attempted but with unsuccessful cannulation of any ductal system, see 43235-43259, 43266, 43270				
(For percutaneous biliary catheter procedures, see 47490-47544)				
Codes 43274, 43275……..……				
43260		*Endoscopic retrograde cholangiopancreatography (ERCP); diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)* *(Do not report 43260 in conjunction with 43261, 43262, 43263, 43264, 43265, 43274, 43275, 43276, 43277, 43278)*		
⊙*43261*		*with biopsy, single or multiple* *(Do not report 43261 in conjunction with 43260)* (For percutaneous endoluminal biopsy of biliary tree, use 47543)		
⊙*43262*		*with sphincterotomy/papillotomy* *(43262 may be reported when sphincterotomy is performed in addition to 43261, 43263, 43264, 43265, 43275, 43278)* *(Do not report 43262 in conjunction with 43274 for stent placement or with 43276 for stent replacement [exchange] in the same location)* *(Do not report 43262 in conjunction with 43260, 43277)* **(**For percutaneous balloon dilation of biliary duct(s) or of ampulla, use 47542)		
⊙*43263*		*with pressure measurement of sphincter of Oddi* *(Do not report 43263 in conjunction with 43260)*		

	(Do not report 43263 more than once per session)
⊙43264	*with removal of calculi/debris from biliary/pancreatic duct(s)*
	(Do not report 43264 if no calculi or debris are found, even if balloon catheter is deployed)
	(Do not report 43264 in conjunction with 43260, 43265)
	(For percutaneous removal of calculi/debris, use 47544)
⊙43265	*with destruction of calculi, any method (eg, mechanical, electrohydraulic, lithotripsy)*
	(Do not report 43265 in conjunction with 43260, 43264)
	(For percutaneous removal of calculi/debris, use 47544)
#⊙43274	*with placement of endoscopic stent into biliary or pancreatic duct, including pre- and post-dilation and guide wire passage, when performed, including sphincterotomy , when performed, each stent*
	(Do not report 43274 in conjunction with 43262, 43275, 43276, 43277 for stent placement or replacement [exchange] in the same duct)
	(For stent placement in both the pancreatic duct and the common bile duct during the same operative session, placement of separate stents in both the right and left hepatic ducts, or placement of two side-by-side stents in the same duct, 43274 may be reported for each additional stent placed, using modifier 59 with the subsequent procedure[s])
	(To report naso-biliary or naso-pancreatic drainage tube placement, use 43274)
	(For percutaneous placements of biliary stent(s), see 47538, 47539, 47540)
#⊙43275	*with removal of foreign body(s) or stent(s) from biliary/pancreatic duct(s)*
	(Do not report 43275 in conjunction with 43260, 43274, 43276)
	(For removal of stent from biliary or pancreatic duct without ERCP, use 43247)
	(Report 43275 only once for removal of one or more stents or foreign bodies from biliary/pancreatic duct[s] during the same session)
	(For percutaneous removal of calculi/debris, use 47544)
#⊙43276	*with removal and exchange of stent(s), biliary or pancreatic duct, including pre- and post-dilation and guide wire passage, when performed, including sphincterotomy, when performed, each stent exchanged*

(43276 includes removal and replacement [exchange] of one stent. For replacement [exchange] of additional stent[s] during the same session, report 43276 with modifier 59 for each additional replacement [exchange])

(Do not report 43276 in conjunction with 43260, 43275)

(Do not report 43276 in conjunction with 43262, 43274 for stent placement or exchange in the same duct)

#⊙43277 *with trans-endoscopic balloon dilation of biliary/pancreatic duct(s) or of ampulla (sphincteroplasty), including sphincterotomy, when performed, each duct*

(For bilateral balloon dilation [both right and left hepatic ducts], 43277 may be reported twice with modifier 59 appended to the second procedure)

(For percutaneous balloon dilation of biliary duct(s) or of ampulla (sphincteroplasty), use 47542)

Digestive System
Biliary Tract
Introduction

Percutaneous biliary procedures (eg, transhepatic, transcholecystic) are described by 47490 and 47531-47544, and are performed with imaging guidance. They are differentiated from endoscopic procedures that utilize an access to the biliary tree from a hollow viscus for diagnosis and therapy. Diagnostic cholangiography is typically performed with percutaneous biliary procedures, and is included in 47490, 47533, 47534, 47535, 47536, 47537, 47538, 47539, 47540, and 47541.

Codes 47531 and 47532 describe percutaneous diagnostic cholangiography that includes injection(s) of contrast material, all associated radiological supervision and interpretation, and procedural imaging guidance (eg, ultrasound and/or fluoroscopy). Code 47532 also includes accessing the biliary system with a needle or catheter. Codes 47531 and 47532 may not be reported with codes 47533, 47534, 47535, 47536, 47537, 47538, 47539, 47540, and 47541.

An external biliary drainage catheter is a catheter placed into a bile duct that does not terminate in bowel, and that drains bile externally only. An internal-external biliary drainage catheter is a single, externally accessible catheter that terminates in the small intestine, and may drain bile into the small intestine and/or externally. A “stent,” as used in this code set, is a percutaneously placed device (eg, self-expanding metallic mesh stent, plastic tube) that is positioned within the biliary tree and is completely internal, with no portion extending outside the patient.

Codes 47533, 47534, 47535, 47536, 47537, 47538, 47539, and 47540 describe percutaneous therapeutic biliary procedures that include catheter or stent placement, catheter removal and replacement (exchange), and/or catheter removal. These codes include the elements of access, drainage catheter manipulations, diagnostic cholangiography, imaging guidance (eg, ultrasonography and/or fluoroscopy), and all associated radiological supervision and interpretation. Codes 47533, 47534, 47538, 47539, 47540 may be reported once for each catheter or

stent placed (eg, bilobar placement, multi-segmental placement). Codes 47535, 47536, and 47537 may be reported once for each catheter conversion, exchange, or removal (eg, bilobar, bisegmental).

Codes 47538, 47539, 47540 may be reported only once per session to describe one or more overlapping or serial stent(s) placed within a single bile duct, or bridging more than one ductal segment (eg, left hepatic duct and common bile duct) through a single percutaneous access. Codes 47538, 47539, 47540 may be reported more than once in the same session using modifier 59 for the additional procedures in the following circumstances: (i) placement of side-by-side (double-barrel) stents within a single bile duct; (ii) placement of two or more stents into separate bile ducts through a single percutaneous access; or (iii) placement of stents through two or more percutaneous access sites (eg, placement of one stent through the interstices of another stent). Code 47538 describes biliary stent placement through an existing access. Therefore, 47538 should not be reported together with 47536 if a biliary drainage catheter (eg, external or internal-external) is replaced after the biliary stent is placed. Code 47540 describes biliary stent placement with the additional service of placing a biliary drainage catheter (eg, external or internal-external). Therefore, 47540 should not be reported with 47533, 47534 for the same ductal system.

Code 47541 describes a procedure to assist with endoscopic procedures performed in conjunction with other physician specialists. Access placed may include wire and/or catheter. Code 47541 may not be reported if a wire is placed through existing percutaneous access.

Codes 47542, 47543, and 47544 describe procedures that may be performed in conjunction with other codes in this family, are add-on codes and do not include access, catheter placement, or diagnostic imaging. Do not report 47542 with 47538, 47539, 47540 because balloon dilation is included in 47538, 47539, and 47540. Code 47544 should not be reported with 47531-47543 for removal of incidental sludge and/or debris. Code 47542 should not be reported with 47544, if a balloon is used for removal of calculi, debris, and/or sludge rather than for dilation.

47490 *Cholecystostomy, percutaneous, complete procedure, including imaging guidance, catheter placement, cholecystogram when performed, and radiological supervision and interpretation*

(Do not report 47490 in conjunction with 47531, 47532, 75989, 76942, 77002, 77012, 77021)

Surgery
Digestive System
Biliary Tract
Laparoscopy

✚48400 *Injection procedure for intraoperative pancreatography (List separately in addition to code for primary procedure)*

(For intraoperative pancreatography radiologic supervision and interpretation, see 74300-74301)

~~*47560* *Laparoscopy, surgical; with guided transhepatic cholangiography, without biopsy*~~

~~*47561* *with guided transhepatic cholangiography with biopsy*~~

(For percutaneous cholangiography, see 47531 or 47532)

47563 *Laparascopy, surgical; cholecystectomy with cholangiography*

(For intraoperative cholangiography radiologic supervision and interpretation, see 74300-74301)

(For percutaneous cholangiography, see 47531-47532)

~~47630 Biliary duct stone extraction, percutaneous via T-tube tract, basket, or snare (eg, Burhenne technique)~~

~~(For radiological supervision and interpretation, use 74327)~~

(47630 has been deleted. For percutaneous biliary duct stone extraction, use 47544)

Radiology
Diagnostic Radiology (Diagnostic Imaging)
Gastrointestinal Tract

74300 *Cholangiography and/or pancreatography; intraoperative, radiological supervision and interpretation*

+74301 *additional set intraoperative, radiological supervision and interpretation (List separately in addition to code for primary procedure)*

(Use 74301 in conjunction with 74300)

(For injection procedure, see 47563, 48400)

Category I
Radiology
Diagnostic Radiology (Diagnostic Imaging)
Transcatheter Procedures

75984 *Change of percutaneous tube or drainage catheter with contrast monitoring (eg, genitourinary system, abscess), radiological supervision and interpretation*

(For percutaneous replacement of gastronomy, duodenostomy, jejunostomy, gastro-jejunostomy, or cerostomy [or other colonic] tube including fluoroscopic imaging guidance, see 49450-49452)

		(To report exchange of a percutaneous nephrostomy catheter, use 50435) (For percutaneous cholecystostomy, use 47490) (For percutaneous biliary procedures, including radiological supervision and interpretation, see 47531-47554) (*For percutaneous nephrostolithotomy or pyelostolithotomy, see 50080, 50081)* *(For removal and/or replacement of an internally dwelling ureteral stent via a transurethral approach, see 50385-50386)*		
~~D47500~~		~~*Injection procedure for percutaneous transhepatic cholangiography*~~ ~~*(For radiological supervision and interpretation, use 74320)*~~	~~000~~	N/A
~~D47505~~		~~*Injection procedure for cholangiography through an existing catheter (eg percutaneous transhepatic or T-tube)*~~ ~~*(For radiological supervision and interpretation, use 74305)*~~	~~000~~	N/A
~~D47510~~		~~*Introduction of percutaneous transhepatic catheter for biliary drainage*~~ ~~*(For radiological supervision and interpretation, use 75980)*~~	~~090~~	N/A
~~D47511~~		~~*Introduction of percutaneous transhepatic stent for internal and external biliary drainage*~~ ~~*(For radiological supervision and interpretation, use 75982*~~	~~090~~	N/A
~~D47525~~		~~*Change of percutaneous biliary drainage catheter*~~ ~~*(For radiological supervision and interpretation, use 75984)*~~	~~000~~	N/A
~~D47530~~		~~Revision and/or reinsertion of transhepatic tube~~ ~~*(For radiological supervision and interpretation, use 75984)*~~ (47500, 47505, 47510, 47511, 47525, 47530 have been deleted. To report, see 47531-47541)	~~090~~	N/A

●47531	U1	Injection procedure for cholangiography, percutaneous, complete diagnostic procedure including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; existing access	000	1.30
⊙●47532	U2	new access (eg, percutaneous transhepatic cholangiogram) (Do not report 47531, 47532 in conjunction with 47490, 47533, 47534, 47535, 47536, 47537, 47538, 47539, 47540, 47541 for procedures performed through the same percutaneous access) (For intraoperative cholangiography, see 74300, 74301)	000	4.50
⊙●47533	U3	Placement of biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; external	000	5.63
⊙●47534	U4	internal-external	000	7.85
⊙●47535	U5	Conversion of external biliary drainage catheter to internal-external biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation	000	4.20

⊙●47536	U6	Exchange of biliary drainage catheter (eg. external, internal-external , or conversion of internal-external to external only), percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation (Do not report 47536 in conjunction with 47538 for the same access) (47536 includes exchange of one catheter. For exchange of additional catheter[s] during the same session, report 47536 with modifier 59 for each additional exchange)	000	2.86
●47537	U7	Removal of biliary drainage catheter, percutaneous, requiring fluoroscopic guidance (eg, with concurrent indwelling biliary stents), including diagnostic cholangiography when performed, imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation (Do not report 47537 in conjunction with 47538 for the same access) (For removal of biliary drainage catheter not requiring fluoroscopic guidance, see E/M services and report the appropriate level of service provided [eg 99201-99215, 99217, 99218, 99219, 99220, 99221, 99222, 99223, 99224, 99225, 99226, 99231, 99232, 99233])	000	1.84
⊙●47538	U8	Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (eg, fluoroscopy and/or ultrasound), balloon dilation, catheter exchange(s) and catheter removal(s) when performed, and all associated radiological supervision and interpretation, each stent; existing access (Do not report 47538 in conjunction with 47536, 47537 for the same percutaneous access)	000	5.00

⊙●47539	U9	new access, without placement of separate biliary drainage catheter	000	9.00
⊙●47540	U10	new access, with placement of separate biliary drainage catheter (eg, external or internal-external) (Do not report 47538, 47539, 47540 in conjunction with 43277, 47542, 47555, 47556 for the same lesion in the same session) (Do not report 47540 in conjunction with 47533, 47534 for the same percutaneous access)	000	9.28
⊙●47541	U11	Placement of access through the biliary tree and into small bowel to assist with an endoscopic biliary procedure (eg, rendezvous procedure), percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; new access (Do not report 47541 in conjunction with 47531, 47532, 47533, 47534, 47535, 47536, 47537, 47538, 47539, 47540) (Do not use 47541 when there is existing catheter access. (For use of existing access through the biliary tree into small bowel to assist with an endoscopic biliary procedure, see 47535, 47536, 47537)	000	7.00

⊙✚●47542	U12	Balloon dilation of biliary duct(s) or of ampulla (sphincteroplasty), percutaneous, including imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation, each duct (List separately in addition to code for primary procedure) (Use 47542 in conjunction with 47531, 47532, 47533, 47534, 47535, 47536, 47537, 47541) (Do not report 47542 in conjunction with 43262, 43277, 47538, 47539, 47540, 47555, 47556) (Do not report 47542 in conjunction with 47544 if a balloon is used for removal of calculi, debris, and/or sludge rather than for dilation) (For percutaneous balloon dilation of multiple ducts during the same session, report an additional dilation once with 47542 and modifier 59, regardless of the number of additional ducts dilated) (For Endoscopic balloon dilation, see 43277, 47555, 47556)	ZZZ	2.85
⊙✚●47543	U13	Endoluminal biopsy(ies) of biliary tree, percutaneous, any method(s) (eg, brush, forceps and/or needle), including imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation, single or multiple (List separately in addition to code for primary procedure) (Use 47543 in conjunction with 47531, 47532, 47533, 47534, 47535, 47536, 47537, 47538, 47539, 47540) (Report 47543 once per session) (For endoscopic brushings, see 43260, 47552) (For endoscopic biopsy, see 43261, 47553)	ZZZ	3.00

⊙✚●47544	U14	Removal of calculi/debris from biliary duct(s) and/or gallbladder, percutaneous, including destruction of calculi by any method (eg, mechanical, electrohydraulic, lithotripsy) when performed, imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation (List separately in addition to code for primary procedure) (Use 47544 in conjunction with 47531, 47532, 47533, 47534, 47535, 47536, 47537, 47538, 47539, 47540) (Do not report 47544 if no calculi or debris are found, even if removal device is deployed) (Do not report 47544 in conjunction with 43264, 47554) (Do not report 47544 in conjunction with 47531-47543 for removal of incidental sludge and/or debris) (For endoscopic removal of calculi see 43264, 47554) (For endoscopic destruction of calculi, use 43265)	ZZZ	3.28
~~D74305~~		~~*Cholangiography and/or pancreatography;* through existing catheter, radiological supervision and interpretation~~ ~~(For procedure, see 47505, 48400, 47560-47561, 47563, 48400)~~ ~~(For biliary stone extraction, percutaneous, see 47630, 74327)~~	~~XXX~~	N/A
~~D74320~~		~~Cholangiography, percutaneous, transhepatic, radiological supervision and interpretation~~ (74305 and 74320 have been deleted. To report, see 47531, 47532)	~~XXX~~	N/A

~~D74327~~		~~Postoperative biliary duct calculus removal, percutaneous via T-tube tract, basket, or snare (eg, Burhenne technique), radiological supervision and interpretation~~ ~~(For procedure, use 47630)~~ (74327 has been deleted. For percutaneous biliary stone extraction, use 47544)	~~XXX~~	N/A
~~D75980~~		~~Percutaneous transhepatic biliary drainage with contrast monitoring, radiological supervision and interpretation~~ (75980 has been deleted. To report, see 47533, 47534, 47535, 47536, 47537)	~~XXX~~	N/A
~~D75982~~		~~Percutaneous placement of drainage catheter for combined internal and external biliary drainage or of a drainage stent for internal biliary drainage in patients with an inoperable mechanical biliary obstruction, radiological supervision and interpretation~~ (75982 has been deleted. To report, see 47533, 47534, 47535, 47536, 47537, 47538, 47539, 47540)	~~XXX~~	N/A

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:47531 Tracking Number U1 Original Specialty Recommended RVU: **1.50**
Presented Recommended RVU: **1.50**
Global Period: 000 RUC Recommended RVU: **1.30**

CPT Descriptor: Injection procedure for cholangiography, percutaneous, complete diagnostic procedure including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; existing access

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A 61-year-old man presents with an obstructive pancreatic head mass presents with worsening liver enzymes and hyperbilirubinemia following recent placement of an internal/external percutaneous biliary drain.

Percentage of Survey Respondents who found Vignette to be Typical: 98%

Site of Service (Complete for 010 and 090 Globals Only)

Percent of survey respondents who stated they perform the procedure; In the hospital 0% , In the ASC 0%, In the office 0%

Percent of survey respondents who stated they typically perform this procedure in the hospital, stated the patient is; Discharged the same day 0% , Overnight stay-less than 24 hours 0% , Overnight stay-more than 24 hours 0%

Percent of survey respondents who stated that if the patient is typically kept overnight also stated that they perform an E&M service later on the same day 0%

Moderate Sedation

Is moderate sedation inherent to this procedure in the Hospital/ASC setting? No
Percent of survey respondents who stated moderate sedation is typical in the Hospital/ASC setting?

Is moderate sedation inherent to this procedure in the office setting? No
Percent of survey respondents who stated moderate sedation is typical in the office setting?

Description of Pre-Service Work: The patient's medical history, physical exam, and laboratory studies are reviewed and consent is obtained. Relevant preoperative diagnostic imaging studies are retrieved and reviewed. The case is discussed with the referring clinician. A time out is performed. The patient is placed supine on the angiographic table. Prophylactic antiobiotics are administered.

Description of Intra-Service Work: The existing tube and abdomen surrounding this region is prepared and draped in sterile fashion and local anesthetic is given. Contrast is injected through the existing tube under fluoroscopic guidance. Multiple radiographs are obtained in multiple projections. The tube is flushed with saline and left in place.

Description of Post-Service Work: The patient is transported to the recovery room for hemodynamic monitoring and pain control. The procedure is documented in the permanent record. Diagnostic cholangiogram results, and patient status are communicated to the patient's family. Permanent surgical procedure and image interpretation reports are created for the medical record and copies of the reports are sent to the patient's referring physician.

SURVEY DATA

RUC Meeting Date (mm/yyyy)	10/2015				
Presenter(s):	Jerry Niedzwiecki, MD, Michael Hall, MD, Bob Vogelzang, MD, Tim Swan, MD, Matt Hawkins, MD, Zeke Silva, MD and Kurt Schoppe, MD				
Specialty(s):	Interventional Radiology				
CPT Code:	47531				
Sample Size:	1730	**Resp N:**	42	**Response:** 2.4 %	
Description of Sample:	Random Sample: SIR 980/ACR 750				

	Low	**25th pctl**	**Median***	**75th pctl**	**High**
Service Performance Rate	1.00	10.00	**20.00**	35.00	200.00
Survey RVW:	1.00	1.50	**2.13**	3.15	9.00
Pre-Service Evaluation Time:			**20.00**		
Pre-Service Positioning Time:			**10.00**		
Pre-Service Scrub, Dress, Wait Time:			**10.00**		
Intra-Service Time:	5.00	10.00	**15.00**	20.00	120.00

Immediate Post Service-Time:	**12.00**	
Post Operative Visits	**Total Min****	**CPT Code and Number of Visits**
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.00** 99239x **0.00** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

**Physician standard total minutes per E/M visit: 99291 (70); 99292 (30); 99231 (20); 99232 (40); 99233 (55); 99238(38); 99239 (55); 99217 (38); 99211 (7); 99212 (16); 99213 (23); 99214 (40); 99215 (55); 99224 (20); 99225 (40); 99226 (55); 99354 (60); 99355 (30); 99356 (60); 99357 (30)

Specialty Society Recommended Data

Please, pick the pre-service time package that best corresponds to the data which was collected in the survey process. (Note: your recommended pre time should not exceed your survey median time for any category)

2a-FAC Diff Pat/Straightfor Proc(no sedation/anes)

CPT Code:	47531	**Recommended Physician Work RVU: 1.30**		
		Specialty Recommended Pre-Service Time	**Specialty Recommended Pre Time Package**	**Adjustments/Recommended Pre-Service Time**
Pre-Service Evaluation Time:		**18.00**	**18.00**	**0.00**
Pre-Service Positioning Time:		**3.00**	**1.00**	**2.00**
Pre-Service Scrub, Dress, Wait Time:		**6.00**	**6.00**	**0.00**
Intra-Service Time:		**15.00**		

Please, pick the post-service time package that best corresponds to the data which was collected in the survey process: (Note: your recommended post time should not exceed your survey median time)

7A Local/Simple Procedure

	Specialty Recommended Post-Service Time	**Specialty Recommended Post Time Package**	**Adjustments/Recommended Post-Service Time**
Immediate Post Service-Time:	**12.00**	**18.00**	**-6.00**

Post-Operative Visits	Total Min**	CPT Code and Number of Visits
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.0** 99239x **0.0** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

Modifier -51 Exempt Status
Is the recommended value for the new/revised procedure based on its modifier -51 exempt status? No

New Technology/Service:
Is this new/revised procedure considered to be a new technology or service? No

TOP KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
49450	000	1.36	**RUC Time**

CPT Descriptor Replacement of gastrostomy or cecostomy (or other colonic) tube, percutaneous, under fluoroscopic guidance including contrast injection(s), image documentation and report

SECOND HIGHEST KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
49083	000	2.00	**RUC Time**

CPT Descriptor Abdominal paracentesis (diagnostic or therapeutic); with imaging guidance

KEY MPC COMPARISON CODES:
Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU	Time Source	Most Recent Medicare Utilization
55876	000	1.73	**RUC Time**	15,185

CPT Descriptor 1 Placement of interstitial device(s) for radiation therapy guidance (eg, fiducial markers, dosimeter), prostate (via needle, any approach), single or multiple

MPC CPT Code 2	Global	Work RVU	Time Source	Most Recent Medicare Utilization
31622	000	2.78	**RUC Time**	68,721

CPT Descriptor 2 Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with cell washing, when performed (separate procedure)

Other Reference CPT Code	Global	Work RVU	Time Source
		0.00	

CPT Descriptor

RELATIONSHIP OF CODE BEING REVIEWED TO TOP TWO KEY REFERENCE SERVICES:

Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the top two chosen key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Top Key Reference Code: 16 **% of respondents:** 38.0 **%**

Number of respondents who choose 2nd Key Reference Code: 5 **% of respondents:** 11.9 **%**

TIME ESTIMATES (Median)

	CPT Code: 47531	Top Key Reference CPT Code: 49450	2nd Key Reference CPT Code: **49083**
Median Pre-Service Time	27.00	30.00	25.00
Median Intra-Service Time	15.00	10.00	25.00
Median Immediate Post-service Time	12.00	10.00	10.00
Median Critical Care Time	0.0	0.00	0.00
Median Other Hospital Visit Time	0.0	0.00	0.00
Median Discharge Day Management Time	0.0	0.00	0.00
Median Office Visit Time	0.0	0.00	0.00
Prolonged Services Time	0.0	0.00	0.00
Median Subsequent Observation Care Time	0.0	0.00	0.00
Median Total Time	**54.00**	**50.00**	**60.00**
Other time if appropriate			

INTENSITY/COMPLEXITY MEASURES
(of those that selected Key Reference codes)

Survey respondents are rating the survey code relative to the key reference code.

Intensity & Complexity Rating Scale: (much less= -2.00, somewhat less= -1.00, identical= 0.00, somewhat more= 1.00, much more= 2.00)

	Top Key Ref Code	2nd Key Ref Code
Mental Effort and Judgment (Mean)		
The number of possible diagnosis and/or the number of management options that must be considered		
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed		
Urgency of medical decision making		
Technical Skill/Physical Effort (Mean)		
Technical skill required		
Physical effort required		

Psychological Stress (Mean)

The risk of significant complications, morbidity and/or mortality		
Outcome depends on the skill and judgment of physician		
Estimated risk of malpractice suit with poor outcome		

INTENSITY/COMPLEXITY MEASURES	**Top Key Ref Code**	**2nd Key Ref Code**
Time Segment (Mean)		
Overall intensity/complexity	-0.12	0.40

Additional Rationale and Comments

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

The Joint CPT-RUC Workgroup identified (Group 12) codes 47500, 74320-26, 47505, 74305-26, 47510, 75980-26, 47511, 75982-26, 74305-26, 47505, 74320-26, 47500, 75980-26, 47510, 75982-26 as being reported together at least 75% of the time. The specialties updated the percutaneous biliary code family based on the current practice of medicine, and in so doing, deleted 10 percutaneous biliary procedure codes while creating 14 new bundled codes that describe percutaneous biliary procedures including imaging.

This new 'biliary family' was recently surveyed and presented at the April 2015 RUC meeting. However, the RUC and specialty societies agreed that the survey data for this family of services was problematic. Specifically, the RUC noted codes 47532, 47533 and 47534 all had identical median intra-service time of 60 minutes. CPT code 47533 includes the work of 47532 plus the work of an additional access and drain placement. Furthermore, 47534 includes the work of 47533 plus the work of crossing the occlusion and placement of an internal/external drain. Given this time anomaly, the RUC agreed to provide interim recommendations at this meeting, while allowing the specialty societies to re-survey the entire family of codes for October 2015.

The specialty societies worked with the research subcommittee to develop a modified survey tool in an attempt to facilitate gathering more accurate rank order survey data from the surveyed physicians. The entire family of codes was included on one single survey. The research subcommittee approved this survey method, which collected:
• overall complexity/intensity data;
• service performance rates for just the surveyed codes; and
• only whether the vignette is typical or not.
We did not ask for them to provide details if the vignette is not typical.

Compelling Evidence
SIR/ACR believe that the current values for CPT codes now used for the percutaneous, image guided biliary interventional procedures newly described in Tab 4 are no longer rational or appropriate for the detailed, granular and far more accurately descriptive codes in this new group. In our opinion, there have been significant changes in technique, knowledge and technology, patient population and physician time.

Technique, Knowledge and Technology
The codes currently used for this family of biliary procedures no longer reflect the techniques now used for image-guided, catheter-based biliary procedures. Indeed, as can be seen, there are 14 new codes in this family which will henceforth be used to describe a diverse range of procedures. As an index example of these significant changes in technique, one of the most widely used of the current codes, 47510, *Introduction of percutaneous transhepatic catheter for biliary drainage*, was previously performed by a method in which the biliary tree was first opacified and often distended by blind needle puncture (not ultrasound), after which an optimal duct was identified and punctured under fluoroscopy using large sheathed needles or even the trocar technique. These techniques have all changed since this code was introduced and valued as noted below.

Virtually all the medical devices currently used in biliary catheter procedures have been developed since the current codes were adopted. The past twenty years have witnessed major advances in our knowledge base including:
1) using imaging guidance, such as ultrasound, and preoperative mapping to avoid hepatic hilar structures and thus prevent bleeding and bile leaks
2) new insights into how segmental biliary ductal anatomy can help avoid bleeding and septic complications
3) development of much less aggressive and safer guidewire-based methods which involve more steps and more effort, skill and physician time such as micropuncture access with gradual stepwise transition to heavy-duty guidewires, tract dilation and placement of catheters over safer, more stable wires and use of real-time ultrasound guidance for needle access. The ductal system is never distended to avoid septic complications.

We would note that the example of 47510 is reflective of the majority of the existing codes for biliary catheter procedures. Simply put, the new codes reflect new thinking and understanding as well as considerable improvements and advances in techniques which render the current values inappropriate for these new codes.

In another example, the existing code 47511, *Introduction of percutaneous transhepatic stent for internal and external biliary drainage*. Current methods utilize a wide range of self-expanding open, as well as covered, metallic stents of various designs designed specifically for biliary pathology and using percutaneous methods as well as plastic and even retrievable metallic stents. These devices were not available when the existing codes were proposed or adopted.

A number of the codes, for example, 47543, *Endoluminal biopsy(ies) of biliary tree, percutaneous, any method(s) (eg, brush, forceps and/or needle),* 47544 *Removal of calculi/debris from biliary duct(s) and/or gallbladder, percutaneous, including destruction of calculi by any method (eg, mechanical, electrohydraulic, lithotripsy),* 47542, *Balloon dilation of biliary duct(s) or of ampulla (sphincteroplasty), percutaneous,* or 47541, *Placement of access through the biliary tree and into small bowel to assist with an endoscopic biliary procedure (eg, rendezvous procedure), percutaneous*, describe procedures which did not exist previously and, thus, are new technology not able to be described at all under the old codes.

Patient Population

SIR/ACR assert that the population of patients treated with the new family of procedures described herein has changed considerably in at least three major ways:

1) Previously the majority of all biliary catheter procedures were used for basic relief of distal ductal biliary obstruction either acutely or chronically often related to pancreatic cancer and/or stone disease. These patients previously drained and stented percutaneously are now largely treated by endoscopic methods. The significant majority of all of the biliary diseases referred for interventional percutaneous treatment now have higher and more complex levels of benign and malignant biliary occlusion, including hilar and segmental obstruction. Treatment of these lesions involves considerably more work, time, effort and risk to achieve satisfactory outcomes.
2) The widespread use of liver transplantation has introduced an entirely different patient population: the postoperative liver transplant patient with ischemic biliary strictures (intrahepatic and/or extrahepatic), which requires major investments of time, skill and effort to obtain access and drain, stent and dilate these complex situations.
3) Hepatic surgery for malignancy has also become far more sophisticated and segmental or lobar resections will frequently result in referrals for drainage of biliary leaks from nondilated ducts. These patients also present challenges in drainage and management.

An example of the change in patient populations can also be seen in the management of biliary stone disease. Previously, patients with distal biliary calculi were referred for external biliary drainage and stone manipulation. These patients are no longer sent for percutaneous treatment. The stone diseases seen currently are intrahepatic lithiasis or extensive stone formation as a result of biliary-enteric anastomoses both of which require far more skill and time to achieve satisfactory initial access but also need much different time-consuming and labor intensive methods to extract or expel the stones.

New Biliary Family

The CPT editorial panel established 14 bundled codes that describe percutaneous biliary procedures including imaging. Below is a table demonstrating the relationship between the new codes:

000 Code Set:

47531: Direct crosswalk to 46611 (work RVU= 1.30)

47532: Recommendation of 25th percentile RVW 4.50 based on survey (N=42) with median intra-service time of 45 and total time of 98 minutes. This recommendation is well supported by the #1 KRS (49407: RVW 4.50 (exactly the same), Intra 45 (exactly the

same), total 110 (slightly higher)). The recommendation is also well bracketed by MPCs 55214 (RVW 3.50, Intra 30, total 79) and 52235 (RVW 5.44, Intra 45 (same as 47532), and total 94 (less than 47532)).

47533: The RUC recommends the survey 25th percentile of 4.50 work RVUs

47534: The RUC recommends the survey 25th percentile of 7.85 work RVUs

47535: Recommendation of 25th percentile RVW 4.20 based on survey (N=42) with median intra-service time of 45 and total time of 93 minutes. The societies feel that the work of 47535 is similar to 47532 and that the survey and our recommendations are therefore also consistent. This recommendation is well bracketed by the #1 and #2 KRS (36247: RVW 6.29, Intra 60, Total 131, and 32550: RVW 4.17, Intra 30, Total 90). The recommendation is also well bracketed by MPCs 52214 (RVW 3.50, Intra 30, Total 79) and 52235 (RVW 5.44, Intra 45, Total 94).

47536: The RUC recommends the survey 25th percentile of 2.86 work RVUs

47537: Recommendation of 25th percentile RVW 1.84 based on survey (N=42) with median intra-service time of 15 and total time of 52 minutes. This work is similar to 47531with the additional work of fluoroscopic drain removal. The societies feel that this extra work is reflective of clinical practice and similarly reflected in the survey median and 25th RVW. This recommendation is well bracketed by the #1 and #2 KRS (49083: RVW 2.00, Intra 25, Total 60, and 49450: RVW 1.36, Intra 10, Total 50).

47538: The RUC recommends the survey 25th percentile of 5.00 work RVUs

47539: Recommendation of 25th percentile RVW 9.00 based on survey (N=41) with median intra-service time of 75 and total time of 136 minutes. This recommendation is well bracketed by MPC 52353 (RVW 7.50, Intra 60, Total 133) and the #1 KRS (37226: RVW 10.49, Intra 90, Total 168).

47540: The RUC recommends the survey 25th percentile of 9.28 work RVUs

47541: Recommendation of 25th percentile RVW 7.00 based on survey (N=42) with median intra-service time of 60 and total time of 121 minutes. The societies feel that the intensity and complexity of this work is in between that of 47533 and 47534 based on magnitude estimation and therefore are recommending a value greater than 47533 but less than 47534. This recommendation is well bracketed by the #1 and #2 KRS (37226: RVW 10.49, Intra 90, Total 168, and 37213: RVW 5.00, Intra 33, Total 99). This recommendation is also supported by MPC 52353 (RVW 7.50, Intra 60, Total 133).

ZZZ Code Set:

47542**:** The RUC recommends the survey 25th percentile of 2.85 work RVUs

47543**:** Recommendation of 25th percentile RVW 3.00 based on survey (N=42) with median intra-service time of 30. This recommendation is well bracketed by MPC 99292 (RVW 2.25, Intra 30) and #1 KRS (37185: RVW 3.28, Intra 40).

47544**:** The RUC recommends a direct crosswalk to 37185 and 92973 (work RVU= 3.28)

PreService Time

We selected pre time package 2B for 47532, 47533, 47534, 47535, 47536, 47541, 47538, 47539, and 47540. For 47531 and 47537, we selected pre time package 2A, because moderate sedation was not inherent in those two procedures. We also added two additional minutes of positioning time to account for positioning patient on angiographic table, as well as optimize lead placement to avoid obscuring imaging.

Relativity

The consensus panel reviewed the survey data for the family this new family of biliary procedures and analyzed the relativity within the family. The consensus panel felt the appropriate recommendations for 47533, 47534, 47538 and 47542 fell between the surveyed 25th percentile and the survey median. As such, we are recommending crosswalk values for those codes.

The consensus panel reviewed the survey data and believe the recommendations compare favorably to (1) the new family of biliary codes, (2) interventional radiology and (3) MPCs. Below is an outline of the comparisons:

	CPT Code	Global Period	Work RVU	Total Time	Pre Time			Intra Time	Post Time	IWPUT
					Eval	Pos	SDW			

reference	49450	000	1.36	50	20	5	5	10	10	0.054
surveyed	47531	000	1.30	54	18	3	6	15	12	0.047
MPC	55876	000	1.73	59	19	10		20	10	0.043
surveyed	47537	000	1.84	52	18	3	6	15	10	0.073
reference	49083	000	2.00	60	15	5	5	25	10	0.052
MPC	31622	000	2.78	65	10	5	5	30	15	0.069
reference	49452	000	2.86	60	20	5	5	20	10	0.102
surveyed	47536	000	2.86	61	20	3	5	20	13	0.111
MPC	52214	000	3.50	79	19	5	5	30	20	0.083
reference	32550	000	4.17	90	15	15	10	30	20	0.099
surveyed	47535	000	4.20	93	25	3	5	45	15	0.071
reference	49407	000	4.50	110	35	5	5	45	20	0.069
surveyed	47532	000	4.50	98	30	3	5	45	15	0.075
reference	37191	000	4.71	83	30	3	5	30	15	0.120
reference	37213	000	5.00	99	33	3	5	33	25	0.109
MPC	52235	000	5.44	94	19	5	5	45	20	0.098
surveyed	47538	000	5.00	106	30	3	5	53	15	0.082
crosswalk	31267	000	5.45	110	30			50	30	0.082
reference	36247	000	6.29	131	33	3	5	60	30	0.080
surveyed	47533	000	5.63	121	33	3	5	60	20	0.083
crosswalk	37197	000	6.29	121	33	3	5	60	20	0.083
surveyed	47541	000	7.00	121	33	3	5	60	20	0.095
MPC	52353	000	7.50	133	33	5	15	60	20	0.101
reference	37211	000	8.00	138	40	3	5	60	30	0.105
surveyed	47534	000	7.85	129	33	3	5	68	20	0.107
crosswalk	43274	000	8.58	139	33	10	5	68	23	0.104
surveyed	47539	000	9.00	136	33	3	5	75	20	0.103
reference	37226	000	10.49	168	40	3	5	90	30	0.098
reference	37228	000	11.00	168	40	3	5	90	30	0.104
surveyed	47540	000	9.28	146	33	3	5	85	20	0.114
reference	37230	000	13.80	198	40	3	5	120	30	0.101
MPC	99292	ZZZ	2.25	30				30		0.075
surveyed	47542	ZZZ	2.85	30				30		0.099
crosswalk	37239	ZZZ	2.97	32	1			30	1	0.098
surveyed	47543	ZZZ	3.00	30				30		0.100
reference	37185	ZZZ	3.28	40				40		0.082
reference	37222	ZZZ	3.73	42	1			40	1	0.092
surveyed	47544	ZZZ	3.28	45				45		0.088
MPC	57267	ZZZ	4.88	45				45		0.108
reference	37235	ZZZ	7.80	82	1			80	1	0.097

Recommendations

The consensus panel reviewed the (1) RUC survey data, (2) the family relationship between the new codes, (2) the relativity to codes within interventional radiology specialty, (3) rank order within the Fee Schedule, (4) compelling evidence, (5) standard packages and (6) RUC guidelines and makes the following physician work recommendations:

CPT	Global	Work	Total	Pre Time			Intra	Post	IWPUT
Code	Period	RVU	Time	Eval	Pos	SDW	Time	Time	
47531	000	1.30	54	18	3	6	15	12	0.047
47532	000	4.50	98	30	3	5	45	15	0.075

47533	000	5.63	121	33	3	5	60	20	0.083
47534	000	7.85	129	33	3	5	68	20	0.107
47535	000	4.20	93	25	3	5	45	15	0.071
47536	000	2.86	61	20	3	5	20	13	0.111
47537	000	1.84	52	18	3	6	15	10	0.073
47538	000	5.00	106	30	3	5	53	15	0.082
47539	000	9.00	136	33	3	5	75	20	0.103
47540	000	9.28	146	33	3	5	85	20	0.114
47541	000	7.00	121	33	3	5	60	20	0.095
47542	ZZZ	2.85	30				30		0.099
47543	ZZZ	3.00	30				30		0.100
47544	ZZZ	3.28	45				45		0.088

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions: No

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☐ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.
   - ☐ Historical precedents.
   - ☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) 47505 and 74305

How often do physicians in your specialty perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty Interventional Radiology How often? Commonly

Specialty How often?

Specialty How often?

Estimate the number of times this service might be provided nationally in a one-year period?

If the recommendation is from multiple specialties, please provide the frequency and percentage for each specialty. Please explain the rationale for this estimate. A national number is not available.

Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? 0 If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty. Please explain the rationale for this estimate. A national number is not available.

Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%
Specialty	Frequency 0	Percentage 0.00	%

Do many physicians perform this service across the United States? Yes

---

Berenson-Eggers Type of Service (BETOS) Assignment

Please pick the appropriate BETOS classification that best corresponds to the clinical nature of this CPT code. Please select the main BETOS classification and sub-classification to the greatest level of specificity possible.

Main BETOS Classification:
Procedures

BETOS Sub-classification:
Minor procedure

BETOS Sub-classification Level II:
Other

Professional Liability Insurance Information (PLI)

If the surveyed code is an existing code and the specialty believes the specialty utilization mix will not change, enter the surveyed existing CPT code number

If this code is a new/revised code or an existing code in which the specialty utilization mix will change, please select another crosswalk based on a similar specialty mix. 49450

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:47532 Tracking Number U2 Original Specialty Recommended RVU: **4.50**
Presented Recommended RVU: **4.50**
Global Period: 000 RUC Recommended RVU: **4.50**

CPT Descriptor: Injection procedure for cholangiography, percutaneous, complete diagnostic procedure including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; new access (eg, percutaneous transhepatic cholangiogram)

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A 61-year-old man presents with worsening liver enzymes and hyperbilirubinemia of unknown etiology. ERCP was unsuccessful.

Percentage of Survey Respondents who found Vignette to be Typical: 98%

Site of Service (Complete for 010 and 090 Globals Only)

Percent of survey respondents who stated they perform the procedure; In the hospital 0% , In the ASC 0%, In the office 0%

Percent of survey respondents who stated they typically perform this procedure in the hospital, stated the patient is; Discharged the same day 0% , Overnight stay-less than 24 hours 0% , Overnight stay-more than 24 hours 0%

Percent of survey respondents who stated that if the patient is typically kept overnight also stated that they perform an E&M service later on the same day 0%

Moderate Sedation

Is moderate sedation inherent to this procedure in the Hospital/ASC setting? Yes
Percent of survey respondents who stated moderate sedation is typical in the Hospital/ASC setting? 83%

Is moderate sedation inherent to this procedure in the office setting? Yes
Percent of survey respondents who stated moderate sedation is typical in the office setting? 75%

Description of Pre-Service Work: The patient's medical history, physical exam, and laboratory studies are reviewed and consent is obtained. Relevant preoperative diagnostic imaging studies are retrieved and reviewed. The case is discussed with the referring clinician. A time out is performed. The patient is placed supine on the angiographic table. Prophylactic antiobiotics are administered. Local anesthetic is given.

Description of Intra-Service Work: Ultrasound and fluoroscopy are used to identify a safe tract into a peripheral bile duct in the liver. The abdomen and right flank are prepared and draped in sterile fashion. Under ultrasound and fluoroscopic guidance, multiple needle passes are made and ultimately a needle is placed into a peripheral bile duct and contrast is injected to opacify the bile ducts. Multiple radiographs are obtained in multiple projections. The needle is removed.

Description of Post-Service Work: A sterile dressing is applied. The patient is transported to the recovery room for hemodynamic monitoring, sedation recovery, and pain control. The procedure is documented in the permanent record. Diagnostic cholangiogram results, and patient status are communicated to the patient's family. Permanent surgical procedure and image interpretation reports are created for the medical record and copies of the reports are sent to the patient's referring physician.

SURVEY DATA

RUC Meeting Date (mm/yyyy)	10/2015				
Presenter(s):	Jerry Niedzwiecki, MD, Michael Hall, MD, Bob Vogelzang, MD, Tim Swan, MD, Matt Hawkins, MD, Zeke Silva, MD and Kurt Schoppe, MD				
Specialty(s):	Interventional Radiology				
CPT Code:	47532				
Sample Size:	1730	**Resp N:**	42	**Response:** 2.4 %	
Description of Sample:	Random Sample: SIR 980/ACR 750				

	Low	**25th pctl**	**Median***	**75th pctl**	**High**
Service Performance Rate	0.00	3.00	**6.00**	20.00	100.00
Survey RVW:	2.09	4.50	**5.50**	8.00	14.00
Pre-Service Evaluation Time:			**30.00**		
Pre-Service Positioning Time:			**10.00**		
Pre-Service Scrub, Dress, Wait Time:			**10.00**		
Intra-Service Time:	15.00	30.00	**45.00**	60.00	120.00

Immediate Post Service-Time:	**15.00**	
Post Operative Visits	**Total Min****	**CPT Code and Number of Visits**
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.00** 99239x **0.00** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

**Physician standard total minutes per E/M visit: 99291 (70); 99292 (30); 99231 (20); 99232 (40); 99233 (55); 99238(38); 99239 (55); 99217 (38); 99211 (7); 99212 (16); 99213 (23); 99214 (40); 99215 (55); 99224 (20); 99225 (40); 99226 (55); 99354 (60); 99355 (30); 99356 (60); 99357 (30)

Specialty Society Recommended Data

Please, pick the pre-service time package that best corresponds to the data which was collected in the survey process. (Note: your recommended pre time should not exceed your survey median time for any category)

2b-FAC Diff Pat/Straightfor Proc(w sedation/anes)

CPT Code:	47532	**Recommended Physician Work RVU: 4.50**		
		Specialty Recommended Pre-Service Time	**Specialty Recommended Pre Time Package**	**Adjustments/Recommended Pre-Service Time**
Pre-Service Evaluation Time:		**30.00**	**33.00**	**-3.00**
Pre-Service Positioning Time:		**3.00**	**1.00**	**2.00**
Pre-Service Scrub, Dress, Wait Time:		**5.00**	**5.00**	**0.00**
Intra-Service Time:		**45.00**		

Please, pick the post-service time package that best corresponds to the data which was collected in the survey process: (Note: your recommended post time should not exceed your survey median time)

8A IV Sedation/Simple Procedure

	Specialty Recommended Post-Service Time	**Specialty Recommended Post Time Package**	**Adjustments/Recommended Post-Service Time**
Immediate Post Service-Time:	**15.00**	**25.00**	**-10.00**

Post-Operative Visits	Total Min**	CPT Code and Number of Visits
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.0** 99239x **0.0** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

Modifier -51 Exempt Status
Is the recommended value for the new/revised procedure based on its modifier -51 exempt status? No

New Technology/Service:
Is this new/revised procedure considered to be a new technology or service? No

TOP KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
49407	000	4.50	**RUC Time**

CPT Descriptor Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst); peritoneal or retroperitoneal, transvaginal or transrectal

SECOND HIGHEST KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
36247	000	6.29	**RUC Time**

CPT Descriptor Selective catheter placement, arterial system; initial third order or more selective abdominal, pelvic, or lower extremity artery branch, within a vascular family

KEY MPC COMPARISON CODES:
Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU	Time Source	Most Recent Medicare Utilization
52214	000	3.50	**RUC Time**	20,091

CPT Descriptor 1 Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) of trigone, bladder neck, prostatic fossa, urethra, or periurethral glands

MPC CPT Code 2	Global	Work RVU	Time Source	Most Recent Medicare Utilization
52235	000	5.44	**RUC Time**	31,688

CPT Descriptor 2 Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of; MEDIUM bladder tumor(s) (2.0 to 5.0 cm)

Other Reference CPT Code	Global	Work RVU	Time Source
		0.00	

CPT Descriptor

RELATIONSHIP OF CODE BEING REVIEWED TO TOP TWO KEY REFERENCE SERVICES:

Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the top two chosen key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Top Key Reference Code: 6 **% of respondents:** 14.2 **%**

Number of respondents who choose 2nd Key Reference Code: 6 **% of respondents:** 14.2 **%**

TIME ESTIMATES (Median)

	CPT Code: 47532	**Top Key Reference CPT Code:** 49407	**2nd Key Reference CPT Code:** **36247**
Median Pre-Service Time	38.00	45.00	41.00
Median Intra-Service Time	45.00	45.00	60.00
Median Immediate Post-service Time	15.00	20.00	30.00
Median Critical Care Time	0.0	0.00	0.00
Median Other Hospital Visit Time	0.0	0.00	0.00
Median Discharge Day Management Time	0.0	0.00	0.00
Median Office Visit Time	0.0	0.00	0.00
Prolonged Services Time	0.0	0.00	0.00
Median Subsequent Observation Care Time	0.0	0.00	0.00
Median Total Time	**98.00**	**110.00**	**131.00**
Other time if appropriate			

INTENSITY/COMPLEXITY MEASURES
(of those that selected Key Reference codes)

Survey respondents are rating the survey code relative to the key reference code.

Intensity & Complexity Rating Scale: (much less= -2.00, somewhat less= -1.00, identical= 0.00, somewhat more= 1.00, much more= 2.00)

	Top Key Ref Code	**2nd Key Ref Code**
Mental Effort and Judgment (Mean)		
The number of possible diagnosis and/or the number of management options that must be considered		
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed		
Urgency of medical decision making		
Technical Skill/Physical Effort (Mean)		
Technical skill required		
Physical effort required		

Psychological Stress (Mean)

The risk of significant complications, morbidity and/or mortality		
Outcome depends on the skill and judgment of physician		
Estimated risk of malpractice suit with poor outcome		

INTENSITY/COMPLEXITY MEASURES	**Top Key Ref Code**	**2nd Key Ref Code**
Time Segment (Mean)		
Overall intensity/complexity	0.33	0.40

Additional Rationale and Comments

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

THE ADDITIONAL RATIONALE BELOW IS THE ORIGINAL RATIONALE SUBMITTED BY THE SPECIALTY SOCIETY(IES) PRIOR TO THE RUC MEETING AND DOES NOT NECESSARILY REPRESENT THE RATIONALE FOR THE RUC RECOMMENDATION. TO VIEW THE RUC'S RATIONALE, PLEASE REVIEW THE SEPARATE RUC RECOMMENDATION DOCUMENT.

The Joint CPT-RUC Workgroup identified (Group 12) codes 47500, 74320-26, 47505, 74305-26, 47510, 75980-26, 47511, 75982-26, 74305-26, 47505, 74320-26, 47500, 75980-26, 47510, 75982-26 as being reported together at least 75% of the time. The specialties updated the percutaneous biliary code family based on the current practice of medicine, and in so doing, deleted 10 percutaneous biliary procedure codes while creating 14 new bundled codes that describe percutaneous biliary procedures including imaging.

This new 'biliary family' was recently surveyed and presented at the April 2015 RUC meeting. However, the RUC and specialty societies agreed that the survey data for this family of services was problematic. Specifically, the RUC noted codes 47532, 47533 and 47534 all had identical median intra-service time of 60 minutes. CPT code 47533 includes the work of 47532 plus the work of an additional access and drain placement. Furthermore, 47534 includes the work of 47533 plus the work of crossing the occlusion and placement of an internal/external drain. Given this time anomaly, the RUC agreed to provide interim recommendations at this meeting, while allowing the specialty societies to re-survey the entire family of codes for October 2015.

The specialty societies worked with the research subcommittee to develop a modified survey tool in an attempt to facilitate gathering more accurate rank order survey data from the surveyed physicians. The entire family of codes was included on one single survey. The research subcommittee approved this survey method, which collected:
• overall complexity/intensity data;
• service performance rates for just the surveyed codes; and
• only whether the vignette is typical or not.
We did not ask for them to provide details if the vignette is not typical.

Compelling Evidence
SIR/ACR believe that the current values for CPT codes now used for the percutaneous, image guided biliary interventional procedures newly described in Tab 4 are no longer rational or appropriate for the detailed, granular and far more accurately descriptive codes in this new group. In our opinion, there have been significant changes in technique, knowledge and technology, patient population and physician time.

Technique, Knowledge and Technology
The codes currently used for this family of biliary procedures no longer reflect the techniques now used for image-guided, catheter-based biliary procedures. Indeed, as can be seen, there are 14 new codes in this family which will henceforth be used to describe a diverse range of procedures. As an index example of these significant changes in technique, one of the most widely used of the

current codes, 47510, *Introduction of percutaneous transhepatic catheter for biliary drainage*, was previously performed by a method in which the biliary tree was first opacified and often distended by blind needle puncture (not ultrasound), after which an optimal duct was identified and punctured under fluoroscopy using large sheathed needles or even the trocar technique. These techniques have all changed since this code was introduced and valued as noted below.

Virtually all the medical devices currently used in biliary catheter procedures have been developed since the current codes were adopted. The past twenty years have witnessed major advances in our knowledge base including:
1) using imaging guidance, such as ultrasound, and preoperative mapping to avoid hepatic hilar structures and thus prevent bleeding and bile leaks
2) new insights into how segmental biliary ductal anatomy can help avoid bleeding and septic complications
3) development of much less aggressive and safer guidewire-based methods which involve more steps and more effort, skill and physician time such as micropuncture access with gradual stepwise transition to heavy-duty guidewires, tract dilation and placement of catheters over safer, more stable wires and use of real-time ultrasound guidance for needle access. The ductal system is never distended to avoid septic complications.

We would note that the example of 47510 is reflective of the majority of the existing codes for biliary catheter procedures. Simply put, the new codes reflect new thinking and understanding as well as considerable improvements and advances in techniques which render the current values inappropriate for these new codes.

In another example, the existing code 47511, *Introduction of percutaneous transhepatic stent for internal and external biliary drainage*. Current methods utilize a wide range of self-expanding open, as well as covered, metallic stents of various designs designed specifically for biliary pathology and using percutaneous methods as well as plastic and even retrievable metallic stents. These devices were not available when the existing codes were proposed or adopted.

A number of the codes, for example, 47543, *Endoluminal biopsy(ies) of biliary tree, percutaneous, any method(s) (eg, brush, forceps and/or needle)*, 47544 *Removal of calculi/debris from biliary duct(s) and/or gallbladder, percutaneous, including destruction of calculi by any method (eg, mechanical, electrohydraulic, lithotripsy)*, 47542, *Balloon dilation of biliary duct(s) or of ampulla (sphincteroplasty), percutaneous,* or 47541, *Placement of access through the biliary tree and into small bowel to assist with an endoscopic biliary procedure (eg, rendezvous procedure), percutaneous*, describe procedures which did not exist previously and, thus, are new technology not able to be described at all under the old codes.

Patient Population

SIR/ACR assert that the population of patients treated with the new family of procedures described herein has changed considerably in at least three major ways:

1) Previously the majority of all biliary catheter procedures were used for basic relief of distal ductal biliary obstruction either acutely or chronically often related to pancreatic cancer and/or stone disease. These patients previously drained and stented percutaneously are now largely treated by endoscopic methods. The significant majority of all of the biliary diseases referred for interventional percutaneous treatment now have higher and more complex levels of benign and malignant biliary occlusion, including hilar and segmental obstruction. Treatment of these lesions involves considerably more work, time, effort and risk to achieve satisfactory outcomes.
2) The widespread use of liver transplantation has introduced an entirely different patient population: the postoperative liver transplant patient with ischemic biliary strictures (intrahepatic and/or extrahepatic), which requires major investments of time, skill and effort to obtain access and drain, stent and dilate these complex situations.
3) Hepatic surgery for malignancy has also become far more sophisticated and segmental or lobar resections will frequently result in referrals for drainage of biliary leaks from nondilated ducts. These patients also present challenges in drainage and management.

An example of the change in patient populations can also be seen in the management of biliary stone disease. Previously, patients with distal biliary calculi were referred for external biliary drainage and stone manipulation. These patients are no longer sent for percutaneous treatment. The stone diseases seen currently are intrahepatic lithiasis or extensive stone formation as a result of biliary-enteric anastomoses both of which require far more skill and time to achieve satisfactory initial access but also need much different time-consuming and labor intensive methods to extract or expel the stones.

New Biliary Family

The CPT editorial panel established 14 bundled codes that describe percutaneous biliary procedures including imaging. Below is a table demonstrating the relationship between the new codes:

000 Code Set:

47531: Direct crosswalk to 46611 (work RVU= 1.30)

47532: Recommendation of 25th percentile RVW 4.50 based on survey (N=42) with median intra-service time of 45 and total time of 98 minutes. This recommendation is well supported by the #1 KRS (49407: RVW 4.50 (exactly the same), Intra 45 (exactly the same), total 110 (slightly higher)). The recommendation is also well bracketed by MPCs 55214 (RVW 3.50, Intra 30, total 79) and 52235 (RVW 5.44, Intra 45 (same as 47532), and total 94 (less than 47532)).

47533: The RUC recommends the survey 25th percentile of 4.50 work RVUs

47534: The RUC recommends the survey 25th percentile of 7.85 work RVUs

47535: Recommendation of 25th percentile RVW 4.20 based on survey (N=42) with median intra-service time of 45 and total time of 93 minutes. The societies feel that the work of 47535 is similar to 47532 and that the survey and our recommendations are therefore also consistent. This recommendation is well bracketed by the #1 and #2 KRS (36247: RVW 6.29, Intra 60, Total 131, and 32550: RVW 4.17, Intra 30, Total 90). The recommendation is also well bracketed by MPCs 52214 (RVW 3.50, Intra 30, Total 79) and 52235 (RVW 5.44, Intra 45, Total 94).

47536: The RUC recommends the survey 25th percentile of 2.86 work RVUs

47537: Recommendation of 25th percentile RVW 1.84 based on survey (N=42) with median intra-service time of 15 and total time of 52 minutes. This work is similar to 47531with the additional work of fluoroscopic drain removal. The societies feel that this extra work is reflective of clinical practice and similarly reflected in the survey median and 25th RVW. This recommendation is well bracketed by the #1 and #2 KRS (49083: RVW 2.00, Intra 25, Total 60, and 49450: RVW 1.36, Intra 10, Total 50).

47538: The RUC recommends the survey 25th percentile of 5.00 work RVUs

47539: Recommendation of 25th percentile RVW 9.00 based on survey (N=41) with median intra-service time of 75 and total time of 136 minutes. This recommendation is well bracketed by MPC 52353 (RVW 7.50, Intra 60, Total 133) and the #1 KRS (37226: RVW 10.49, Intra 90, Total 168).

47540: The RUC recommends the survey 25th percentile of 9.28 work RVUs

47541: Recommendation of 25th percentile RVW 7.00 based on survey (N=42) with median intra-service time of 60 and total time of 121 minutes. The societies feel that the intensity and complexity of this work is in between that of 47533 and 47534 based on magnitude estimation and therefore are recommending a value greater than 47533 but less than 47534. This recommendation is well bracketed by the #1 and #2 KRS (37226: RVW 10.49, Intra 90, Total 168, and 37213: RVW 5.00, Intra 33, Total 99). This recommendation is also supported by MPC 52353 (RVW 7.50, Intra 60, Total 133).

ZZZ Code Set:

47542**:** The RUC recommends the survey 25th percentile of 2.85 work RVUs

47543**:** Recommendation of 25th percentile RVW 3.00 based on survey (N=42) with median intra-service time of 30. This recommendation is well bracketed by MPC 99292 (RVW 2.25, Intra 30) and #1 KRS (37185: RVW 3.28, Intra 40).

47544**:** The RUC recommends a direct crosswalk to 37185 and 92973 (work RVU= 3.28)

PreService Time

We selected pre time package 2B for 47532, 47533, 47534, 47535, 47536, 47541, 47538, 47539, and 47540. For 47531 and 47537, we selected pre time package 2A, because moderate sedation was not inherent in those two procedures. We also added two additional minutes of positioning time to account for positioning patient on angiographic table, as well as optimize lead placement to avoid obscuring imaging.

Relativity

The consensus panel reviewed the survey data for the family this new family of biliary procedures and analyzed the relativity within the family. The consensus panel felt the appropriate recommendations for 47533, 47534, 47538 and 47542 fell between the surveyed 25th percentile and the survey median. As such, we are recommending crosswalk values for those codes.

The consensus panel reviewed the survey data and believe the recommendations compare favorably to (1) the new family of biliary codes, (2) interventional radiology and (3) MPCs. Below is an outline of the comparisons:

	CPT Code	Global Period	Work RVU	Total Time	Pre Time			Intra Time	Post Time	IWPUT
					Eval	Pos	SDW			
reference	49450	000	1.36	50	20	5	5	10	10	0.054
surveyed	47531	000	1.30	54	18	3	6	15	12	0.047
MPC	55876	000	1.73	59	19	10		20	10	0.043
surveyed	47537	000	1.84	52	18	3	6	15	10	0.073
reference	49083	000	2.00	60	15	5	5	25	10	0.052
MPC	31622	000	2.78	65	10	5	5	30	15	0.069
reference	49452	000	2.86	60	20	5	5	20	10	0.102
surveyed	47536	000	2.86	61	20	3	5	20	13	0.111
MPC	52214	000	3.50	79	19	5	5	30	20	0.083
reference	32550	000	4.17	90	15	15	10	30	20	0.099
surveyed	47535	000	4.20	93	25	3	5	45	15	0.071
reference	49407	000	4.50	110	35	5	5	45	20	0.069
surveyed	47532	000	4.50	98	30	3	5	45	15	0.075
reference	37191	000	4.71	83	30	3	5	30	15	0.120
reference	37213	000	5.00	99	33	3	5	33	25	0.109
MPC	52235	000	5.44	94	19	5	5	45	20	0.098
surveyed	47538	000	5.00	106	30	3	5	53	15	0.082
crosswalk	31267	000	5.45	110	30			50	30	0.082
reference	36247	000	6.29	131	33	3	5	60	30	0.080
surveyed	47533	000	5.63	121	33	3	5	60	20	0.083
crosswalk	37197	000	6.29	121	33	3	5	60	20	0.083
surveyed	47541	000	7.00	121	33	3	5	60	20	0.095
MPC	52353	000	7.50	133	33	5	15	60	20	0.101
reference	37211	000	8.00	138	40	3	5	60	30	0.105
surveyed	47534	000	7.85	129	33	3	5	68	20	0.107
crosswalk	43274	000	8.58	139	33	10	5	68	23	0.104
surveyed	47539	000	9.00	136	33	3	5	75	20	0.103
reference	37226	000	10.49	168	40	3	5	90	30	0.098
reference	37228	000	11.00	168	40	3	5	90	30	0.104
surveyed	47540	000	9.28	146	33	3	5	85	20	0.114
reference	37230	000	13.80	198	40	3	5	120	30	0.101
MPC	99292	ZZZ	2.25	30				30		0.075
surveyed	47542	ZZZ	2.85	30				30		0.099
crosswalk	37239	ZZZ	2.97	32	1			30	1	0.098
surveyed	47543	ZZZ	3.00	30				30		0.100
reference	37185	ZZZ	3.28	40				40		0.082
reference	37222	ZZZ	3.73	42	1			40	1	0.092
surveyed	47544	ZZZ	3.28	45				45		0.088
MPC	57267	ZZZ	4.88	45				45		0.108
reference	37235	ZZZ	7.80	82	1			80	1	0.097

Recommendations

The consensus panel reviewed the (1) RUC survey data, (2) the family relationship between the new codes, (2) the relativity to codes within interventional radiology specialty, (3) rank order within the Fee Schedule, (4) compelling evidence, (5) standard packages and (6) RUC guidelines and makes the following physician work recommendations:

CPT	Global	Work	Total	Pre Time	Intra	Post	IWPUT

Code	Period	RVU	Time	Eval	Pos	SDW	Time	Time	
47531	000	1.30	54	18	3	6	15	12	0.047
47532	000	4.50	98	30	3	5	45	15	0.075
47533	000	5.63	121	33	3	5	60	20	0.083
47534	000	7.85	129	33	3	5	68	20	0.107
47535	000	4.20	93	25	3	5	45	15	0.071
47536	000	2.86	61	20	3	5	20	13	0.111
47537	000	1.84	52	18	3	6	15	10	0.073
47538	000	5.00	106	30	3	5	53	15	0.082
47539	000	9.00	136	33	3	5	75	20	0.103
47540	000	9.28	146	33	3	5	85	20	0.114
47541	000	7.00	121	33	3	5	60	20	0.095
47542	ZZZ	2.85	30				30		0.099
47543	ZZZ	3.00	30				30		0.100
47544	ZZZ	3.28	45				45		0.088

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions: No

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☐ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.
   - ☐ Historical precedents.
   - ☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) 76942, 47500 and 74320

How often do physicians <u>in your specialty</u> perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty Interventional Radiology How often? Commonly

Specialty How often?

Specialty How often?

Estimate the number of times this service might be provided nationally in a one-year period?
If the recommendation is from multiple specialties, please provide the frequency and percentage for each specialty. Please explain the rationale for this estimate. A national number is not available.

Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? 0 If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty. Please explain the rationale for this estimate. A national number is not available.

Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%
Specialty	Frequency 0	Percentage 0.00	%

Do many physicians perform this service across the United States? Yes

---

Berenson-Eggers Type of Service (BETOS) Assignment
Please pick the appropriate BETOS classification that best corresponds to the clinical nature of this CPT code. Please select the main BETOS classification and sub-classification to the greatest level of specificity possible.

Main BETOS Classification:
Procedures

BETOS Sub-classification:
Minor procedure

BETOS Sub-classification Level II:
Other

Professional Liability Insurance Information (PLI)

If the surveyed code is an existing code and the specialty believes the specialty utilization mix will not change, enter the surveyed existing CPT code number

If this code is a new/revised code or an existing code in which the specialty utilization mix will change, please select another crosswalk based on a similar specialty mix. 49407

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:47533 Tracking Number U3 Original Specialty Recommended RVU: **6.29**
Presented Recommended RVU: **6.29**
Global Period: 000 RUC Recommended RVU: **5.63**

CPT Descriptor: Placement of biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; external

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A 61-year-old man presents with a new pancreatic head mass, jaundice, hyperbilirubinemia, elevated white blood cell count. Percutaneous therapeutic management is performed.

Percentage of Survey Respondents who found Vignette to be Typical: 98%

Site of Service (Complete for 010 and 090 Globals Only)

Percent of survey respondents who stated they perform the procedure; In the hospital 0% , In the ASC 0%, In the office 0%

Percent of survey respondents who stated they typically perform this procedure in the hospital, stated the patient is; Discharged the same day 0% , Overnight stay-less than 24 hours 0% , Overnight stay-more than 24 hours 0%

Percent of survey respondents who stated that if the patient is typically kept overnight also stated that they perform an E&M service later on the same day 0%

Moderate Sedation

Is moderate sedation inherent to this procedure in the Hospital/ASC setting? Yes
Percent of survey respondents who stated moderate sedation is typical in the Hospital/ASC setting? 85%

Is moderate sedation inherent to this procedure in the office setting? Yes
Percent of survey respondents who stated moderate sedation is typical in the office setting? 75%

Description of Pre-Service Work: The patient's medical history, physical exam, and laboratory studies are reviewed and consent is obtained. Relevant preoperative diagnostic imaging studies are retrieved and reviewed. The case is discussed with the referring clinician. A time out is performed. The patient is placed supine on the angiographic table. Moderate conscious sedation is administered. Prophylactic antiobiotics are administered.

Description of Intra-Service Work: Ultrasound and fluoroscopy are used to identify a potential safe tract into a peripheral bile duct in the liver. The abdomen and right flank are prepared and draped in sterile fashion. Under ultrasound and fluoroscopic guidance, a needle is placed into a peripheral bile duct and contrast is injected to ensure biliary placement and identify the level of obstruction. Cholangiography is performed with imaging in multiple projections. A wire is passed through the needle into the bile ducts. The tract is dilated with a transitional dilator set and a combination of diagnostic catheters and wires are used to attempt to cross the level of obstruction. The obstruction precludes passage of a wire, and ultimately the transitional dilator set is exchanged for a external biliary drainage catheter. The catheter is connected to gravity bag drainage and the catheter is anchored at the skin surface with a retention suture. A bile specimen is obtained and sent to the lab for culture.

Description of Post-Service Work: Sterile dressings are applied. The patient is transported to the recovery room for hemodynamic monitoring, sedation recovery, and pain control. The procedure is documented in the permanent record. Diagnostic cholangiogram results, and patient status are communicated to the patient's family. Permanent surgical procedure and image interpretation reports are created for the medical record and copies of the reports are sent to the patient's referring physician.

SURVEY DATA

RUC Meeting Date (mm/yyyy)	10/2015				
Presenter(s):	Jerry Niedzwiecki, MD, Michael Hall, MD, Bob Vogelzang, MD, Tim Swan, MD, Matt Hawkins, MD, Zeke Silva, MD and Kurt Schoppe, MD				
Specialty(s):	Interventional Radiology				
CPT Code:	47533				
Sample Size:	1730	**Resp N:**	42	**Response:** 2.4 %	
Description of Sample:	Random Sample: SIR 980/ACR 750				

	Low	**25th pctl**	**Median***	**75th pctl**	**High**
Service Performance Rate	0.00	5.00	**10.00**	15.00	50.00
Survey RVW:	2.09	5.63	**7.95**	9.98	14.00
Pre-Service Evaluation Time:			**33.00**		
Pre-Service Positioning Time:			**10.00**		
Pre-Service Scrub, Dress, Wait Time:			**10.00**		
Intra-Service Time:	15.00	45.00	**60.00**	80.00	120.00

Immediate Post Service-Time:	**20.00**	
Post Operative Visits	**Total Min****	**CPT Code and Number of Visits**
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.00** 99239x **0.00** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

**Physician standard total minutes per E/M visit: 99291 (70); 99292 (30); 99231 (20); 99232 (40); 99233 (55); 99238(38); 99239 (55); 99217 (38); 99211 (7); 99212 (16); 99213 (23); 99214 (40); 99215 (55); 99224 (20); 99225 (40); 99226 (55); 99354 (60); 99355 (30); 99356 (60); 99357 (30)

Specialty Society Recommended Data

Please, pick the pre-service time package that best corresponds to the data which was collected in the survey process. (Note: your recommended pre time should not exceed your survey median time for any category)

2b-FAC Diff Pat/Straightfor Proc(w sedation/anes)

CPT Code:	47533	**Recommended Physician Work RVU: 5.63**		
		Specialty Recommended Pre-Service Time	**Specialty Recommended Pre Time Package**	**Adjustments/Recommended Pre-Service Time**
Pre-Service Evaluation Time:		**33.00**	**33.00**	**0.00**
Pre-Service Positioning Time:		**3.00**	**1.00**	**2.00**
Pre-Service Scrub, Dress, Wait Time:		**5.00**	**5.00**	**0.00**
Intra-Service Time:		**60.00**		

Please, pick the post-service time package that best corresponds to the data which was collected in the survey process: (Note: your recommended post time should not exceed your survey median time)

8A IV Sedation/Simple Procedure

	Specialty Recommended Post-Service Time	**Specialty Recommended Post Time Package**	**Adjustments/Recommended Post-Service Time**
Immediate Post Service-Time:	**20.00**	**25.00**	**-5.00**

Post-Operative Visits	Total Min**	CPT Code and Number of Visits
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.0** 99239x **0.0** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

Modifier -51 Exempt Status
Is the recommended value for the new/revised procedure based on its modifier -51 exempt status? No

New Technology/Service:
Is this new/revised procedure considered to be a new technology or service? No

TOP KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
37226	000	10.49	**RUC Time**

CPT Descriptor Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed

SECOND HIGHEST KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
49407	000	4.50	**RUC Time**

CPT Descriptor Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst); peritoneal or retroperitoneal, transvaginal or transrectal

KEY MPC COMPARISON CODES:
Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU	Time Source	Most Recent Medicare Utilization
52235	000	5.44	**RUC Time**	31,688

CPT Descriptor 1 Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of; MEDIUM bladder tumor(s) (2.0 to 5.0 cm)

MPC CPT Code 2	Global	Work RVU	Time Source	Most Recent Medicare Utilization
52353	000	7.50	**RUC Time**	16,401

CPT Descriptor 2 Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy (ureteral catheterization is included)

Other Reference CPT Code	Global	Work RVU	Time Source
		0.00	

CPT Descriptor

RELATIONSHIP OF CODE BEING REVIEWED TO TOP TWO KEY REFERENCE SERVICES:

Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the top two chosen key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Top Key Reference Code: 8 **% of respondents:** 19.0 **%**

Number of respondents who choose 2nd Key Reference Code: 7 **% of respondents:** 16.6 **%**

TIME ESTIMATES (Median)

	CPT Code: 47533	Top Key Reference CPT Code: 37226	2nd Key Reference CPT Code: **49407**
Median Pre-Service Time	41.00	48.00	45.00
Median Intra-Service Time	60.00	90.00	45.00
Median Immediate Post-service Time	20.00	30.00	20.00
Median Critical Care Time	0.0	0.00	0.00
Median Other Hospital Visit Time	0.0	0.00	0.00
Median Discharge Day Management Time	0.0	0.00	0.00
Median Office Visit Time	0.0	0.00	0.00
Prolonged Services Time	0.0	0.00	0.00
Median Subsequent Observation Care Time	0.0	0.00	0.00
Median Total Time	**121.00**	**168.00**	**110.00**
Other time if appropriate			

INTENSITY/COMPLEXITY MEASURES
(of those that selected Key Reference codes)

Survey respondents are rating the survey code relative to the key reference code.

Intensity & Complexity Rating Scale: (much less= -2.00, somewhat less= -1.00, identical= 0.00, somewhat more= 1.00, much more= 2.00)

	Top Key Ref Code	2nd Key Ref Code
Mental Effort and Judgment (Mean)		
The number of possible diagnosis and/or the number of management options that must be considered		
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed		
Urgency of medical decision making		
Technical Skill/Physical Effort (Mean)		
Technical skill required		
Physical effort required		

Psychological Stress (Mean)

The risk of significant complications, morbidity and/or mortality		
Outcome depends on the skill and judgment of physician		
Estimated risk of malpractice suit with poor outcome		

INTENSITY/COMPLEXITY MEASURES	**Top Key Ref Code**	**2nd Key Ref Code**
Time Segment (Mean)		
Overall intensity/complexity	0.12	1.14

Additional Rationale and Comments

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

The Joint CPT-RUC Workgroup identified (Group 12) codes 47500, 74320-26, 47505, 74305-26, 47510, 75980-26, 47511, 75982-26, 74305-26, 47505, 74320-26, 47500, 75980-26, 47510, 75982-26 as being reported together at least 75% of the time. The specialties updated the percutaneous biliary code family based on the current practice of medicine, and in so doing, deleted 10 percutaneous biliary procedure codes while creating 14 new bundled codes that describe percutaneous biliary procedures including imaging.

This new 'biliary family' was recently surveyed and presented at the April 2015 RUC meeting. However, the RUC and specialty societies agreed that the survey data for this family of services was problematic. Specifically, the RUC noted codes 47532, 47533 and 47534 all had identical median intra-service time of 60 minutes. CPT code 47533 includes the work of 47532 plus the work of an additional access and drain placement. Furthermore, 47534 includes the work of 47533 plus the work of crossing the occlusion and placement of an internal/external drain. Given this time anomaly, the RUC agreed to provide interim recommendations at this meeting, while allowing the specialty societies to re-survey the entire family of codes for October 2015.

The specialty societies worked with the research subcommittee to develop a modified survey tool in an attempt to facilitate gathering more accurate rank order survey data from the surveyed physicians. The entire family of codes was included on one single survey. The research subcommittee approved this survey method, which collected:
• overall complexity/intensity data;
• service performance rates for just the surveyed codes; and
• only whether the vignette is typical or not.
We did not ask for them to provide details if the vignette is not typical.

Compelling Evidence
SIR/ACR believe that the current values for CPT codes now used for the percutaneous, image guided biliary interventional procedures newly described in Tab 4 are no longer rational or appropriate for the detailed, granular and far more accurately descriptive codes in this new group. In our opinion, there have been significant changes in technique, knowledge and technology, patient population and physician time.

Technique, Knowledge and Technology
The codes currently used for this family of biliary procedures no longer reflect the techniques now used for image-guided, catheter-based biliary procedures. Indeed, as can be seen, there are 14 new codes in this family which will henceforth be used to describe a diverse range of procedures. As an index example of these significant changes in technique, one of the most widely used of the current codes, 47510, *Introduction of percutaneous transhepatic catheter for biliary drainage*, was previously performed by a method in which the biliary tree was first opacified and often distended by blind needle puncture (not ultrasound), after which an optimal duct was identified and punctured under fluoroscopy using large sheathed needles or even the trocar technique. These techniques have all changed since this code was introduced and valued as noted below.

Virtually all the medical devices currently used in biliary catheter procedures have been developed since the current codes were adopted. The past twenty years have witnessed major advances in our knowledge base including:
1) using imaging guidance, such as ultrasound, and preoperative mapping to avoid hepatic hilar structures and thus prevent bleeding and bile leaks
2) new insights into how segmental biliary ductal anatomy can help avoid bleeding and septic complications
3) development of much less aggressive and safer guidewire-based methods which involve more steps and more effort, skill and physician time such as micropuncture access with gradual stepwise transition to heavy-duty guidewires, tract dilation and placement of catheters over safer, more stable wires and use of real-time ultrasound guidance for needle access. The ductal system is never distended to avoid septic complications.

We would note that the example of 47510 is reflective of the majority of the existing codes for biliary catheter procedures. Simply put, the new codes reflect new thinking and understanding as well as considerable improvements and advances in techniques which render the current values inappropriate for these new codes.

In another example, the existing code 47511, *Introduction of percutaneous transhepatic stent for internal and external biliary drainage*. Current methods utilize a wide range of self-expanding open, as well as covered, metallic stents of various designs designed specifically for biliary pathology and using percutaneous methods as well as plastic and even retrievable metallic stents. These devices were not available when the existing codes were proposed or adopted.

A number of the codes, for example, 47543, *Endoluminal biopsy(ies) of biliary tree, percutaneous, any method(s) (eg, brush, forceps and/or needle),* 47544 *Removal of calculi/debris from biliary duct(s) and/or gallbladder, percutaneous, including destruction of calculi by any method (eg, mechanical, electrohydraulic, lithotripsy),* 47542, *Balloon dilation of biliary duct(s) or of ampulla (sphincteroplasty), percutaneous,* or 47541, *Placement of access through the biliary tree and into small bowel to assist with an endoscopic biliary procedure (eg, rendezvous procedure), percutaneous*, describe procedures which did not exist previously and, thus, are new technology not able to be described at all under the old codes.

Patient Population

SIR/ACR assert that the population of patients treated with the new family of procedures described herein has changed considerably in at least three major ways:

1) Previously the majority of all biliary catheter procedures were used for basic relief of distal ductal biliary obstruction either acutely or chronically often related to pancreatic cancer and/or stone disease. These patients previously drained and stented percutaneously are now largely treated by endoscopic methods. The significant majority of all of the biliary diseases referred for interventional percutaneous treatment now have higher and more complex levels of benign and malignant biliary occlusion, including hilar and segmental obstruction. Treatment of these lesions involves considerably more work, time, effort and risk to achieve satisfactory outcomes.
2) The widespread use of liver transplantation has introduced an entirely different patient population: the postoperative liver transplant patient with ischemic biliary strictures (intrahepatic and/or extrahepatic), which requires major investments of time, skill and effort to obtain access and drain, stent and dilate these complex situations.
3) Hepatic surgery for malignancy has also become far more sophisticated and segmental or lobar resections will frequently result in referrals for drainage of biliary leaks from nondilated ducts. These patients also present challenges in drainage and management.

An example of the change in patient populations can also be seen in the management of biliary stone disease. Previously, patients with distal biliary calculi were referred for external biliary drainage and stone manipulation. These patients are no longer sent for percutaneous treatment. The stone diseases seen currently are intrahepatic lithiasis or extensive stone formation as a result of biliary-enteric anastomoses both of which require far more skill and time to achieve satisfactory initial access but also need much different time-consuming and labor intensive methods to extract or expel the stones.

New Biliary Family

The CPT editorial panel established 14 bundled codes that describe percutaneous biliary procedures including imaging. Below is a table demonstrating the relationship between the new codes:

000 Code Set:

47531: Direct crosswalk to 46611 (work RVU= 1.30)

47532: Recommendation of 25th percentile RVW 4.50 based on survey (N=42) with median intra-service time of 45 and total time of 98 minutes. This recommendation is well supported by the #1 KRS (49407: RVW 4.50 (exactly the same), Intra 45 (exactly the

same), total 110 (slightly higher)). The recommendation is also well bracketed by MPCs 55214 (RVW 3.50, Intra 30, total 79) and 52235 (RVW 5.44, Intra 45 (same as 47532), and total 94 (less than 47532)).

47533: The RUC recommends the survey 25th percentile of 4.50 work RVUs

47534: The RUC recommends the survey 25th percentile of 7.85 work RVUs

47535: Recommendation of 25th percentile RVW 4.20 based on survey (N=42) with median intra-service time of 45 and total time of 93 minutes. The societies feel that the work of 47535 is similar to 47532 and that the survey and our recommendations are therefore also consistent. This recommendation is well bracketed by the #1 and #2 KRS (36247: RVW 6.29, Intra 60, Total 131, and 32550: RVW 4.17, Intra 30, Total 90). The recommendation is also well bracketed by MPCs 52214 (RVW 3.50, Intra 30, Total 79) and 52235 (RVW 5.44, Intra 45, Total 94).

47536: The RUC recommends the survey 25th percentile of 2.86 work RVUs

47537: Recommendation of 25th percentile RVW 1.84 based on survey (N=42) with median intra-service time of 15 and total time of 52 minutes. This work is similar to 47531with the additional work of fluoroscopic drain removal. The societies feel that this extra work is reflective of clinical practice and similarly reflected in the survey median and 25th RVW. This recommendation is well bracketed by the #1 and #2 KRS (49083: RVW 2.00, Intra 25, Total 60, and 49450: RVW 1.36, Intra 10, Total 50).

47538: The RUC recommends the survey 25th percentile of 5.00 work RVUs

47539: Recommendation of 25th percentile RVW 9.00 based on survey (N=41) with median intra-service time of 75 and total time of 136 minutes. This recommendation is well bracketed by MPC 52353 (RVW 7.50, Intra 60, Total 133) and the #1 KRS (37226: RVW 10.49, Intra 90, Total 168).

47540: The RUC recommends the survey 25th percentile of 9.28 work RVUs

47541: Recommendation of 25th percentile RVW 7.00 based on survey (N=42) with median intra-service time of 60 and total time of 121 minutes. The societies feel that the intensity and complexity of this work is in between that of 47533 and 47534 based on magnitude estimation and therefore are recommending a value greater than 47533 but less than 47534. This recommendation is well bracketed by the #1 and #2 KRS (37226: RVW 10.49, Intra 90, Total 168, and 37213: RVW 5.00, Intra 33, Total 99). This recommendation is also supported by MPC 52353 (RVW 7.50, Intra 60, Total 133).

ZZZ Code Set:

47542**:** The RUC recommends the survey 25th percentile of 2.85 work RVUs

47543**:** Recommendation of 25th percentile RVW 3.00 based on survey (N=42) with median intra-service time of 30. This recommendation is well bracketed by MPC 99292 (RVW 2.25, Intra 30) and #1 KRS (37185: RVW 3.28, Intra 40).

47544**:** The RUC recommends a direct crosswalk to 37185 and 92973 (work RVU= 3.28)

PreService Time

We selected pre time package 2B for 47532, 47533, 47534, 47535, 47536, 47541, 47538, 47539, and 47540. For 47531 and 47537, we selected pre time package 2A, because moderate sedation was not inherent in those two procedures. We also added two additional minutes of positioning time to account for positioning patient on angiographic table, as well as optimize lead placement to avoid obscuring imaging.

Relativity

The consensus panel reviewed the survey data for the family this new family of biliary procedures and analyzed the relativity within the family. The consensus panel felt the appropriate recommendations for 47533, 47534, 47538 and 47542 fell between the surveyed 25th percentile and the survey median. As such, we are recommending crosswalk values for those codes.

The consensus panel reviewed the survey data and believe the recommendations compare favorably to (1) the new family of biliary codes, (2) interventional radiology and (3) MPCs. Below is an outline of the comparisons:

	CPT Code	Global Period	Work RVU	Total Time	Pre Time			Intra Time	Post Time	IWPUT
					Eval	Pos	SDW			

reference	49450	000	1.36	50	20	5	5	10	10	0.054
surveyed	47531	000	1.30	54	18	3	6	15	12	0.047
MPC	55876	000	1.73	59	19	10		20	10	0.043
surveyed	47537	000	1.84	52	18	3	6	15	10	0.073
reference	49083	000	2.00	60	15	5	5	25	10	0.052
MPC	31622	000	2.78	65	10	5	5	30	15	0.069
reference	49452	000	2.86	60	20	5	5	20	10	0.102
surveyed	47536	000	2.86	61	20	3	5	20	13	0.111
MPC	52214	000	3.50	79	19	5	5	30	20	0.083
reference	32550	000	4.17	90	15	15	10	30	20	0.099
surveyed	47535	000	4.20	93	25	3	5	45	15	0.071
reference	49407	000	4.50	110	35	5	5	45	20	0.069
surveyed	47532	000	4.50	98	30	3	5	45	15	0.075
reference	37191	000	4.71	83	30	3	5	30	15	0.120
reference	37213	000	5.00	99	33	3	5	33	25	0.109
MPC	52235	000	5.44	94	19	5	5	45	20	0.098
surveyed	47538	000	5.00	106	30	3	5	53	15	0.082
crosswalk	31267	000	5.45	110	30			50	30	0.082
reference	36247	000	6.29	131	33	3	5	60	30	0.080
surveyed	47533	000	5.63	121	33	3	5	60	20	0.083
crosswalk	37197	000	6.29	121	33	3	5	60	20	0.083
surveyed	47541	000	7.00	121	33	3	5	60	20	0.095
MPC	52353	000	7.50	133	33	5	15	60	20	0.101
reference	37211	000	8.00	138	40	3	5	60	30	0.105
surveyed	47534	000	7.85	129	33	3	5	68	20	0.107
crosswalk	43274	000	8.58	139	33	10	5	68	23	0.104
surveyed	47539	000	9.00	136	33	3	5	75	20	0.103
reference	37226	000	10.49	168	40	3	5	90	30	0.098
reference	37228	000	11.00	168	40	3	5	90	30	0.104
surveyed	47540	000	9.28	146	33	3	5	85	20	0.114
reference	37230	000	13.80	198	40	3	5	120	30	0.101
MPC	99292	ZZZ	2.25	30				30		0.075
surveyed	47542	ZZZ	2.85	30				30		0.099
crosswalk	37239	ZZZ	2.97	32	1			30	1	0.098
surveyed	47543	ZZZ	3.00	30				30		0.100
reference	37185	ZZZ	3.28	40				40		0.082
reference	37222	ZZZ	3.73	42	1			40	1	0.092
surveyed	47544	ZZZ	3.28	45				45		0.088
MPC	57267	ZZZ	4.88	45				45		0.108
reference	37235	ZZZ	7.80	82	1			80	1	0.097

Recommendations

The consensus panel reviewed the (1) RUC survey data, (2) the family relationship between the new codes, (2) the relativity to codes within interventional radiology specialty, (3) rank order within the Fee Schedule, (4) compelling evidence, (5) standard packages and (6) RUC guidelines and makes the following physician work recommendations:

CPT	Global	Work	Total	Pre Time			Intra	Post	IWPUT
Code	Period	RVU	Time	Eval	Pos	SDW	Time	Time	
47531	000	1.30	54	18	3	6	15	12	0.047
47532	000	4.50	98	30	3	5	45	15	0.075

47533	000	5.63	121	33	3	5	60	20	0.083
47534	000	7.85	129	33	3	5	68	20	0.107
47535	000	4.20	93	25	3	5	45	15	0.071
47536	000	2.86	61	20	3	5	20	13	0.111
47537	000	1.84	52	18	3	6	15	10	0.073
47538	000	5.00	106	30	3	5	53	15	0.082
47539	000	9.00	136	33	3	5	75	20	0.103
47540	000	9.28	146	33	3	5	85	20	0.114
47541	000	7.00	121	33	3	5	60	20	0.095
47542	ZZZ	2.85	30				30		0.099
47543	ZZZ	3.00	30				30		0.100
47544	ZZZ	3.28	45				45		0.088

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions: No

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☐ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.
   - ☐ Historical precedents.
   - ☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) 47500, 74320, 76942, 47510 and 75980

How often do physicians <u>in your specialty</u> perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty Interventional Radiology How often? Commonly

Specialty How often?

Specialty How often?

Estimate the number of times this service might be provided nationally in a one-year period?
If the recommendation is from multiple specialties, please provide the frequency and <u>percentage</u> for each specialty. Please explain the rationale for this estimate. A national number is not available.

Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? 0 If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty. Please explain the rationale for this estimate. A national number is not available.

Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%
Specialty	Frequency 0	Percentage 0.00	%

Do many physicians perform this service across the United States? Yes

---

Berenson-Eggers Type of Service (BETOS) Assignment

Please pick the appropriate BETOS classification that best corresponds to the clinical nature of this CPT code. Please select the main BETOS classification and sub-classification to the greatest level of specificity possible.

Main BETOS Classification:
Procedures

BETOS Sub-classification:
Minor procedure

BETOS Sub-classification Level II:
Other

Professional Liability Insurance Information (PLI)

If the surveyed code is an existing code and the specialty believes the specialty utilization mix will not change, enter the surveyed existing CPT code number

If this code is a new/revised code or an existing code in which the specialty utilization mix will change, please select another crosswalk based on a similar specialty mix. 37191

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:47534 Tracking Number U4 Original Specialty Recommended RVU: **8.58**
Presented Recommended RVU: **8.58**
Global Period: 000 RUC Recommended RVU: **7.85**

CPT Descriptor: Placement of biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; internal-external

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A 61-year-old man presents with a new pancreatic mass, obstructive jaundice, and hyperbilirubinemia). Percutaneous therapeutic management is performed.

Percentage of Survey Respondents who found Vignette to be Typical: 95%

Site of Service (Complete for 010 and 090 Globals Only)

Percent of survey respondents who stated they perform the procedure; In the hospital 0% , In the ASC 0%, In the office 0%

Percent of survey respondents who stated they typically perform this procedure in the hospital, stated the patient is; Discharged the same day 0% , Overnight stay-less than 24 hours 0% , Overnight stay-more than 24 hours 0%

Percent of survey respondents who stated that if the patient is typically kept overnight also stated that they perform an E&M service later on the same day 0%

Moderate Sedation

Is moderate sedation inherent to this procedure in the Hospital/ASC setting? Yes
Percent of survey respondents who stated moderate sedation is typical in the Hospital/ASC setting? 85%

Is moderate sedation inherent to this procedure in the office setting? Yes
Percent of survey respondents who stated moderate sedation is typical in the office setting? 75%

Description of Pre-Service Work: The patient's medical history, physical exam, and laboratory studies are reviewed and consent is obtained. Relevant preoperative diagnostic imaging studies are retrieved and reviewed. The case is discussed with the referring clinician. A time out is performed. The patient is placed supine on the angiographic table. Moderate conscious sedation is administered. Prophylactic antiobiotics are administered.

Description of Intra-Service Work: Ultrasound and fluoroscopy are used to identify a potential safe tract into a peripheral bile duct in the liver. The abdomen and right flank are prepared and draped in sterile fashion. Under ultrasound and fluoroscopic guidance, a needle is placed into a peripheral bile duct and contrast is injected to ensure biliary placement and identify the level of obstruction. Cholangiography is performed with imaging in multiple projections. A bile specimen is obtained and sent to the lab for culture. A wire is passed through the needle into the bile ducts. The tract is dilated with a transitional dilator set and a new 0.035 wire is used to cross the level of obstruction and terminate in the small bowel. The tract is sesrially dilated and an 8F internal/external biliary drainage catheter is placed over the wire terminating within the small bowel. Contrast injection under fluoroscopic guidance confirms placement in small bowel and that side-holes are positioned appropriately within the bile ducts. The catheter is connected to gravity bag drainage and the catheter is anchored at the skin surface with a retention suture.

Description of Post-Service Work: Sterile dressings are applied. The patient is transported to the recovery room for hemodynamic monitoring, sedation recovery, and pain control. The procedure is documented in the permanent record. Diagnostic cholangiogram results, and patient status are communicated to the patient's family. Permanent surgical

procedure and image interpretation reports are created for the medical record and copies of the reports are sent to the patient’s referring physician.

SURVEY DATA

RUC Meeting Date (mm/yyyy)	10/2015				
Presenter(s):	Jerry Niedzwiecki, MD, Michael Hall, MD, Bob Vogelzang, MD, Tim Swan, MD, Matt Hawkins, MD, Zeke Silva, MD and Kurt Schoppe, MD				
Specialty(s):	Interventional Radiology				
CPT Code:	47534				
Sample Size:	1730	**Resp N:**	42	**Response:** 2.4 %	
Description of Sample:	Random Sample: SIR 980/ACR 750				

	Low	**25th pctl**	**Median***	**75th pctl**	**High**
Service Performance Rate	1.00	7.00	**15.00**	30.00	75.00
Survey RVW:	2.09	7.85	**9.50**	11.00	15.00
Pre-Service Evaluation Time:			**35.00**		
Pre-Service Positioning Time:			**10.00**		
Pre-Service Scrub, Dress, Wait Time:			**10.00**		
Intra-Service Time:	25.00	50.00	**68.00**	80.00	125.00

Immediate Post Service-Time:	**20.00**	
Post Operative Visits	**Total Min****	**CPT Code and Number of Visits**
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.00** 99239x **0.00** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

**Physician standard total minutes per E/M visit: 99291 (70); 99292 (30); 99231 (20); 99232 (40); 99233 (55); 99238(38); 99239 (55); 99217 (38); 99211 (7); 99212 (16); 99213 (23); 99214 (40); 99215 (55); 99224 (20); 99225 (40); 99226 (55); 99354 (60); 99355 (30); 99356 (60); 99357 (30)

Specialty Society Recommended Data

Please, pick the pre-service time package that best corresponds to the data which was collected in the survey process. (Note: your recommended pre time should not exceed your survey median time for any category)

2b-FAC Diff Pat/Straightfor Proc(w sedation/anes)

CPT Code:	47534	**Recommended Physician Work RVU: 7.85**		
		Specialty Recommended Pre-Service Time	**Specialty Recommended Pre Time Package**	**Adjustments/Recommended Pre-Service Time**
Pre-Service Evaluation Time:		**33.00**	**33.00**	**0.00**
Pre-Service Positioning Time:		**3.00**	**1.00**	**2.00**
Pre-Service Scrub, Dress, Wait Time:		**5.00**	**5.00**	**0.00**
Intra-Service Time:		**68.00**		

Please, pick the post-service time package that best corresponds to the data which was collected in the survey process: (Note: your recommended post time should not exceed your survey median time)

8A IV Sedation/Simple Procedure

	Specialty Recommended Post-Service Time	**Specialty Recommended Post Time Package**	**Adjustments/Recommended Post-Service Time**
Immediate Post Service-Time:	**20.00**	**25.00**	**-5.00**

Post-Operative Visits	Total Min**	CPT Code and Number of Visits
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.0** 99239x **0.0** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

Modifier -51 Exempt Status
Is the recommended value for the new/revised procedure based on its modifier -51 exempt status? No

New Technology/Service:
Is this new/revised procedure considered to be a new technology or service? No

TOP KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
37226	000	10.49	**RUC Time**

CPT Descriptor Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed

SECOND HIGHEST KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
37211	000	8.00	**RUC Time**

CPT Descriptor Transcatheter therapy, arterial infusion for thrombolysis other than coronary, any method, including radiological supervision and interpretation, initial treatment day

KEY MPC COMPARISON CODES:
Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU	Time Source	Most Recent Medicare Utilization
52353	000	7.50	**RUC Time**	16,401

CPT Descriptor 1 Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy (ureteral catheterization is included)

MPC CPT Code 2	Global	Work RVU	Time Source	Most Recent Medicare Utilization
		0.00		

CPT Descriptor 2

Other Reference CPT Code	Global	Work RVU	Time Source
		0.00	

CPT Descriptor

RELATIONSHIP OF CODE BEING REVIEWED TO TOP TWO KEY REFERENCE SERVICES:

Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the top two chosen key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Top Key Reference Code: 11 **% of respondents:** 26.1 **%**

Number of respondents who choose 2nd Key Reference Code: 6 **% of respondents:** 14.2 **%**

TIME ESTIMATES (Median)

	CPT Code: 47534	Top Key Reference CPT Code: 37226	2nd Key Reference CPT Code: **37211**
Median Pre-Service Time	41.00	48.00	48.00
Median Intra-Service Time	68.00	90.00	60.00
Median Immediate Post-service Time	20.00	30.00	30.00
Median Critical Care Time	0.0	0.00	0.00
Median Other Hospital Visit Time	0.0	0.00	0.00
Median Discharge Day Management Time	0.0	0.00	0.00
Median Office Visit Time	0.0	0.00	0.00
Prolonged Services Time	0.0	0.00	0.00
Median Subsequent Observation Care Time	0.0	0.00	0.00
Median Total Time	**129.00**	**168.00**	**138.00**
Other time if appropriate			

INTENSITY/COMPLEXITY MEASURES
(of those that selected Key Reference codes)

Survey respondents are rating the survey code relative to the key reference code.

Intensity & Complexity Rating Scale: (much less= -2.00, somewhat less= -1.00, identical= 0.00, somewhat more= 1.00, much more= 2.00)

	Top Key Ref Code	2nd Key Ref Code
Mental Effort and Judgment (Mean)		
The number of possible diagnosis and/or the number of management options that must be considered		
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed		
Urgency of medical decision making		
Technical Skill/Physical Effort (Mean)		
Technical skill required		
Physical effort required		

Psychological Stress (Mean)

The risk of significant complications, morbidity and/or mortality		
Outcome depends on the skill and judgment of physician		
Estimated risk of malpractice suit with poor outcome		

INTENSITY/COMPLEXITY MEASURES	**Top Key Ref Code**	**2nd Key Ref Code**
Time Segment (Mean)		
Overall intensity/complexity	0.45	0.33

Additional Rationale and Comments

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

The Joint CPT-RUC Workgroup identified (Group 12) codes 47500, 74320-26, 47505, 74305-26, 47510, 75980-26, 47511, 75982-26, 74305-26, 47505, 74320-26, 47500, 75980-26, 47510, 75982-26 as being reported together at least 75% of the time. The specialties updated the percutaneous biliary code family based on the current practice of medicine, and in so doing, deleted 10 percutaneous biliary procedure codes while creating 14 new bundled codes that describe percutaneous biliary procedures including imaging.

This new 'biliary family' was recently surveyed and presented at the April 2015 RUC meeting. However, the RUC and specialty societies agreed that the survey data for this family of services was problematic. Specifically, the RUC noted codes 47532, 47533 and 47534 all had identical median intra-service time of 60 minutes. CPT code 47533 includes the work of 47532 plus the work of an additional access and drain placement. Furthermore, 47534 includes the work of 47533 plus the work of crossing the occlusion and placement of an internal/external drain. Given this time anomaly, the RUC agreed to provide interim recommendations at this meeting, while allowing the specialty societies to re-survey the entire family of codes for October 2015.

The specialty societies worked with the research subcommittee to develop a modified survey tool in an attempt to facilitate gathering more accurate rank order survey data from the surveyed physicians. The entire family of codes was included on one single survey. The research subcommittee approved this survey method, which collected:
• overall complexity/intensity data;
• service performance rates for just the surveyed codes; and
• only whether the vignette is typical or not.
We did not ask for them to provide details if the vignette is not typical.

Compelling Evidence
SIR/ACR believe that the current values for CPT codes now used for the percutaneous, image guided biliary interventional procedures newly described in Tab 4 are no longer rational or appropriate for the detailed, granular and far more accurately descriptive codes in this new group. In our opinion, there have been significant changes in technique, knowledge and technology, patient population and physician time.

Technique, Knowledge and Technology
The codes currently used for this family of biliary procedures no longer reflect the techniques now used for image-guided, catheter-based biliary procedures. Indeed, as can be seen, there are 14 new codes in this family which will henceforth be used to describe a diverse range of procedures. As an index example of these significant changes in technique, one of the most widely used of the current codes, 47510, *Introduction of percutaneous transhepatic catheter for biliary drainage*, was previously performed by a method in which the biliary tree was first opacified and often distended by blind needle puncture (not ultrasound), after which an optimal duct was identified and punctured under fluoroscopy using large sheathed needles or even the trocar technique. These techniques have all changed since this code was introduced and valued as noted below.

Virtually all the medical devices currently used in biliary catheter procedures have been developed since the current codes were adopted. The past twenty years have witnessed major advances in our knowledge base including:
1) using imaging guidance, such as ultrasound, and preoperative mapping to avoid hepatic hilar structures and thus prevent bleeding and bile leaks
2) new insights into how segmental biliary ductal anatomy can help avoid bleeding and septic complications
3) development of much less aggressive and safer guidewire-based methods which involve more steps and more effort, skill and physician time such as micropuncture access with gradual stepwise transition to heavy-duty guidewires, tract dilation and placement of catheters over safer, more stable wires and use of real-time ultrasound guidance for needle access. The ductal system is never distended to avoid septic complications.

We would note that the example of 47510 is reflective of the majority of the existing codes for biliary catheter procedures. Simply put, the new codes reflect new thinking and understanding as well as considerable improvements and advances in techniques which render the current values inappropriate for these new codes.

In another example, the existing code 47511, *Introduction of percutaneous transhepatic stent for internal and external biliary drainage*. Current methods utilize a wide range of self-expanding open, as well as covered, metallic stents of various designs designed specifically for biliary pathology and using percutaneous methods as well as plastic and even retrievable metallic stents. These devices were not available when the existing codes were proposed or adopted.

A number of the codes, for example, 47543, *Endoluminal biopsy(ies) of biliary tree, percutaneous, any method(s) (eg, brush, forceps and/or needle),* 47544 *Removal of calculi/debris from biliary duct(s) and/or gallbladder, percutaneous, including destruction of calculi by any method (eg, mechanical, electrohydraulic, lithotripsy),* 47542, *Balloon dilation of biliary duct(s) or of ampulla (sphincteroplasty), percutaneous,* or 47541, *Placement of access through the biliary tree and into small bowel to assist with an endoscopic biliary procedure (eg, rendezvous procedure), percutaneous*, describe procedures which did not exist previously and, thus, are new technology not able to be described at all under the old codes.

Patient Population

SIR/ACR assert that the population of patients treated with the new family of procedures described herein has changed considerably in at least three major ways:

1) Previously the majority of all biliary catheter procedures were used for basic relief of distal ductal biliary obstruction either acutely or chronically often related to pancreatic cancer and/or stone disease. These patients previously drained and stented percutaneously are now largely treated by endoscopic methods. The significant majority of all of the biliary diseases referred for interventional percutaneous treatment now have higher and more complex levels of benign and malignant biliary occlusion, including hilar and segmental obstruction. Treatment of these lesions involves considerably more work, time, effort and risk to achieve satisfactory outcomes.
2) The widespread use of liver transplantation has introduced an entirely different patient population: the postoperative liver transplant patient with ischemic biliary strictures (intrahepatic and/or extrahepatic), which requires major investments of time, skill and effort to obtain access and drain, stent and dilate these complex situations.
3) Hepatic surgery for malignancy has also become far more sophisticated and segmental or lobar resections will frequently result in referrals for drainage of biliary leaks from nondilated ducts. These patients also present challenges in drainage and management.

An example of the change in patient populations can also be seen in the management of biliary stone disease. Previously, patients with distal biliary calculi were referred for external biliary drainage and stone manipulation. These patients are no longer sent for percutaneous treatment. The stone diseases seen currently are intrahepatic lithiasis or extensive stone formation as a result of biliary-enteric anastomoses both of which require far more skill and time to achieve satisfactory initial access but also need much different time-consuming and labor intensive methods to extract or expel the stones.

New Biliary Family

The CPT editorial panel established 14 bundled codes that describe percutaneous biliary procedures including imaging. Below is a table demonstrating the relationship between the new codes:

000 Code Set:

47531: Direct crosswalk to 46611 (work RVU= 1.30)

47532: Recommendation of 25th percentile RVW 4.50 based on survey (N=42) with median intra-service time of 45 and total time of 98 minutes. This recommendation is well supported by the #1 KRS (49407: RVW 4.50 (exactly the same), Intra 45 (exactly the

same), total 110 (slightly higher)). The recommendation is also well bracketed by MPCs 55214 (RVW 3.50, Intra 30, total 79) and 52235 (RVW 5.44, Intra 45 (same as 47532), and total 94 (less than 47532)).

47533: The RUC recommends the survey 25th percentile of 4.50 work RVUs

47534: The RUC recommends the survey 25th percentile of 7.85 work RVUs

47535: Recommendation of 25th percentile RVW 4.20 based on survey (N=42) with median intra-service time of 45 and total time of 93 minutes. The societies feel that the work of 47535 is similar to 47532 and that the survey and our recommendations are therefore also consistent. This recommendation is well bracketed by the #1 and #2 KRS (36247: RVW 6.29, Intra 60, Total 131, and 32550: RVW 4.17, Intra 30, Total 90). The recommendation is also well bracketed by MPCs 52214 (RVW 3.50, Intra 30, Total 79) and 52235 (RVW 5.44, Intra 45, Total 94).

47536: The RUC recommends the survey 25th percentile of 2.86 work RVUs

47537: Recommendation of 25th percentile RVW 1.84 based on survey (N=42) with median intra-service time of 15 and total time of 52 minutes. This work is similar to 47531with the additional work of fluoroscopic drain removal. The societies feel that this extra work is reflective of clinical practice and similarly reflected in the survey median and 25th RVW. This recommendation is well bracketed by the #1 and #2 KRS (49083: RVW 2.00, Intra 25, Total 60, and 49450: RVW 1.36, Intra 10, Total 50).

47538: The RUC recommends the survey 25th percentile of 5.00 work RVUs

47539: Recommendation of 25th percentile RVW 9.00 based on survey (N=41) with median intra-service time of 75 and total time of 136 minutes. This recommendation is well bracketed by MPC 52353 (RVW 7.50, Intra 60, Total 133) and the #1 KRS (37226: RVW 10.49, Intra 90, Total 168).

47540: The RUC recommends the survey 25th percentile of 9.28 work RVUs

47541: Recommendation of 25th percentile RVW 7.00 based on survey (N=42) with median intra-service time of 60 and total time of 121 minutes. The societies feel that the intensity and complexity of this work is in between that of 47533 and 47534 based on magnitude estimation and therefore are recommending a value greater than 47533 but less than 47534. This recommendation is well bracketed by the #1 and #2 KRS (37226: RVW 10.49, Intra 90, Total 168, and 37213: RVW 5.00, Intra 33, Total 99). This recommendation is also supported by MPC 52353 (RVW 7.50, Intra 60, Total 133).

ZZZ Code Set:

47542**:** The RUC recommends the survey 25th percentile of 2.85 work RVUs

47543**:** Recommendation of 25th percentile RVW 3.00 based on survey (N=42) with median intra-service time of 30. This recommendation is well bracketed by MPC 99292 (RVW 2.25, Intra 30) and #1 KRS (37185: RVW 3.28, Intra 40).

47544**:** The RUC recommends a direct crosswalk to 37185 and 92973 (work RVU= 3.28)

PreService Time

We selected pre time package 2B for 47532, 47533, 47534, 47535, 47536, 47541, 47538, 47539, and 47540. For 47531 and 47537, we selected pre time package 2A, because moderate sedation was not inherent in those two procedures. We also added two additional minutes of positioning time to account for positioning patient on angiographic table, as well as optimize lead placement to avoid obscuring imaging.

Relativity

The consensus panel reviewed the survey data for the family this new family of biliary procedures and analyzed the relativity within the family. The consensus panel felt the appropriate recommendations for 47533, 47534, 47538 and 47542 fell between the surveyed 25th percentile and the survey median. As such, we are recommending crosswalk values for those codes.

The consensus panel reviewed the survey data and believe the recommendations compare favorably to (1) the new family of biliary codes, (2) interventional radiology and (3) MPCs. Below is an outline of the comparisons:

	CPT Code	Global Period	Work RVU	Total Time	Pre Time			Intra Time	Post Time	IWPUT
					Eval	Pos	SDW			

reference	49450	000	1.36	50	20	5	5	10	10	0.054
surveyed	47531	000	1.30	54	18	3	6	15	12	0.047
MPC	55876	000	1.73	59	19	10		20	10	0.043
surveyed	47537	000	1.84	52	18	3	6	15	10	0.073
reference	49083	000	2.00	60	15	5	5	25	10	0.052
MPC	31622	000	2.78	65	10	5	5	30	15	0.069
reference	49452	000	2.86	60	20	5	5	20	10	0.102
surveyed	47536	000	2.86	61	20	3	5	20	13	0.111
MPC	52214	000	3.50	79	19	5	5	30	20	0.083
reference	32550	000	4.17	90	15	15	10	30	20	0.099
surveyed	47535	000	4.20	93	25	3	5	45	15	0.071
reference	49407	000	4.50	110	35	5	5	45	20	0.069
surveyed	47532	000	4.50	98	30	3	5	45	15	0.075
reference	37191	000	4.71	83	30	3	5	30	15	0.120
reference	37213	000	5.00	99	33	3	5	33	25	0.109
MPC	52235	000	5.44	94	19	5	5	45	20	0.098
surveyed	47538	000	5.00	106	30	3	5	53	15	0.082
crosswalk	31267	000	5.45	110	30			50	30	0.082
reference	36247	000	6.29	131	33	3	5	60	30	0.080
surveyed	47533	000	5.63	121	33	3	5	60	20	0.083
crosswalk	37197	000	6.29	121	33	3	5	60	20	0.083
surveyed	47541	000	7.00	121	33	3	5	60	20	0.095
MPC	52353	000	7.50	133	33	5	15	60	20	0.101
reference	37211	000	8.00	138	40	3	5	60	30	0.105
surveyed	47534	000	7.85	129	33	3	5	68	20	0.107
crosswalk	43274	000	8.58	139	33	10	5	68	23	0.104
surveyed	47539	000	9.00	136	33	3	5	75	20	0.103
reference	37226	000	10.49	168	40	3	5	90	30	0.098
reference	37228	000	11.00	168	40	3	5	90	30	0.104
surveyed	47540	000	9.28	146	33	3	5	85	20	0.114
reference	37230	000	13.80	198	40	3	5	120	30	0.101
MPC	99292	ZZZ	2.25	30				30		0.075
surveyed	47542	ZZZ	2.85	30				30		0.099
crosswalk	37239	ZZZ	2.97	32	1			30	1	0.098
surveyed	47543	ZZZ	3.00	30				30		0.100
reference	37185	ZZZ	3.28	40				40		0.082
reference	37222	ZZZ	3.73	42	1			40	1	0.092
surveyed	47544	ZZZ	3.28	45				45		0.088
MPC	57267	ZZZ	4.88	45				45		0.108
reference	37235	ZZZ	7.80	82	1			80	1	0.097

Recommendations

The consensus panel reviewed the (1) RUC survey data, (2) the family relationship between the new codes, (2) the relativity to codes within interventional radiology specialty, (3) rank order within the Fee Schedule, (4) compelling evidence, (5) standard packages and (6) RUC guidelines and makes the following physician work recommendations:

CPT	Global	Work	Total	Pre Time			Intra	Post	IWPUT
Code	Period	RVU	Time	Eval	Pos	SDW	Time	Time	
47531	000	1.30	54	18	3	6	15	12	0.047
47532	000	4.50	98	30	3	5	45	15	0.075

47533	000	5.63	121	33	3	5	60	20	0.083
47534	000	7.85	129	33	3	5	68	20	0.107
47535	000	4.20	93	25	3	5	45	15	0.071
47536	000	2.86	61	20	3	5	20	13	0.111
47537	000	1.84	52	18	3	6	15	10	0.073
47538	000	5.00	106	30	3	5	53	15	0.082
47539	000	9.00	136	33	3	5	75	20	0.103
47540	000	9.28	146	33	3	5	85	20	0.114
47541	000	7.00	121	33	3	5	60	20	0.095
47542	ZZZ	2.85	30				30		0.099
47543	ZZZ	3.00	30				30		0.100
47544	ZZZ	3.28	45				45		0.088

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions: No

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☐ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.
   - ☐ Historical precedents.
   - ☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) 47500, 74320, 76942, 47511 and 75982

How often do physicians <u>in your specialty</u> perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty Interventional Radiology How often? Commonly

Specialty How often?

Specialty How often?

Estimate the number of times this service might be provided nationally in a one-year period?
If the recommendation is from multiple specialties, please provide the frequency and <u>percentage</u> for each specialty. Please explain the rationale for this estimate. A national number is not available.

Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? 0 If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty. Please explain the rationale for this estimate. A national number is not available.

Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%
Specialty	Frequency 0	Percentage 0.00	%

Do many physicians perform this service across the United States? Yes

---

Berenson-Eggers Type of Service (BETOS) Assignment

Please pick the appropriate BETOS classification that best corresponds to the clinical nature of this CPT code. Please select the main BETOS classification and sub-classification to the greatest level of specificity possible.

Main BETOS Classification:
Procedures

BETOS Sub-classification:
Minor procedure

BETOS Sub-classification Level II:
Other

Professional Liability Insurance Information (PLI)

If the surveyed code is an existing code and the specialty believes the specialty utilization mix will not change, enter the surveyed existing CPT code number

If this code is a new/revised code or an existing code in which the specialty utilization mix will change, please select another crosswalk based on a similar specialty mix. 36247

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:47535 Tracking Number U5 Original Specialty Recommended RVU: **4.20**
Presented Recommended RVU: **4.20**
Global Period: 000 RUC Recommended RVU: **4.20**

CPT Descriptor: Conversion of external biliary drainage catheter to internal-external biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A 61-year-old man presents following placement of an external biliary drainage catheter, which was recently placed to treat cholangitis in the setting of biliary obstruction. At the time of placement, the level of obstruction could not be crossed with a wire or catheter. The patient presents for conversion of his external biliary drainage catheter to an internal-external biliary drainage catheter.

Percentage of Survey Respondents who found Vignette to be Typical: 100%

Site of Service (Complete for 010 and 090 Globals Only)

Percent of survey respondents who stated they perform the procedure; In the hospital 0% , In the ASC 0%, In the office 0%

Percent of survey respondents who stated they typically perform this procedure in the hospital, stated the patient is; Discharged the same day 0% , Overnight stay-less than 24 hours 0% , Overnight stay-more than 24 hours 0%

Percent of survey respondents who stated that if the patient is typically kept overnight also stated that they perform an E&M service later on the same day 0%

Moderate Sedation

Is moderate sedation inherent to this procedure in the Hospital/ASC setting? Yes
Percent of survey respondents who stated moderate sedation is typical in the Hospital/ASC setting? 98%

Is moderate sedation inherent to this procedure in the office setting? Yes
Percent of survey respondents who stated moderate sedation is typical in the office setting? 93%

Description of Pre-Service Work: The patient's medical history, physical exam, and laboratory studies are reviewed and consent is obtained. Relevant preoperative diagnostic imaging studies are retrieved and reviewed. The case is discussed with the referring clinician. A time out is performed. The patient is placed supine on the angiographic table. Moderate conscious sedation is administered. Prophylactic antiobiotics are administered.

Description of Intra-Service Work: The existing tube, abdomen and right flank are prepared and draped in sterile fashion. Under fluoroscopic guidance, a wire is placed through the existing tube into the bile ducts. The tube is exchanged for a sheath. Cholangiogram is performed through the sheath. Multiple radiographs in multiple projections are obtained. Under fluoroscopic guidance, a catheter and wire are used through the sheath to cross the level of obstruction. The sheath is exchanged for a new internal/external biliary drainage catheter, which terminates in small bowel. Contrast injection under fluoroscopic guidance confirms placement in small bowel and that side-holes are positioned appropriately within the bile ducts. The catheter is connected to gravity bag drainage and the catheter is anchored at the skin surface with a retention suture. Sterile dressings are applied.

Description of Post-Service Work: The patient is transported to the recovery room for hemodynamic monitoring, sedation recovery, and pain control. The procedure is documented in the permanent record. Diagnostic cholangiogram results, and patient status are communicated to the patient's family. Permanent surgical procedure and image interpretation reports are created for the medical record and copies of the reports are sent to the patient's referring physician.

SURVEY DATA

RUC Meeting Date (mm/yyyy)	10/2015				
Presenter(s):	Jerry Niedzwiecki, MD, Michael Hall, MD, Bob Vogelzang, MD, Tim Swan, MD, Matt Hawkins, MD, Zeke Silva, MD and Kurt Schoppe, MD				
Specialty(s):	Interventional Radiology				
CPT Code:	47535				
Sample Size:	1730	**Resp N:**	42	**Response:** 2.4 %	
Description of Sample:	Random Sample: SIR 980/ACR 750				

	Low	**25th pctl**	**Median***	**75th pctl**	**High**
Service Performance Rate	1.00	5.00	**10.00**	20.00	100.00
Survey RVW:	3.00	4.20	**5.40**	6.95	10.00
Pre-Service Evaluation Time:			**25.00**		
Pre-Service Positioning Time:			**10.00**		
Pre-Service Scrub, Dress, Wait Time:			**10.00**		
Intra-Service Time:	15.00	30.00	**45.00**	60.00	120.00

Immediate Post Service-Time:	**15.00**	
Post Operative Visits	**Total Min****	**CPT Code and Number of Visits**
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.00** 99239x **0.00** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

**Physician standard total minutes per E/M visit: 99291 (70); 99292 (30); 99231 (20); 99232 (40); 99233 (55); 99238(38); 99239 (55); 99217 (38); 99211 (7); 99212 (16); 99213 (23); 99214 (40); 99215 (55); 99224 (20); 99225 (40); 99226 (55); 99354 (60); 99355 (30); 99356 (60); 99357 (30)

Specialty Society Recommended Data

Please, pick the pre-service time package that best corresponds to the data which was collected in the survey process. (Note: your recommended pre time should not exceed your survey median time for any category)

2b-FAC Diff Pat/Straightfor Proc(w sedation/anes)

CPT Code:	47535	**Recommended Physician Work RVU: 4.20**		
		Specialty Recommended Pre-Service Time	**Specialty Recommended Pre Time Package**	**Adjustments/Recommended Pre-Service Time**
Pre-Service Evaluation Time:		**25.00**	**33.00**	**-8.00**
Pre-Service Positioning Time:		**3.00**	**1.00**	**2.00**
Pre-Service Scrub, Dress, Wait Time:		**5.00**	**5.00**	**0.00**
Intra-Service Time:		**45.00**		

Please, pick the post-service time package that best corresponds to the data which was collected in the survey process: (Note: your recommended post time should not exceed your survey median time)

8A IV Sedation/Simple Procedure

	Specialty Recommended Post-Service Time	**Specialty Recommended Post Time Package**	**Adjustments/Recommended Post-Service Time**
Immediate Post Service-Time:	**15.00**	**25.00**	**-10.00**

Post-Operative Visits	Total Min**	CPT Code and Number of Visits
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.0** 99239x **0.0** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

Modifier -51 Exempt Status

Is the recommended value for the new/revised procedure based on its modifier -51 exempt status? No

New Technology/Service:

Is this new/revised procedure considered to be a new technology or service? No

TOP KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
36247	000	6.29	**RUC Time**

CPT Descriptor Selective catheter placement, arterial system; initial third order or more selective abdominal, pelvic, or lower extremity artery branch, within a vascular family

SECOND HIGHEST KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
32550	000	4.17	**RUC Time**

CPT Descriptor Insertion of indwelling tunneled pleural catheter with cuff

KEY MPC COMPARISON CODES:

Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU	Time Source	Most Recent Medicare Utilization
52214	000	3.50	**RUC Time**	20,091

CPT Descriptor 1 Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) of trigone, bladder neck, prostatic fossa, urethra, or periurethral glands

MPC CPT Code 2	Global	Work RVU	Time Source	Most Recent Medicare Utilization
52235	000	5.44	**RUC Time**	31,688

CPT Descriptor 2 Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of; MEDIUM bladder tumor(s) (2.0 to 5.0 cm)

Other Reference CPT Code	Global	Work RVU	Time Source
		0.00	

CPT Descriptor

RELATIONSHIP OF CODE BEING REVIEWED TO TOP TWO KEY REFERENCE SERVICES:

Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the top two chosen key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Top Key Reference Code: 10 **% of respondents:** 23.8 **%**

Number of respondents who choose 2nd Key Reference Code: 7 **% of respondents:** 16.6 **%**

TIME ESTIMATES (Median)

	CPT Code: 47535	**Top Key Reference CPT Code:** 36247	**2nd Key Reference CPT Code:** **32550**
Median Pre-Service Time	33.00	41.00	40.00
Median Intra-Service Time	45.00	60.00	30.00
Median Immediate Post-service Time	15.00	30.00	20.00
Median Critical Care Time	0.0	0.00	0.00
Median Other Hospital Visit Time	0.0	0.00	0.00
Median Discharge Day Management Time	0.0	0.00	0.00
Median Office Visit Time	0.0	0.00	0.00
Prolonged Services Time	0.0	0.00	0.00
Median Subsequent Observation Care Time	0.0	0.00	0.00
Median Total Time	**93.00**	**131.00**	**90.00**
Other time if appropriate			

INTENSITY/COMPLEXITY MEASURES
(of those that selected Key Reference codes)

Survey respondents are rating the survey code relative to the key reference code.

Intensity & Complexity Rating Scale: (much less= -2.00, somewhat less= -1.00, identical= 0.00, somewhat more= 1.00, much more= 2.00)

	Top Key Ref Code	**2nd Key Ref Code**
Mental Effort and Judgment (Mean)		
The number of possible diagnosis and/or the number of management options that must be considered		
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed		
Urgency of medical decision making		
Technical Skill/Physical Effort (Mean)		
Technical skill required		
Physical effort required		

Psychological Stress (Mean)

The risk of significant complications, morbidity and/or mortality		
Outcome depends on the skill and judgment of physician		
Estimated risk of malpractice suit with poor outcome		

INTENSITY/COMPLEXITY MEASURES	**Top Key Ref Code**	**2nd Key Ref Code**
Time Segment (Mean)		
Overall intensity/complexity	0.20	0.00

Additional Rationale and Comments

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

The Joint CPT-RUC Workgroup identified (Group 12) codes 47500, 74320-26, 47505, 74305-26, 47510, 75980-26, 47511, 75982-26, 74305-26, 47505, 74320-26, 47500, 75980-26, 47510, 75982-26 as being reported together at least 75% of the time. The specialties updated the percutaneous biliary code family based on the current practice of medicine, and in so doing, deleted 10 percutaneous biliary procedure codes while creating 14 new bundled codes that describe percutaneous biliary procedures including imaging.

This new 'biliary family' was recently surveyed and presented at the April 2015 RUC meeting. However, the RUC and specialty societies agreed that the survey data for this family of services was problematic. Specifically, the RUC noted codes 47532, 47533 and 47534 all had identical median intra-service time of 60 minutes. CPT code 47533 includes the work of 47532 plus the work of an additional access and drain placement. Furthermore, 47534 includes the work of 47533 plus the work of crossing the occlusion and placement of an internal/external drain. Given this time anomaly, the RUC agreed to provide interim recommendations at this meeting, while allowing the specialty societies to re-survey the entire family of codes for October 2015.

The specialty societies worked with the research subcommittee to develop a modified survey tool in an attempt to facilitate gathering more accurate rank order survey data from the surveyed physicians. The entire family of codes was included on one single survey. The research subcommittee approved this survey method, which collected:
• overall complexity/intensity data;
• service performance rates for just the surveyed codes; and
• only whether the vignette is typical or not.
We did not ask for them to provide details if the vignette is not typical.

Compelling Evidence
SIR/ACR believe that the current values for CPT codes now used for the percutaneous, image guided biliary interventional procedures newly described in Tab 4 are no longer rational or appropriate for the detailed, granular and far more accurately descriptive codes in this new group. In our opinion, there have been significant changes in technique, knowledge and technology, patient population and physician time.

Technique, Knowledge and Technology
The codes currently used for this family of biliary procedures no longer reflect the techniques now used for image-guided, catheter-based biliary procedures. Indeed, as can be seen, there are 14 new codes in this family which will henceforth be used to describe a diverse range of procedures. As an index example of these significant changes in technique, one of the most widely used of the current codes, 47510, *Introduction of percutaneous transhepatic catheter for biliary drainage*, was previously performed by a method in which the biliary tree was first opacified and often distended by blind needle puncture (not ultrasound), after which an optimal duct was identified and punctured under fluoroscopy using large sheathed needles or even the trocar technique. These techniques have all changed since this code was introduced and valued as noted below.

Virtually all the medical devices currently used in biliary catheter procedures have been developed since the current codes were adopted. The past twenty years have witnessed major advances in our knowledge base including:
1) using imaging guidance, such as ultrasound, and preoperative mapping to avoid hepatic hilar structures and thus prevent bleeding and bile leaks
2) new insights into how segmental biliary ductal anatomy can help avoid bleeding and septic complications
3) development of much less aggressive and safer guidewire-based methods which involve more steps and more effort, skill and physician time such as micropuncture access with gradual stepwise transition to heavy-duty guidewires, tract dilation and placement of catheters over safer, more stable wires and use of real-time ultrasound guidance for needle access. The ductal system is never distended to avoid septic complications.

We would note that the example of 47510 is reflective of the majority of the existing codes for biliary catheter procedures. Simply put, the new codes reflect new thinking and understanding as well as considerable improvements and advances in techniques which render the current values inappropriate for these new codes.

In another example, the existing code 47511, *Introduction of percutaneous transhepatic stent for internal and external biliary drainage*. Current methods utilize a wide range of self-expanding open, as well as covered, metallic stents of various designs designed specifically for biliary pathology and using percutaneous methods as well as plastic and even retrievable metallic stents. These devices were not available when the existing codes were proposed or adopted.

A number of the codes, for example, 47543, *Endoluminal biopsy(ies) of biliary tree, percutaneous, any method(s) (eg, brush, forceps and/or needle)*, 47544 *Removal of calculi/debris from biliary duct(s) and/or gallbladder, percutaneous, including destruction of calculi by any method (eg, mechanical, electrohydraulic, lithotripsy)*, 47542, *Balloon dilation of biliary duct(s) or of ampulla (sphincteroplasty), percutaneous*, or 47541, *Placement of access through the biliary tree and into small bowel to assist with an endoscopic biliary procedure (eg, rendezvous procedure), percutaneous*, describe procedures which did not exist previously and, thus, are new technology not able to be described at all under the old codes.

Patient Population

SIR/ACR assert that the population of patients treated with the new family of procedures described herein has changed considerably in at least three major ways:

1) Previously the majority of all biliary catheter procedures were used for basic relief of distal ductal biliary obstruction either acutely or chronically often related to pancreatic cancer and/or stone disease. These patients previously drained and stented percutaneously are now largely treated by endoscopic methods. The significant majority of all of the biliary diseases referred for interventional percutaneous treatment now have higher and more complex levels of benign and malignant biliary occlusion, including hilar and segmental obstruction. Treatment of these lesions involves considerably more work, time, effort and risk to achieve satisfactory outcomes.
2) The widespread use of liver transplantation has introduced an entirely different patient population: the postoperative liver transplant patient with ischemic biliary strictures (intrahepatic and/or extrahepatic), which requires major investments of time, skill and effort to obtain access and drain, stent and dilate these complex situations.
3) Hepatic surgery for malignancy has also become far more sophisticated and segmental or lobar resections will frequently result in referrals for drainage of biliary leaks from nondilated ducts. These patients also present challenges in drainage and management.

An example of the change in patient populations can also be seen in the management of biliary stone disease. Previously, patients with distal biliary calculi were referred for external biliary drainage and stone manipulation. These patients are no longer sent for percutaneous treatment. The stone diseases seen currently are intrahepatic lithiasis or extensive stone formation as a result of biliary-enteric anastomoses both of which require far more skill and time to achieve satisfactory initial access but also need much different time-consuming and labor intensive methods to extract or expel the stones.

New Biliary Family

The CPT editorial panel established 14 bundled codes that describe percutaneous biliary procedures including imaging. Below is a table demonstrating the relationship between the new codes:

000 Code Set:

47531: Direct crosswalk to 46611 (work RVU= 1.30)

47532: Recommendation of 25th percentile RVW 4.50 based on survey (N=42) with median intra-service time of 45 and total time of 98 minutes. This recommendation is well supported by the #1 KRS (49407: RVW 4.50 (exactly the same), Intra 45 (exactly the

same), total 110 (slightly higher)). The recommendation is also well bracketed by MPCs 55214 (RVW 3.50, Intra 30, total 79) and 52235 (RVW 5.44, Intra 45 (same as 47532), and total 94 (less than 47532)).

47533: The RUC recommends the survey 25th percentile of 4.50 work RVUs

47534: The RUC recommends the survey 25th percentile of 7.85 work RVUs

47535: Recommendation of 25th percentile RVW 4.20 based on survey (N=42) with median intra-service time of 45 and total time of 93 minutes. The societies feel that the work of 47535 is similar to 47532 and that the survey and our recommendations are therefore also consistent. This recommendation is well bracketed by the #1 and #2 KRS (36247: RVW 6.29, Intra 60, Total 131, and 32550: RVW 4.17, Intra 30, Total 90). The recommendation is also well bracketed by MPCs 52214 (RVW 3.50, Intra 30, Total 79) and 52235 (RVW 5.44, Intra 45, Total 94).

47536: The RUC recommends the survey 25th percentile of 2.86 work RVUs

47537: Recommendation of 25th percentile RVW 1.84 based on survey (N=42) with median intra-service time of 15 and total time of 52 minutes. This work is similar to 47531with the additional work of fluoroscopic drain removal. The societies feel that this extra work is reflective of clinical practice and similarly reflected in the survey median and 25th RVW. This recommendation is well bracketed by the #1 and #2 KRS (49083: RVW 2.00, Intra 25, Total 60, and 49450: RVW 1.36, Intra 10, Total 50).

47538: The RUC recommends the survey 25th percentile of 5.00 work RVUs

47539: Recommendation of 25th percentile RVW 9.00 based on survey (N=41) with median intra-service time of 75 and total time of 136 minutes. This recommendation is well bracketed by MPC 52353 (RVW 7.50, Intra 60, Total 133) and the #1 KRS (37226: RVW 10.49, Intra 90, Total 168).

47540: The RUC recommends the survey 25th percentile of 9.28 work RVUs

47541: Recommendation of 25th percentile RVW 7.00 based on survey (N=42) with median intra-service time of 60 and total time of 121 minutes. The societies feel that the intensity and complexity of this work is in between that of 47533 and 47534 based on magnitude estimation and therefore are recommending a value greater than 47533 but less than 47534. This recommendation is well bracketed by the #1 and #2 KRS (37226: RVW 10.49, Intra 90, Total 168, and 37213: RVW 5.00, Intra 33, Total 99). This recommendation is also supported by MPC 52353 (RVW 7.50, Intra 60, Total 133).

ZZZ Code Set:

47542**:** The RUC recommends the survey 25th percentile of 2.85 work RVUs

47543**:** Recommendation of 25th percentile RVW 3.00 based on survey (N=42) with median intra-service time of 30. This recommendation is well bracketed by MPC 99292 (RVW 2.25, Intra 30) and #1 KRS (37185: RVW 3.28, Intra 40).

47544**:** The RUC recommends a direct crosswalk to 37185 and 92973 (work RVU= 3.28)

PreService Time

We selected pre time package 2B for 47532, 47533, 47534, 47535, 47536, 47541, 47538, 47539, and 47540. For 47531 and 47537, we selected pre time package 2A, because moderate sedation was not inherent in those two procedures. We also added two additional minutes of positioning time to account for positioning patient on angiographic table, as well as optimize lead placement to avoid obscuring imaging.

Relativity

The consensus panel reviewed the survey data for the family this new family of biliary procedures and analyzed the relativity within the family. The consensus panel felt the appropriate recommendations for 47533, 47534, 47538 and 47542 fell between the surveyed 25th percentile and the survey median. As such, we are recommending crosswalk values for those codes.

The consensus panel reviewed the survey data and believe the recommendations compare favorably to (1) the new family of biliary codes, (2) interventional radiology and (3) MPCs. Below is an outline of the comparisons:

	CPT Code	Global Period	Work RVU	Total Time	Pre Time			Intra Time	Post Time	IWPUT
					Eval	Pos	SDW			

reference	49450	000	1.36	50	20	5	5	10	10	0.054
surveyed	47531	000	1.30	54	18	3	6	15	12	0.047
MPC	55876	000	1.73	59	19	10		20	10	0.043
surveyed	47537	000	1.84	52	18	3	6	15	10	0.073
reference	49083	000	2.00	60	15	5	5	25	10	0.052
MPC	31622	000	2.78	65	10	5	5	30	15	0.069
reference	49452	000	2.86	60	20	5	5	20	10	0.102
surveyed	47536	000	2.86	61	20	3	5	20	13	0.111
MPC	52214	000	3.50	79	19	5	5	30	20	0.083
reference	32550	000	4.17	90	15	15	10	30	20	0.099
surveyed	47535	000	4.20	93	25	3	5	45	15	0.071
reference	49407	000	4.50	110	35	5	5	45	20	0.069
surveyed	47532	000	4.50	98	30	3	5	45	15	0.075
reference	37191	000	4.71	83	30	3	5	30	15	0.120
reference	37213	000	5.00	99	33	3	5	33	25	0.109
MPC	52235	000	5.44	94	19	5	5	45	20	0.098
surveyed	47538	000	5.00	106	30	3	5	53	15	0.082
crosswalk	31267	000	5.45	110	30			50	30	0.082
reference	36247	000	6.29	131	33	3	5	60	30	0.080
surveyed	47533	000	5.63	121	33	3	5	60	20	0.083
crosswalk	37197	000	6.29	121	33	3	5	60	20	0.083
surveyed	47541	000	7.00	121	33	3	5	60	20	0.095
MPC	52353	000	7.50	133	33	5	15	60	20	0.101
reference	37211	000	8.00	138	40	3	5	60	30	0.105
surveyed	47534	000	7.85	129	33	3	5	68	20	0.107
crosswalk	43274	000	8.58	139	33	10	5	68	23	0.104
surveyed	47539	000	9.00	136	33	3	5	75	20	0.103
reference	37226	000	10.49	168	40	3	5	90	30	0.098
reference	37228	000	11.00	168	40	3	5	90	30	0.104
surveyed	47540	000	9.28	146	33	3	5	85	20	0.114
reference	37230	000	13.80	198	40	3	5	120	30	0.101
MPC	99292	ZZZ	2.25	30				30		0.075
surveyed	47542	ZZZ	2.85	30				30		0.099
crosswalk	37239	ZZZ	2.97	32	1			30	1	0.098
surveyed	47543	ZZZ	3.00	30				30		0.100
reference	37185	ZZZ	3.28	40				40		0.082
reference	37222	ZZZ	3.73	42	1			40	1	0.092
surveyed	47544	ZZZ	3.28	45				45		0.088
MPC	57267	ZZZ	4.88	45				45		0.108
reference	37235	ZZZ	7.80	82	1			80	1	0.097

Recommendations

The consensus panel reviewed the (1) RUC survey data, (2) the family relationship between the new codes, (2) the relativity to codes within interventional radiology specialty, (3) rank order within the Fee Schedule, (4) compelling evidence, (5) standard packages and (6) RUC guidelines and makes the following physician work recommendations:

CPT	Global	Work	Total	Pre Time			Intra	Post	IWPUT
Code	Period	RVU	Time	Eval	Pos	SDW	Time	Time	
47531	000	1.30	54	18	3	6	15	12	0.047
47532	000	4.50	98	30	3	5	45	15	0.075

47533	000	5.63	121	33	3	5	60	20	0.083
47534	000	7.85	129	33	3	5	68	20	0.107
47535	000	4.20	93	25	3	5	45	15	0.071
47536	000	2.86	61	20	3	5	20	13	0.111
47537	000	1.84	52	18	3	6	15	10	0.073
47538	000	5.00	106	30	3	5	53	15	0.082
47539	000	9.00	136	33	3	5	75	20	0.103
47540	000	9.28	146	33	3	5	85	20	0.114
47541	000	7.00	121	33	3	5	60	20	0.095
47542	ZZZ	2.85	30				30		0.099
47543	ZZZ	3.00	30				30		0.100
47544	ZZZ	3.28	45				45		0.088

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions: No

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☐ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.
   - ☐ Historical precedents.
   - ☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) 47505, 74305, 47511 and 75982

How often do physicians <u>in your specialty</u> perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty Interventional Radiology How often? Commonly

Specialty How often?

Specialty How often?

Estimate the number of times this service might be provided nationally in a one-year period?
If the recommendation is from multiple specialties, please provide the frequency and <u>percentage</u> for each specialty. Please explain the rationale for this estimate. A national number is not available.

Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? 0 If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty. Please explain the rationale for this estimate. A national number is not available.

Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%
Specialty	Frequency 0	Percentage 0.00	%

Do many physicians perform this service across the United States? Yes

---

Berenson-Eggers Type of Service (BETOS) Assignment

Please pick the appropriate BETOS classification that best corresponds to the clinical nature of this CPT code. Please select the main BETOS classification and sub-classification to the greatest level of specificity possible.

Main BETOS Classification:
Procedures

BETOS Sub-classification:
Minor procedure

BETOS Sub-classification Level II:
Other

Professional Liability Insurance Information (PLI)

If the surveyed code is an existing code and the specialty believes the specialty utilization mix will not change, enter the surveyed existing CPT code number

If this code is a new/revised code or an existing code in which the specialty utilization mix will change, please select another crosswalk based on a similar specialty mix. 36247

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:47536 Tracking Number U6 Original Specialty Recommended RVU: **3.06**
Presented Recommended RVU: **3.06**
Global Period: 000 RUC Recommended RVU: **2.86**

CPT Descriptor: Exchange of biliary drainage catheter (eg. external, internal-external , or conversion of internal-external to external only), percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A 61-year-old man presents following placement of an internal/external biliary drainage catheter for an obstructive pancreatic head mass. The patient has been experiencing fevers and leakage around the existing tube. The patient presents for exchange of the existing internal-external biliary drain.

Percentage of Survey Respondents who found Vignette to be Typical: 100%

Site of Service (Complete for 010 and 090 Globals Only)

Percent of survey respondents who stated they perform the procedure; In the hospital 0% , In the ASC 0%, In the office 0%

Percent of survey respondents who stated they typically perform this procedure in the hospital, stated the patient is; Discharged the same day 0% , Overnight stay-less than 24 hours 0% , Overnight stay-more than 24 hours 0%

Percent of survey respondents who stated that if the patient is typically kept overnight also stated that they perform an E&M service later on the same day 0%

Moderate Sedation

Is moderate sedation inherent to this procedure in the Hospital/ASC setting? Yes
Percent of survey respondents who stated moderate sedation is typical in the Hospital/ASC setting? 82%

Is moderate sedation inherent to this procedure in the office setting? Yes
Percent of survey respondents who stated moderate sedation is typical in the office setting? 69%

Description of Pre-Service Work: The patient's medical history, physical exam, and laboratory studies are reviewed and consent is obtained. Relevant preoperative diagnostic imaging studies are retrieved and reviewed. The case is discussed with the referring clinician. A time out is performed. The patient is placed supine on the angiographic table. Moderate conscious sedation is administered. Prophylactic antiobiotics are administered.

Description of Intra-Service Work: The existing tube, abdomen and right flank are prepared and draped in sterile fashion. Under fluoroscopic guidance, a wire is placed through the existing tube into the small bowel. The tube is exchanged for a sheath. Cholangiogram is performed through the sheath. Multiple radiographs in multiple projections are obtained. The sheath is exchanged over the wire for a new internal/external biliary drainage catheter. Contrast injection under fluoroscopic guidance confirms placement in small bowel and that side-holes are positioned appropriately within the bile ducts. The catheter is connected to gravity bag drainage and the catheter is anchored at the skin surface with a retention suture. Sterile dressings are applied.

Description of Post-Service Work: The patient is transported to the recovery room for hemodynamic monitoring, sedation recovery, and pain control. The procedure is documented in the permanent record. Diagnostic cholangiogram results, and patient status are communicated to the patient's family. Permanent surgical procedure and image interpretation reports are created for the medical record and copies of the reports are sent to the patient's referring physician.

SURVEY DATA

RUC Meeting Date (mm/yyyy)	10/2015				
Presenter(s):	Jerry Niedzwiecki, MD, Michael Hall, MD, Bob Vogelzang, MD, Tim Swan, MD, Matt Hawkins, MD, Zeke Silva, MD and Kurt Schoppe, MD				
Specialty(s):	Interventional Radiology				
CPT Code:	47536				
Sample Size:	1730	**Resp N:**	42	**Response:** 2.4 %	
Description of Sample:	Random Sample: SIR 980/ACR 750				

	Low	**25th pctl**	**Median***	**75th pctl**	**High**
Service Performance Rate	1.00	16.00	**25.00**	50.00	200.00
Survey RVW:	1.40	2.86	**3.38**	4.29	7.00
Pre-Service Evaluation Time:			**20.00**		
Pre-Service Positioning Time:			**10.00**		
Pre-Service Scrub, Dress, Wait Time:			**10.00**		
Intra-Service Time:	10.00	20.00	**20.00**	30.00	90.00

Immediate Post Service-Time:	**13.00**	
Post Operative Visits	**Total Min****	**CPT Code and Number of Visits**
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.00** 99239x **0.00** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

**Physician standard total minutes per E/M visit: 99291 (70); 99292 (30); 99231 (20); 99232 (40); 99233 (55); 99238(38); 99239 (55); 99217 (38); 99211 (7); 99212 (16); 99213 (23); 99214 (40); 99215 (55); 99224 (20); 99225 (40); 99226 (55); 99354 (60); 99355 (30); 99356 (60); 99357 (30)

Specialty Society Recommended Data

Please, pick the pre-service time package that best corresponds to the data which was collected in the survey process. (Note: your recommended pre time should not exceed your survey median time for any category)

2b-FAC Diff Pat/Straightfor Proc(w sedation/anes)

CPT Code:	47536	**Recommended Physician Work RVU: 2.86**		
		Specialty Recommended Pre-Service Time	**Specialty Recommended Pre Time Package**	**Adjustments/Recommended Pre-Service Time**
Pre-Service Evaluation Time:		**20.00**	**33.00**	**-13.00**
Pre-Service Positioning Time:		**3.00**	**1.00**	**2.00**
Pre-Service Scrub, Dress, Wait Time:		**5.00**	**5.00**	**0.00**
Intra-Service Time:		**20.00**		

Please, pick the post-service time package that best corresponds to the data which was collected in the survey process: (Note: your recommended post time should not exceed your survey median time)

8A IV Sedation/Simple Procedure

	Specialty Recommended Post-Service Time	**Specialty Recommended Post Time Package**	**Adjustments/Recommended Post-Service Time**
Immediate Post Service-Time:	**13.00**	**25.00**	**-12.00**

Post-Operative Visits	Total Min**	CPT Code and Number of Visits
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.0** 99239x **0.0** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

Modifier -51 Exempt Status
Is the recommended value for the new/revised procedure based on its modifier -51 exempt status? No

New Technology/Service:
Is this new/revised procedure considered to be a new technology or service? No

TOP KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
49452	000	2.86	**RUC Time**

CPT Descriptor Replacement of gastro-jejunostomy tube, percutaneous, under fluoroscopic guidance including contrast injection(s), image documentation and report

SECOND HIGHEST KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
32550	000	4.17	**RUC Time**

CPT Descriptor Insertion of indwelling tunneled pleural catheter with cuff

KEY MPC COMPARISON CODES:
Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU	Time Source	Most Recent Medicare Utilization
31622	000	2.78	**RUC Time**	68,721

CPT Descriptor 1 Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with cell washing, when performed (separate procedure)

MPC CPT Code 2	Global	Work RVU	Time Source	Most Recent Medicare Utilization
52214	000	3.50	**RUC Time**	20,091

CPT Descriptor 2 Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) of trigone, bladder neck, prostatic fossa, urethra, or periurethral glands

Other Reference CPT Code	Global	Work RVU	Time Source
		0.00	

CPT Descriptor

RELATIONSHIP OF CODE BEING REVIEWED TO TOP TWO KEY REFERENCE SERVICES:

Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the top two chosen key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Top Key Reference Code: 19 **% of respondents:** 45.2 **%**

Number of respondents who choose 2nd Key Reference Code: 5 **% of respondents:** 11.9 **%**

TIME ESTIMATES (Median)

	CPT Code: 47536	Top Key Reference CPT Code: 49452	2nd Key Reference CPT Code: **32550**
Median Pre-Service Time	28.00	30.00	40.00
Median Intra-Service Time	20.00	20.00	30.00
Median Immediate Post-service Time	13.00	10.00	20.00
Median Critical Care Time	0.0	0.00	0.00
Median Other Hospital Visit Time	0.0	0.00	0.00
Median Discharge Day Management Time	0.0	0.00	0.00
Median Office Visit Time	0.0	0.00	0.00
Prolonged Services Time	0.0	0.00	0.00
Median Subsequent Observation Care Time	0.0	0.00	0.00
Median Total Time	**61.00**	**60.00**	**90.00**
Other time if appropriate			

INTENSITY/COMPLEXITY MEASURES
(of those that selected Key Reference codes)

Survey respondents are rating the survey code relative to the key reference code.

Intensity & Complexity Rating Scale: (much less= -2.00, somewhat less= -1.00, identical= 0.00, somewhat more= 1.00, much more= 2.00)

	Top Key Ref Code	2nd Key Ref Code
Mental Effort and Judgment (Mean)		
The number of possible diagnosis and/or the number of management options that must be considered		
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed		
Urgency of medical decision making		
Technical Skill/Physical Effort (Mean)		
Technical skill required		
Physical effort required		

Psychological Stress (Mean)

The risk of significant complications, morbidity and/or mortality		
Outcome depends on the skill and judgment of physician		
Estimated risk of malpractice suit with poor outcome		

INTENSITY/COMPLEXITY MEASURES	**Top Key Ref Code**	**2nd Key Ref Code**
Time Segment (Mean)		
Overall intensity/complexity	0.68	0.40

Additional Rationale and Comments

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

The Joint CPT-RUC Workgroup identified (Group 12) codes 47500, 74320-26, 47505, 74305-26, 47510, 75980-26, 47511, 75982-26, 74305-26, 47505, 74320-26, 47500, 75980-26, 47510, 75982-26 as being reported together at least 75% of the time. The specialties updated the percutaneous biliary code family based on the current practice of medicine, and in so doing, deleted 10 percutaneous biliary procedure codes while creating 14 new bundled codes that describe percutaneous biliary procedures including imaging.

This new 'biliary family' was recently surveyed and presented at the April 2015 RUC meeting. However, the RUC and specialty societies agreed that the survey data for this family of services was problematic. Specifically, the RUC noted codes 47532, 47533 and 47534 all had identical median intra-service time of 60 minutes. CPT code 47533 includes the work of 47532 plus the work of an additional access and drain placement. Furthermore, 47534 includes the work of 47533 plus the work of crossing the occlusion and placement of an internal/external drain. Given this time anomaly, the RUC agreed to provide interim recommendations at this meeting, while allowing the specialty societies to re-survey the entire family of codes for October 2015.

The specialty societies worked with the research subcommittee to develop a modified survey tool in an attempt to facilitate gathering more accurate rank order survey data from the surveyed physicians. The entire family of codes was included on one single survey. The research subcommittee approved this survey method, which collected:
• overall complexity/intensity data;
• service performance rates for just the surveyed codes; and
• only whether the vignette is typical or not.
We did not ask for them to provide details if the vignette is not typical.

Compelling Evidence
SIR/ACR believe that the current values for CPT codes now used for the percutaneous, image guided biliary interventional procedures newly described in Tab 4 are no longer rational or appropriate for the detailed, granular and far more accurately descriptive codes in this new group. In our opinion, there have been significant changes in technique, knowledge and technology, patient population and physician time.

Technique, Knowledge and Technology
The codes currently used for this family of biliary procedures no longer reflect the techniques now used for image-guided, catheter-based biliary procedures. Indeed, as can be seen, there are 14 new codes in this family which will henceforth be used to describe a diverse range of procedures. As an index example of these significant changes in technique, one of the most widely used of the current codes, 47510, *Introduction of percutaneous transhepatic catheter for biliary drainage*, was previously performed by a method in which the biliary tree was first opacified and often distended by blind needle puncture (not ultrasound), after which an optimal duct was identified and punctured under fluoroscopy using large sheathed needles or even the trocar technique. These techniques have all changed since this code was introduced and valued as noted below.

Virtually all the medical devices currently used in biliary catheter procedures have been developed since the current codes were adopted. The past twenty years have witnessed major advances in our knowledge base including:
1) using imaging guidance, such as ultrasound, and preoperative mapping to avoid hepatic hilar structures and thus prevent bleeding and bile leaks
2) new insights into how segmental biliary ductal anatomy can help avoid bleeding and septic complications
3) development of much less aggressive and safer guidewire-based methods which involve more steps and more effort, skill and physician time such as micropuncture access with gradual stepwise transition to heavy-duty guidewires, tract dilation and placement of catheters over safer, more stable wires and use of real-time ultrasound guidance for needle access. The ductal system is never distended to avoid septic complications.

We would note that the example of 47510 is reflective of the majority of the existing codes for biliary catheter procedures. Simply put, the new codes reflect new thinking and understanding as well as considerable improvements and advances in techniques which render the current values inappropriate for these new codes.

In another example, the existing code 47511, *Introduction of percutaneous transhepatic stent for internal and external biliary drainage*. Current methods utilize a wide range of self-expanding open, as well as covered, metallic stents of various designs designed specifically for biliary pathology and using percutaneous methods as well as plastic and even retrievable metallic stents. These devices were not available when the existing codes were proposed or adopted.

A number of the codes, for example, 47543, *Endoluminal biopsy(ies) of biliary tree, percutaneous, any method(s) (eg, brush, forceps and/or needle),* 47544 *Removal of calculi/debris from biliary duct(s) and/or gallbladder, percutaneous, including destruction of calculi by any method (eg, mechanical, electrohydraulic, lithotripsy),* 47542, *Balloon dilation of biliary duct(s) or of ampulla (sphincteroplasty), percutaneous,* or 47541, *Placement of access through the biliary tree and into small bowel to assist with an endoscopic biliary procedure (eg, rendezvous procedure), percutaneous*, describe procedures which did not exist previously and, thus, are new technology not able to be described at all under the old codes.

Patient Population

SIR/ACR assert that the population of patients treated with the new family of procedures described herein has changed considerably in at least three major ways:

1) Previously the majority of all biliary catheter procedures were used for basic relief of distal ductal biliary obstruction either acutely or chronically often related to pancreatic cancer and/or stone disease. These patients previously drained and stented percutaneously are now largely treated by endoscopic methods. The significant majority of all of the biliary diseases referred for interventional percutaneous treatment now have higher and more complex levels of benign and malignant biliary occlusion, including hilar and segmental obstruction. Treatment of these lesions involves considerably more work, time, effort and risk to achieve satisfactory outcomes.
2) The widespread use of liver transplantation has introduced an entirely different patient population: the postoperative liver transplant patient with ischemic biliary strictures (intrahepatic and/or extrahepatic), which requires major investments of time, skill and effort to obtain access and drain, stent and dilate these complex situations.
3) Hepatic surgery for malignancy has also become far more sophisticated and segmental or lobar resections will frequently result in referrals for drainage of biliary leaks from nondilated ducts. These patients also present challenges in drainage and management.

An example of the change in patient populations can also be seen in the management of biliary stone disease. Previously, patients with distal biliary calculi were referred for external biliary drainage and stone manipulation. These patients are no longer sent for percutaneous treatment. The stone diseases seen currently are intrahepatic lithiasis or extensive stone formation as a result of biliary-enteric anastomoses both of which require far more skill and time to achieve satisfactory initial access but also need much different time-consuming and labor intensive methods to extract or expel the stones.

New Biliary Family

The CPT editorial panel established 14 bundled codes that describe percutaneous biliary procedures including imaging. Below is a table demonstrating the relationship between the new codes:

000 Code Set:

47531: Direct crosswalk to 46611 (work RVU= 1.30)

47532: Recommendation of 25th percentile RVW 4.50 based on survey (N=42) with median intra-service time of 45 and total time of 98 minutes. This recommendation is well supported by the #1 KRS (49407: RVW 4.50 (exactly the same), Intra 45 (exactly the

same), total 110 (slightly higher)). The recommendation is also well bracketed by MPCs 55214 (RVW 3.50, Intra 30, total 79) and 52235 (RVW 5.44, Intra 45 (same as 47532), and total 94 (less than 47532)).

47533: The RUC recommends the survey 25th percentile of 4.50 work RVUs

47534: The RUC recommends the survey 25th percentile of 7.85 work RVUs

47535: Recommendation of 25th percentile RVW 4.20 based on survey (N=42) with median intra-service time of 45 and total time of 93 minutes. The societies feel that the work of 47535 is similar to 47532 and that the survey and our recommendations are therefore also consistent. This recommendation is well bracketed by the #1 and #2 KRS (36247: RVW 6.29, Intra 60, Total 131, and 32550: RVW 4.17, Intra 30, Total 90). The recommendation is also well bracketed by MPCs 52214 (RVW 3.50, Intra 30, Total 79) and 52235 (RVW 5.44, Intra 45, Total 94).

47536: The RUC recommends the survey 25th percentile of 2.86 work RVUs

47537: Recommendation of 25th percentile RVW 1.84 based on survey (N=42) with median intra-service time of 15 and total time of 52 minutes. This work is similar to 47531with the additional work of fluoroscopic drain removal. The societies feel that this extra work is reflective of clinical practice and similarly reflected in the survey median and 25th RVW. This recommendation is well bracketed by the #1 and #2 KRS (49083: RVW 2.00, Intra 25, Total 60, and 49450: RVW 1.36, Intra 10, Total 50).

47538: The RUC recommends the survey 25th percentile of 5.00 work RVUs

47539: Recommendation of 25th percentile RVW 9.00 based on survey (N=41) with median intra-service time of 75 and total time of 136 minutes. This recommendation is well bracketed by MPC 52353 (RVW 7.50, Intra 60, Total 133) and the #1 KRS (37226: RVW 10.49, Intra 90, Total 168).

47540: The RUC recommends the survey 25th percentile of 9.28 work RVUs

47541: Recommendation of 25th percentile RVW 7.00 based on survey (N=42) with median intra-service time of 60 and total time of 121 minutes. The societies feel that the intensity and complexity of this work is in between that of 47533 and 47534 based on magnitude estimation and therefore are recommending a value greater than 47533 but less than 47534. This recommendation is well bracketed by the #1 and #2 KRS (37226: RVW 10.49, Intra 90, Total 168, and 37213: RVW 5.00, Intra 33, Total 99). This recommendation is also supported by MPC 52353 (RVW 7.50, Intra 60, Total 133).

ZZZ Code Set:

47542**:** The RUC recommends the survey 25th percentile of 2.85 work RVUs

47543**:** Recommendation of 25th percentile RVW 3.00 based on survey (N=42) with median intra-service time of 30. This recommendation is well bracketed by MPC 99292 (RVW 2.25, Intra 30) and #1 KRS (37185: RVW 3.28, Intra 40).

47544**:** The RUC recommends a direct crosswalk to 37185 and 92973 (work RVU= 3.28)

PreService Time

We selected pre time package 2B for 47532, 47533, 47534, 47535, 47536, 47541, 47538, 47539, and 47540. For 47531 and 47537, we selected pre time package 2A, because moderate sedation was not inherent in those two procedures. We also added two additional minutes of positioning time to account for positioning patient on angiographic table, as well as optimize lead placement to avoid obscuring imaging.

Relativity

The consensus panel reviewed the survey data for the family this new family of biliary procedures and analyzed the relativity within the family. The consensus panel felt the appropriate recommendations for 47533, 47534, 47538 and 47542 fell between the surveyed 25th percentile and the survey median. As such, we are recommending crosswalk values for those codes.

The consensus panel reviewed the survey data and believe the recommendations compare favorably to (1) the new family of biliary codes, (2) interventional radiology and (3) MPCs. Below is an outline of the comparisons:

	CPT Code	Global Period	Work RVU	Total Time	Pre Time			Intra Time	Post Time	IWPUT
					Eval	Pos	SDW			

reference	49450	000	1.36	50	20	5	5	10	10	0.054
surveyed	47531	000	1.30	54	18	3	6	15	12	0.047
MPC	55876	000	1.73	59	19	10		20	10	0.043
surveyed	47537	000	1.84	52	18	3	6	15	10	0.073
reference	49083	000	2.00	60	15	5	5	25	10	0.052
MPC	31622	000	2.78	65	10	5	5	30	15	0.069
reference	49452	000	2.86	60	20	5	5	20	10	0.102
surveyed	47536	000	2.86	61	20	3	5	20	13	0.111
MPC	52214	000	3.50	79	19	5	5	30	20	0.083
reference	32550	000	4.17	90	15	15	10	30	20	0.099
surveyed	47535	000	4.20	93	25	3	5	45	15	0.071
reference	49407	000	4.50	110	35	5	5	45	20	0.069
surveyed	47532	000	4.50	98	30	3	5	45	15	0.075
reference	37191	000	4.71	83	30	3	5	30	15	0.120
reference	37213	000	5.00	99	33	3	5	33	25	0.109
MPC	52235	000	5.44	94	19	5	5	45	20	0.098
surveyed	47538	000	5.00	106	30	3	5	53	15	0.082
crosswalk	31267	000	5.45	110	30			50	30	0.082
reference	36247	000	6.29	131	33	3	5	60	30	0.080
surveyed	47533	000	5.63	121	33	3	5	60	20	0.083
crosswalk	37197	000	6.29	121	33	3	5	60	20	0.083
surveyed	47541	000	7.00	121	33	3	5	60	20	0.095
MPC	52353	000	7.50	133	33	5	15	60	20	0.101
reference	37211	000	8.00	138	40	3	5	60	30	0.105
surveyed	47534	000	7.85	129	33	3	5	68	20	0.107
crosswalk	43274	000	8.58	139	33	10	5	68	23	0.104
surveyed	47539	000	9.00	136	33	3	5	75	20	0.103
reference	37226	000	10.49	168	40	3	5	90	30	0.098
reference	37228	000	11.00	168	40	3	5	90	30	0.104
surveyed	47540	000	9.28	146	33	3	5	85	20	0.114
reference	37230	000	13.80	198	40	3	5	120	30	0.101
MPC	99292	ZZZ	2.25	30				30		0.075
surveyed	47542	ZZZ	2.85	30				30		0.099
crosswalk	37239	ZZZ	2.97	32	1			30	1	0.098
surveyed	47543	ZZZ	3.00	30				30		0.100
reference	37185	ZZZ	3.28	40				40		0.082
reference	37222	ZZZ	3.73	42	1			40	1	0.092
surveyed	47544	ZZZ	3.28	45				45		0.088
MPC	57267	ZZZ	4.88	45				45		0.108
reference	37235	ZZZ	7.80	82	1			80	1	0.097

Recommendations

The consensus panel reviewed the (1) RUC survey data, (2) the family relationship between the new codes, (2) the relativity to codes within interventional radiology specialty, (3) rank order within the Fee Schedule, (4) compelling evidence, (5) standard packages and (6) RUC guidelines and makes the following physician work recommendations:

CPT	Global	Work	Total	Pre Time			Intra	Post	IWPUT
Code	Period	RVU	Time	Eval	Pos	SDW	Time	Time	
47531	000	1.30	54	18	3	6	15	12	0.047
47532	000	4.50	98	30	3	5	45	15	0.075

47533	000	5.63	121	33	3	5	60	20	0.083
47534	000	7.85	129	33	3	5	68	20	0.107
47535	000	4.20	93	25	3	5	45	15	0.071
47536	000	2.86	61	20	3	5	20	13	0.111
47537	000	1.84	52	18	3	6	15	10	0.073
47538	000	5.00	106	30	3	5	53	15	0.082
47539	000	9.00	136	33	3	5	75	20	0.103
47540	000	9.28	146	33	3	5	85	20	0.114
47541	000	7.00	121	33	3	5	60	20	0.095
47542	ZZZ	2.85	30				30		0.099
47543	ZZZ	3.00	30				30		0.100
47544	ZZZ	3.28	45				45		0.088

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions: No

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☐ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.
   - ☐ Historical precedents.
   - ☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) 47505, 74305, 47525 and 75984

How often do physicians <u>in your specialty</u> perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty Interventional Radiology How often? Commonly

Specialty How often?

Specialty How often?

Estimate the number of times this service might be provided nationally in a one-year period?
If the recommendation is from multiple specialties, please provide the frequency and <u>percentage</u> for each specialty. Please explain the rationale for this estimate. A national number is not available.

Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? 0 If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty. Please explain the rationale for this estimate. A national number is not available.

Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%
Specialty	Frequency 0	Percentage 0.00	%

Do many physicians perform this service across the United States? Yes

---

Berenson-Eggers Type of Service (BETOS) Assignment

Please pick the appropriate BETOS classification that best corresponds to the clinical nature of this CPT code. Please select the main BETOS classification and sub-classification to the greatest level of specificity possible.

Main BETOS Classification:
Procedures

BETOS Sub-classification:
Minor procedure

BETOS Sub-classification Level II:
Other

Professional Liability Insurance Information (PLI)

If the surveyed code is an existing code and the specialty believes the specialty utilization mix will not change, enter the surveyed existing CPT code number

If this code is a new/revised code or an existing code in which the specialty utilization mix will change, please select another crosswalk based on a similar specialty mix. 49452

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:47537 Tracking Number U7 Original Specialty Recommended RVU: **1.84**
Presented Recommended RVU: **1.84**
Global Period: 000 RUC Recommended RVU: **1.84**

CPT Descriptor: Removal of biliary drainage catheter, percutaneous, requiring fluoroscopic guidance (eg, with concurrent indwelling biliary stents), including diagnostic cholangiography when performed, imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A 61-year-old man presents following placement of biliary stents for obstructive metastatic pancreatic cancer. An external biliary drain was left at the time of stent placement, and the patient presents for removal of the external biliary drainage catheter under fluoroscopic guidance to ensure the indwelling stents are not displaced during removal.

Percentage of Survey Respondents who found Vignette to be Typical: 100%

Site of Service (Complete for 010 and 090 Globals Only)

Percent of survey respondents who stated they perform the procedure; In the hospital 0% , In the ASC 0%, In the office 0%

Percent of survey respondents who stated they typically perform this procedure in the hospital, stated the patient is; Discharged the same day 0% , Overnight stay-less than 24 hours 0% , Overnight stay-more than 24 hours 0%

Percent of survey respondents who stated that if the patient is typically kept overnight also stated that they perform an E&M service later on the same day 0%

Moderate Sedation

Is moderate sedation inherent to this procedure in the Hospital/ASC setting? No
Percent of survey respondents who stated moderate sedation is typical in the Hospital/ASC setting?

Is moderate sedation inherent to this procedure in the office setting? No
Percent of survey respondents who stated moderate sedation is typical in the office setting?

Description of Pre-Service Work: The patient's medical history, physical exam, and laboratory studies are reviewed and consent is obtained. Relevant preoperative diagnostic imaging studies are retrieved and reviewed. The case is discussed with the referring clinician. A time out is performed. The patient is placed supine on the angiographic table.. Prophylactic antiobiotics are administered.

Description of Intra-Service Work: The existing tube, abdomen and right flank are prepared and draped in sterile fashion. Cholangiogram is performed through the existing external biliary drain. Multiple radiographs in multiple projections are obtained. A wire is placed through the existing catheter under fluoroscopic guidance. The catheter is then removed over the wire. The wire is then removed.

Description of Post-Service Work: Sterile dressings are applied. The patient is transported to the recovery room for hemodynamic monitoring, sedation recovery, and pain control. The procedure is documented in the permanent record. Diagnostic cholangiogram results, and patient status are communicated to the patient's family. Permanent surgical procedure and image interpretation reports are created for the medical record and copies of the reports are sent to the patient's referring physician.

SURVEY DATA

RUC Meeting Date (mm/yyyy)	10/2015				
Presenter(s):	Jerry Niedzwiecki, MD, Michael Hall, MD, Bob Vogelzang, MD, Tim Swan, MD, Matt Hawkins, MD, Zeke Silva, MD and Kurt Schoppe, MD				
Specialty(s):	Interventional Radiology				
CPT Code:	47537				
Sample Size:	1730	**Resp N:**	42	**Response:** 2.4 %	
Description of Sample:	Random Sample: SIR 980/ACR 750				

	Low	**25th pctl**	**Median***	**75th pctl**	**High**
Service Performance Rate	0.00	5.00	**10.00**	15.00	100.00
Survey RVW:	1.00	1.84	**2.50**	3.02	6.00
Pre-Service Evaluation Time:			**20.00**		
Pre-Service Positioning Time:			**5.00**		
Pre-Service Scrub, Dress, Wait Time:			**10.00**		
Intra-Service Time:	5.00	10.00	**15.00**	15.00	90.00

Immediate Post Service-Time:	**10.00**	
Post Operative Visits	**Total Min****	**CPT Code and Number of Visits**
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.00** 99239x **0.00** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

**Physician standard total minutes per E/M visit: 99291 (70); 99292 (30); 99231 (20); 99232 (40); 99233 (55); 99238(38); 99239 (55); 99217 (38); 99211 (7); 99212 (16); 99213 (23); 99214 (40); 99215 (55); 99224 (20); 99225 (40); 99226 (55); 99354 (60); 99355 (30); 99356 (60); 99357 (30)

Specialty Society Recommended Data

Please, pick the pre-service time package that best corresponds to the data which was collected in the survey process. (Note: your recommended pre time should not exceed your survey median time for any category)

2a-FAC Diff Pat/Straightfor Proc(no sedation/anes)

CPT Code:	47537	**Recommended Physician Work RVU: 1.84**		
		Specialty Recommended Pre-Service Time	**Specialty Recommended Pre Time Package**	**Adjustments/Recommended Pre-Service Time**
Pre-Service Evaluation Time:		**18.00**	**18.00**	**0.00**
Pre-Service Positioning Time:		**3.00**	**1.00**	**2.00**
Pre-Service Scrub, Dress, Wait Time:		**6.00**	**6.00**	**0.00**
Intra-Service Time:		**15.00**		

Please, pick the post-service time package that best corresponds to the data which was collected in the survey process: (Note: your recommended post time should not exceed your survey median time)

7A Local/Simple Procedure

	Specialty Recommended Post-Service Time	**Specialty Recommended Post Time Package**	**Adjustments/Recommended Post-Service Time**
Immediate Post Service-Time:	**10.00**	**18.00**	**-8.00**

Post-Operative Visits	Total Min**	CPT Code and Number of Visits
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.0** 99239x **0.0** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

Modifier -51 Exempt Status
Is the recommended value for the new/revised procedure based on its modifier -51 exempt status? No

New Technology/Service:
Is this new/revised procedure considered to be a new technology or service? No

TOP KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
49083	000	2.00	**RUC Time**

CPT Descriptor Abdominal paracentesis (diagnostic or therapeutic); with imaging guidance

SECOND HIGHEST KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
49450	000	1.36	**RUC Time**

CPT Descriptor Replacement of gastrostomy or cecostomy (or other colonic) tube, percutaneous, under fluoroscopic guidance including contrast injection(s), image documentation and report

KEY MPC COMPARISON CODES:
Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU	Time Source	Most Recent Medicare Utilization
55876	000	1.73	**RUC Time**	15,185

CPT Descriptor 1 Placement of interstitial device(s) for radiation therapy guidance (eg, fiducial markers, dosimeter), prostate (via needle, any approach), single or multiple

MPC CPT Code 2	Global	Work RVU	Time Source	Most Recent Medicare Utilization
31622	000	2.78	**RUC Time**	68,721

CPT Descriptor 2 Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with cell washing, when performed (separate procedure)

Other Reference CPT Code	Global	Work RVU	Time Source
		0.00	

CPT Descriptor

RELATIONSHIP OF CODE BEING REVIEWED TO TOP TWO KEY REFERENCE SERVICES:

Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the top two chosen key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Top Key Reference Code: 11 **% of respondents:** 26.1 **%**

Number of respondents who choose 2nd Key Reference Code: 9 **% of respondents:** 21.4 **%**

TIME ESTIMATES (Median)

	CPT Code: 47537	Top Key Reference CPT Code: 49083	2nd Key Reference CPT Code: **49450**
Median Pre-Service Time	27.00	25.00	30.00
Median Intra-Service Time	15.00	25.00	10.00
Median Immediate Post-service Time	10.00	10.00	10.00
Median Critical Care Time	0.0	0.00	0.00
Median Other Hospital Visit Time	0.0	0.00	0.00
Median Discharge Day Management Time	0.0	0.00	0.00
Median Office Visit Time	0.0	0.00	0.00
Prolonged Services Time	0.0	0.00	0.00
Median Subsequent Observation Care Time	0.0	0.00	0.00
Median Total Time	**52.00**	**60.00**	**50.00**
Other time if appropriate			

INTENSITY/COMPLEXITY MEASURES
(of those that selected Key Reference codes)

Survey respondents are rating the survey code relative to the key reference code.

Intensity & Complexity Rating Scale: (much less= -2.00, somewhat less= -1.00, identical= 0.00, somewhat more= 1.00, much more= 2.00)

	Top Key Ref Code	2nd Key Ref Code
Mental Effort and Judgment (Mean)		
The number of possible diagnosis and/or the number of management options that must be considered		
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed		
Urgency of medical decision making		
Technical Skill/Physical Effort (Mean)		
Technical skill required		
Physical effort required		

Psychological Stress (Mean)

The risk of significant complications, morbidity and/or mortality		
Outcome depends on the skill and judgment of physician		
Estimated risk of malpractice suit with poor outcome		

INTENSITY/COMPLEXITY MEASURES	**Top Key Ref Code**	**2nd Key Ref Code**
Time Segment (Mean)		
Overall intensity/complexity	0.72	-0.88

Additional Rationale and Comments

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

The Joint CPT-RUC Workgroup identified (Group 12) codes 47500, 74320-26, 47505, 74305-26, 47510, 75980-26, 47511, 75982-26, 74305-26, 47505, 74320-26, 47500, 75980-26, 47510, 75982-26 as being reported together at least 75% of the time. The specialties updated the percutaneous biliary code family based on the current practice of medicine, and in so doing, deleted 10 percutaneous biliary procedure codes while creating 14 new bundled codes that describe percutaneous biliary procedures including imaging.

This new 'biliary family' was recently surveyed and presented at the April 2015 RUC meeting. However, the RUC and specialty societies agreed that the survey data for this family of services was problematic. Specifically, the RUC noted codes 47532, 47533 and 47534 all had identical median intra-service time of 60 minutes. CPT code 47533 includes the work of 47532 plus the work of an additional access and drain placement. Furthermore, 47534 includes the work of 47533 plus the work of crossing the occlusion and placement of an internal/external drain. Given this time anomaly, the RUC agreed to provide interim recommendations at this meeting, while allowing the specialty societies to re-survey the entire family of codes for October 2015.

The specialty societies worked with the research subcommittee to develop a modified survey tool in an attempt to facilitate gathering more accurate rank order survey data from the surveyed physicians. The entire family of codes was included on one single survey. The research subcommittee approved this survey method, which collected:
• overall complexity/intensity data;
• service performance rates for just the surveyed codes; and
• only whether the vignette is typical or not.
We did not ask for them to provide details if the vignette is not typical.

Compelling Evidence
SIR/ACR believe that the current values for CPT codes now used for the percutaneous, image guided biliary interventional procedures newly described in Tab 4 are no longer rational or appropriate for the detailed, granular and far more accurately descriptive codes in this new group. In our opinion, there have been significant changes in technique, knowledge and technology, patient population and physician time.

Technique, Knowledge and Technology
The codes currently used for this family of biliary procedures no longer reflect the techniques now used for image-guided, catheter-based biliary procedures. Indeed, as can be seen, there are 14 new codes in this family which will henceforth be used to describe a diverse range of procedures. As an index example of these significant changes in technique, one of the most widely used of the current codes, 47510, *Introduction of percutaneous transhepatic catheter for biliary drainage*, was previously performed by a method in which the biliary tree was first opacified and often distended by blind needle puncture (not ultrasound), after which an optimal duct was identified and punctured under fluoroscopy using large sheathed needles or even the trocar technique. These techniques have all changed since this code was introduced and valued as noted below.

Virtually all the medical devices currently used in biliary catheter procedures have been developed since the current codes were adopted. The past twenty years have witnessed major advances in our knowledge base including:
1) using imaging guidance, such as ultrasound, and preoperative mapping to avoid hepatic hilar structures and thus prevent bleeding and bile leaks
2) new insights into how segmental biliary ductal anatomy can help avoid bleeding and septic complications
3) development of much less aggressive and safer guidewire-based methods which involve more steps and more effort, skill and physician time such as micropuncture access with gradual stepwise transition to heavy-duty guidewires, tract dilation and placement of catheters over safer, more stable wires and use of real-time ultrasound guidance for needle access. The ductal system is never distended to avoid septic complications.

We would note that the example of 47510 is reflective of the majority of the existing codes for biliary catheter procedures. Simply put, the new codes reflect new thinking and understanding as well as considerable improvements and advances in techniques which render the current values inappropriate for these new codes.

In another example, the existing code 47511, *Introduction of percutaneous transhepatic stent for internal and external biliary drainage*. Current methods utilize a wide range of self-expanding open, as well as covered, metallic stents of various designs designed specifically for biliary pathology and using percutaneous methods as well as plastic and even retrievable metallic stents. These devices were not available when the existing codes were proposed or adopted.

A number of the codes, for example, 47543, *Endoluminal biopsy(ies) of biliary tree, percutaneous, any method(s) (eg, brush, forceps and/or needle),* 47544 *Removal of calculi/debris from biliary duct(s) and/or gallbladder, percutaneous, including destruction of calculi by any method (eg, mechanical, electrohydraulic, lithotripsy),* 47542, *Balloon dilation of biliary duct(s) or of ampulla (sphincteroplasty), percutaneous,* or 47541, *Placement of access through the biliary tree and into small bowel to assist with an endoscopic biliary procedure (eg, rendezvous procedure), percutaneous*, describe procedures which did not exist previously and, thus, are new technology not able to be described at all under the old codes.

Patient Population

SIR/ACR assert that the population of patients treated with the new family of procedures described herein has changed considerably in at least three major ways:

1) Previously the majority of all biliary catheter procedures were used for basic relief of distal ductal biliary obstruction either acutely or chronically often related to pancreatic cancer and/or stone disease. These patients previously drained and stented percutaneously are now largely treated by endoscopic methods. The significant majority of all of the biliary diseases referred for interventional percutaneous treatment now have higher and more complex levels of benign and malignant biliary occlusion, including hilar and segmental obstruction. Treatment of these lesions involves considerably more work, time, effort and risk to achieve satisfactory outcomes.
2) The widespread use of liver transplantation has introduced an entirely different patient population: the postoperative liver transplant patient with ischemic biliary strictures (intrahepatic and/or extrahepatic), which requires major investments of time, skill and effort to obtain access and drain, stent and dilate these complex situations.
3) Hepatic surgery for malignancy has also become far more sophisticated and segmental or lobar resections will frequently result in referrals for drainage of biliary leaks from nondilated ducts. These patients also present challenges in drainage and management.

An example of the change in patient populations can also be seen in the management of biliary stone disease. Previously, patients with distal biliary calculi were referred for external biliary drainage and stone manipulation. These patients are no longer sent for percutaneous treatment. The stone diseases seen currently are intrahepatic lithiasis or extensive stone formation as a result of biliary-enteric anastomoses both of which require far more skill and time to achieve satisfactory initial access but also need much different time-consuming and labor intensive methods to extract or expel the stones.

New Biliary Family

The CPT editorial panel established 14 bundled codes that describe percutaneous biliary procedures including imaging. Below is a table demonstrating the relationship between the new codes:

000 Code Set:

47531: Direct crosswalk to 46611 (work RVU= 1.30)

47532: Recommendation of 25th percentile RVW 4.50 based on survey (N=42) with median intra-service time of 45 and total time of 98 minutes. This recommendation is well supported by the #1 KRS (49407: RVW 4.50 (exactly the same), Intra 45 (exactly the

same), total 110 (slightly higher)). The recommendation is also well bracketed by MPCs 55214 (RVW 3.50, Intra 30, total 79) and 52235 (RVW 5.44, Intra 45 (same as 47532), and total 94 (less than 47532)).

47533: The RUC recommends the survey 25th percentile of 4.50 work RVUs

47534: The RUC recommends the survey 25th percentile of 7.85 work RVUs

47535: Recommendation of 25th percentile RVW 4.20 based on survey (N=42) with median intra-service time of 45 and total time of 93 minutes. The societies feel that the work of 47535 is similar to 47532 and that the survey and our recommendations are therefore also consistent. This recommendation is well bracketed by the #1 and #2 KRS (36247: RVW 6.29, Intra 60, Total 131, and 32550: RVW 4.17, Intra 30, Total 90). The recommendation is also well bracketed by MPCs 52214 (RVW 3.50, Intra 30, Total 79) and 52235 (RVW 5.44, Intra 45, Total 94).

47536: The RUC recommends the survey 25th percentile of 2.86 work RVUs

47537: Recommendation of 25th percentile RVW 1.84 based on survey (N=42) with median intra-service time of 15 and total time of 52 minutes. This work is similar to 47531with the additional work of fluoroscopic drain removal. The societies feel that this extra work is reflective of clinical practice and similarly reflected in the survey median and 25th RVW. This recommendation is well bracketed by the #1 and #2 KRS (49083: RVW 2.00, Intra 25, Total 60, and 49450: RVW 1.36, Intra 10, Total 50).

47538: The RUC recommends the survey 25th percentile of 5.00 work RVUs

47539: Recommendation of 25th percentile RVW 9.00 based on survey (N=41) with median intra-service time of 75 and total time of 136 minutes. This recommendation is well bracketed by MPC 52353 (RVW 7.50, Intra 60, Total 133) and the #1 KRS (37226: RVW 10.49, Intra 90, Total 168).

47540: The RUC recommends the survey 25th percentile of 9.28 work RVUs

47541: Recommendation of 25th percentile RVW 7.00 based on survey (N=42) with median intra-service time of 60 and total time of 121 minutes. The societies feel that the intensity and complexity of this work is in between that of 47533 and 47534 based on magnitude estimation and therefore are recommending a value greater than 47533 but less than 47534. This recommendation is well bracketed by the #1 and #2 KRS (37226: RVW 10.49, Intra 90, Total 168, and 37213: RVW 5.00, Intra 33, Total 99). This recommendation is also supported by MPC 52353 (RVW 7.50, Intra 60, Total 133).

ZZZ Code Set:

47542**:** The RUC recommends the survey 25th percentile of 2.85 work RVUs

47543**:** Recommendation of 25th percentile RVW 3.00 based on survey (N=42) with median intra-service time of 30. This recommendation is well bracketed by MPC 99292 (RVW 2.25, Intra 30) and #1 KRS (37185: RVW 3.28, Intra 40).

47544**:** The RUC recommends a direct crosswalk to 37185 and 92973 (work RVU= 3.28)

PreService Time

We selected pre time package 2B for 47532, 47533, 47534, 47535, 47536, 47541, 47538, 47539, and 47540. For 47531 and 47537, we selected pre time package 2A, because moderate sedation was not inherent in those two procedures. We also added two additional minutes of positioning time to account for positioning patient on angiographic table, as well as optimize lead placement to avoid obscuring imaging.

Relativity

The consensus panel reviewed the survey data for the family this new family of biliary procedures and analyzed the relativity within the family. The consensus panel felt the appropriate recommendations for 47533, 47534, 47538 and 47542 fell between the surveyed 25th percentile and the survey median. As such, we are recommending crosswalk values for those codes.

The consensus panel reviewed the survey data and believe the recommendations compare favorably to (1) the new family of biliary codes, (2) interventional radiology and (3) MPCs. Below is an outline of the comparisons:

	CPT Code	Global Period	Work RVU	Total Time	Pre Time			Intra Time	Post Time	IWPUT
					Eval	Pos	SDW			

reference	49450	000	1.36	50	20	5	5	10	10	0.054
surveyed	47531	000	1.30	54	18	3	6	15	12	0.047
MPC	55876	000	1.73	59	19	10		20	10	0.043
surveyed	47537	000	1.84	52	18	3	6	15	10	0.073
reference	49083	000	2.00	60	15	5	5	25	10	0.052
MPC	31622	000	2.78	65	10	5	5	30	15	0.069
reference	49452	000	2.86	60	20	5	5	20	10	0.102
surveyed	47536	000	2.86	61	20	3	5	20	13	0.111
MPC	52214	000	3.50	79	19	5	5	30	20	0.083
reference	32550	000	4.17	90	15	15	10	30	20	0.099
surveyed	47535	000	4.20	93	25	3	5	45	15	0.071
reference	49407	000	4.50	110	35	5	5	45	20	0.069
surveyed	47532	000	4.50	98	30	3	5	45	15	0.075
reference	37191	000	4.71	83	30	3	5	30	15	0.120
reference	37213	000	5.00	99	33	3	5	33	25	0.109
MPC	52235	000	5.44	94	19	5	5	45	20	0.098
surveyed	47538	000	5.00	106	30	3	5	53	15	0.082
crosswalk	31267	000	5.45	110	30			50	30	0.082
reference	36247	000	6.29	131	33	3	5	60	30	0.080
surveyed	47533	000	5.63	121	33	3	5	60	20	0.083
crosswalk	37197	000	6.29	121	33	3	5	60	20	0.083
surveyed	47541	000	7.00	121	33	3	5	60	20	0.095
MPC	52353	000	7.50	133	33	5	15	60	20	0.101
reference	37211	000	8.00	138	40	3	5	60	30	0.105
surveyed	47534	000	7.85	129	33	3	5	68	20	0.107
crosswalk	43274	000	8.58	139	33	10	5	68	23	0.104
surveyed	47539	000	9.00	136	33	3	5	75	20	0.103
reference	37226	000	10.49	168	40	3	5	90	30	0.098
reference	37228	000	11.00	168	40	3	5	90	30	0.104
surveyed	47540	000	9.28	146	33	3	5	85	20	0.114
reference	37230	000	13.80	198	40	3	5	120	30	0.101
MPC	99292	ZZZ	2.25	30				30		0.075
surveyed	47542	ZZZ	2.85	30				30		0.099
crosswalk	37239	ZZZ	2.97	32	1			30	1	0.098
surveyed	47543	ZZZ	3.00	30				30		0.100
reference	37185	ZZZ	3.28	40				40		0.082
reference	37222	ZZZ	3.73	42	1			40	1	0.092
surveyed	47544	ZZZ	3.28	45				45		0.088
MPC	57267	ZZZ	4.88	45				45		0.108
reference	37235	ZZZ	7.80	82	1			80	1	0.097

Recommendations

The consensus panel reviewed the (1) RUC survey data, (2) the family relationship between the new codes, (2) the relativity to codes within interventional radiology specialty, (3) rank order within the Fee Schedule, (4) compelling evidence, (5) standard packages and (6) RUC guidelines and makes the following physician work recommendations:

CPT	Global	Work	Total	Pre Time			Intra	Post	IWPUT
Code	Period	RVU	Time	Eval	Pos	SDW	Time	Time	
47531	000	1.30	54	18	3	6	15	12	0.047
47532	000	4.50	98	30	3	5	45	15	0.075

47533	000	5.63	121	33	3	5	60	20	0.083
47534	000	7.85	129	33	3	5	68	20	0.107
47535	000	4.20	93	25	3	5	45	15	0.071
47536	000	2.86	61	20	3	5	20	13	0.111
47537	000	1.84	52	18	3	6	15	10	0.073
47538	000	5.00	106	30	3	5	53	15	0.082
47539	000	9.00	136	33	3	5	75	20	0.103
47540	000	9.28	146	33	3	5	85	20	0.114
47541	000	7.00	121	33	3	5	60	20	0.095
47542	ZZZ	2.85	30				30		0.099
47543	ZZZ	3.00	30				30		0.100
47544	ZZZ	3.28	45				45		0.088

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions: No

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☐ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.
   - ☐ Historical precedents.
   - ☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) 47505 and 74305

How often do physicians <u>in your specialty</u> perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty Interventional Radiology How often? Commonly

Specialty How often?

Specialty How often?

Estimate the number of times this service might be provided nationally in a one-year period?
If the recommendation is from multiple specialties, please provide the frequency and <u>percentage</u> for each specialty. Please explain the rationale for this estimate. A national number is not available.

Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? 0 If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty. Please explain the rationale for this estimate. A national number is not available.

Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%
Specialty	Frequency 0	Percentage 0.00	%

Do many physicians perform this service across the United States? Yes

---

Berenson-Eggers Type of Service (BETOS) Assignment

Please pick the appropriate BETOS classification that best corresponds to the clinical nature of this CPT code. Please select the main BETOS classification and sub-classification to the greatest level of specificity possible.

Main BETOS Classification:
Procedures

BETOS Sub-classification:
Minor procedure

BETOS Sub-classification Level II:
Other

Professional Liability Insurance Information (PLI)

If the surveyed code is an existing code and the specialty believes the specialty utilization mix will not change, enter the surveyed existing CPT code number

If this code is a new/revised code or an existing code in which the specialty utilization mix will change, please select another crosswalk based on a similar specialty mix. 49451

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:47538 Tracking Number U8 Original Specialty Recommended RVU: **5.45**
Presented Recommended RVU: **5.45**
Global Period: 000 RUC Recommended RVU: **5.00**

CPT Descriptor: Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (eg, fluoroscopy and/or ultrasound), balloon dilation, catheter exchange or removal when performed, and all associated radiological supervision and interpretation, each stent; existing access

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A 61-year-old man presents following placement of an internal/-external biliary drainage catheter for an obstructive pancreatic head mass. Biliary stent placement with removal of the biliary drain is performed

Percentage of Survey Respondents who found Vignette to be Typical: 98%

Site of Service (Complete for 010 and 090 Globals Only)

Percent of survey respondents who stated they perform the procedure; In the hospital 0% , In the ASC 0%, In the office 0%

Percent of survey respondents who stated they typically perform this procedure in the hospital, stated the patient is; Discharged the same day 0% , Overnight stay-less than 24 hours 0% , Overnight stay-more than 24 hours 0%

Percent of survey respondents who stated that if the patient is typically kept overnight also stated that they perform an E&M service later on the same day 0%

Moderate Sedation

Is moderate sedation inherent to this procedure in the Hospital/ASC setting? Yes
Percent of survey respondents who stated moderate sedation is typical in the Hospital/ASC setting? 95%

Is moderate sedation inherent to this procedure in the office setting? Yes
Percent of survey respondents who stated moderate sedation is typical in the office setting? 100%

Description of Pre-Service Work: The patient's medical history, physical exam, and laboratory studies are reviewed and consent is obtained. Relevant preoperative diagnostic imaging studies are retrieved and reviewed. The case is discussed with the referring clinician. A time out is performed. The patient is placed supine on the angiographic table. Moderate conscious sedation is administered. Prophylactic antiobiotics are administered.

Description of Intra-Service Work: The existing tube, abdomen and right flank are prepared and draped in sterile fashion. Under fluoroscopic guidance, a wire is placed through the existing tube into the small bowel. The tube is exchanged for a sheath. Cholangiogram is performed through the sheath. Multiple radiographs in multiple projections are obtained. Over the wire, a balloon is placed to dilate the level of obstruction. A biliary stent is then placed under fluoroscopic guidance, crossing the level of obstruction. A new balloon is placed over the wire to dilate the stent to the appropriate diameter. Cholangiogram is again performed through the sheath. Multiple radiographs in multiple projections are obtained. The sheath is exchanged for an external biliary drainage catheter. Contrast injection is performed through the new catheter to confirm appropriate placement in the bile ducts. The catheter is capped and anchored at the skin surface with a retention suture.

Description of Post-Service Work: Sterile dressings are applied. The patient is transported to the recovery room for hemodynamic monitoring, sedation recovery, and pain control. The procedure is documented in the permanent record. Diagnostic cholangiogram results, and patient status are communicated to the patient's family. Permanent surgical procedure and image interpretation reports are created for the medical record and copies of the reports are sent to the patient's referring physician.

SURVEY DATA

RUC Meeting Date (mm/yyyy)	10/2015				
Presenter(s):	Jerry Niedzwiecki, MD, Michael Hall, MD, Bob Vogelzang, MD, Tim Swan, MD, Matt Hawkins, MD, Zeke Silva, MD and Kurt Schoppe, MD				
Specialty(s):	Interventional Radiology				
CPT Code:	47538				
Sample Size:	1730	**Resp N:**	42	**Response:** 2.4 %	
Description of Sample:	Random Sample: SIR 980/ACR 750				

	Low	**25th pctl**	**Median***	**75th pctl**	**High**
Service Performance Rate	0.00	3.00	**6.00**	10.00	40.00
Survey RVW:	4.00	5.00	**7.15**	9.88	16.00
Pre-Service Evaluation Time:			**30.00**		
Pre-Service Positioning Time:			**10.00**		
Pre-Service Scrub, Dress, Wait Time:			**10.00**		
Intra-Service Time:	20.00	40.00	**53.00**	64.00	120.00

Immediate Post Service-Time:	**15.00**	
Post Operative Visits	**Total Min****	**CPT Code and Number of Visits**
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.00** 99239x **0.00** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

**Physician standard total minutes per E/M visit: 99291 (70); 99292 (30); 99231 (20); 99232 (40); 99233 (55); 99238(38); 99239 (55); 99217 (38); 99211 (7); 99212 (16); 99213 (23); 99214 (40); 99215 (55); 99224 (20); 99225 (40); 99226 (55); 99354 (60); 99355 (30); 99356 (60); 99357 (30)

Specialty Society Recommended Data

Please, pick the pre-service time package that best corresponds to the data which was collected in the survey process. (Note: your recommended pre time should not exceed your survey median time for any category)

2b-FAC Diff Pat/Straightfor Proc(w sedation/anes)

CPT Code:	47538	**Recommended Physician Work RVU: 5.00**		
		Specialty Recommended Pre-Service Time	**Specialty Recommended Pre Time Package**	**Adjustments/Recommended Pre-Service Time**
Pre-Service Evaluation Time:		**30.00**	**33.00**	**-3.00**
Pre-Service Positioning Time:		**3.00**	**1.00**	**2.00**
Pre-Service Scrub, Dress, Wait Time:		**5.00**	**5.00**	**0.00**
Intra-Service Time:		**53.00**		

Please, pick the post-service time package that best corresponds to the data which was collected in the survey process: (Note: your recommended post time should not exceed your survey median time)

8A IV Sedation/Simple Procedure

	Specialty Recommended Post-Service Time	**Specialty Recommended Post Time Package**	**Adjustments/Recommended Post-Service Time**
Immediate Post Service-Time:	**15.00**	**25.00**	**-10.00**

Post-Operative Visits	Total Min**	CPT Code and Number of Visits
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.0** 99239x **0.0** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

Modifier -51 Exempt Status

Is the recommended value for the new/revised procedure based on its modifier -51 exempt status? No

New Technology/Service:

Is this new/revised procedure considered to be a new technology or service? No

TOP KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
37191	000	4.71	**RUC Time**

CPT Descriptor Insertion of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy), when performed

SECOND HIGHEST KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
37226	000	10.49	**RUC Time**

CPT Descriptor Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed

KEY MPC COMPARISON CODES:

Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU	Time Source	Most Recent Medicare Utilization
52353	000	7.50	**RUC Time**	16,401

CPT Descriptor 1 Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy (ureteral catheterization is included)

MPC CPT Code 2	Global	Work RVU	Time Source	Most Recent Medicare Utilization
		0.00		

CPT Descriptor 2

Other Reference CPT Code	Global	Work RVU	Time Source
		0.00	

CPT Descriptor

RELATIONSHIP OF CODE BEING REVIEWED TO TOP TWO KEY REFERENCE SERVICES:

Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the top two chosen key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Top Key Reference Code: 11 **% of respondents:** 26.1 **%**

Number of respondents who choose 2nd Key Reference Code: 10 **% of respondents:** 23.8 **%**

TIME ESTIMATES (Median)

	CPT Code: 47538	**Top Key Reference CPT Code:** 37191	**2nd Key Reference CPT Code:** **37226**
Median Pre-Service Time	38.00	38.00	48.00
Median Intra-Service Time	53.00	30.00	90.00
Median Immediate Post-service Time	15.00	15.00	30.00
Median Critical Care Time	0.0	0.00	0.00
Median Other Hospital Visit Time	0.0	0.00	0.00
Median Discharge Day Management Time	0.0	0.00	0.00
Median Office Visit Time	0.0	0.00	0.00
Prolonged Services Time	0.0	0.00	0.00
Median Subsequent Observation Care Time	0.0	0.00	0.00
Median Total Time	**106.00**	**83.00**	**168.00**
Other time if appropriate			

INTENSITY/COMPLEXITY MEASURES
(of those that selected Key Reference codes)

Survey respondents are rating the survey code relative to the key reference code.

Intensity & Complexity Rating Scale: (much less= -2.00, somewhat less= -1.00, identical= 0.00, somewhat more= 1.00, much more= 2.00)

	Top Key Ref Code	**2nd Key Ref Code**
Mental Effort and Judgment (Mean)		
The number of possible diagnosis and/or the number of management options that must be considered		
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed		
Urgency of medical decision making		
Technical Skill/Physical Effort (Mean)		
Technical skill required		
Physical effort required		

Psychological Stress (Mean)

The risk of significant complications, morbidity and/or mortality		
Outcome depends on the skill and judgment of physician		
Estimated risk of malpractice suit with poor outcome		

INTENSITY/COMPLEXITY MEASURES	**Top Key Ref Code**	**2nd Key Ref Code**
Time Segment (Mean)		
Overall intensity/complexity	1.18	-0.40

Additional Rationale and Comments

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

The Joint CPT-RUC Workgroup identified (Group 12) codes 47500, 74320-26, 47505, 74305-26, 47510, 75980-26, 47511, 75982-26, 74305-26, 47505, 74320-26, 47500, 75980-26, 47510, 75982-26 as being reported together at least 75% of the time. The specialties updated the percutaneous biliary code family based on the current practice of medicine, and in so doing, deleted 10 percutaneous biliary procedure codes while creating 14 new bundled codes that describe percutaneous biliary procedures including imaging.

This new 'biliary family' was recently surveyed and presented at the April 2015 RUC meeting. However, the RUC and specialty societies agreed that the survey data for this family of services was problematic. Specifically, the RUC noted codes 47532, 47533 and 47534 all had identical median intra-service time of 60 minutes. CPT code 47533 includes the work of 47532 plus the work of an additional access and drain placement. Furthermore, 47534 includes the work of 47533 plus the work of crossing the occlusion and placement of an internal/external drain. Given this time anomaly, the RUC agreed to provide interim recommendations at this meeting, while allowing the specialty societies to re-survey the entire family of codes for October 2015.

The specialty societies worked with the research subcommittee to develop a modified survey tool in an attempt to facilitate gathering more accurate rank order survey data from the surveyed physicians. The entire family of codes was included on one single survey. The research subcommittee approved this survey method, which collected:
• overall complexity/intensity data;
• service performance rates for just the surveyed codes; and
• only whether the vignette is typical or not.
We did not ask for them to provide details if the vignette is not typical.

Compelling Evidence
SIR/ACR believe that the current values for CPT codes now used for the percutaneous, image guided biliary interventional procedures newly described in Tab 4 are no longer rational or appropriate for the detailed, granular and far more accurately descriptive codes in this new group. In our opinion, there have been significant changes in technique, knowledge and technology, patient population and physician time.

Technique, Knowledge and Technology
The codes currently used for this family of biliary procedures no longer reflect the techniques now used for image-guided, catheter-based biliary procedures. Indeed, as can be seen, there are 14 new codes in this family which will henceforth be used to describe a diverse range of procedures. As an index example of these significant changes in technique, one of the most widely used of the current codes, 47510, *Introduction of percutaneous transhepatic catheter for biliary drainage*, was previously performed by a method in which the biliary tree was first opacified and often distended by blind needle puncture (not ultrasound), after which an optimal duct was identified and punctured under fluoroscopy using large sheathed needles or even the trocar technique. These techniques have all changed since this code was introduced and valued as noted below.

Virtually all the medical devices currently used in biliary catheter procedures have been developed since the current codes were adopted. The past twenty years have witnessed major advances in our knowledge base including:
1) using imaging guidance, such as ultrasound, and preoperative mapping to avoid hepatic hilar structures and thus prevent bleeding and bile leaks
2) new insights into how segmental biliary ductal anatomy can help avoid bleeding and septic complications
3) development of much less aggressive and safer guidewire-based methods which involve more steps and more effort, skill and physician time such as micropuncture access with gradual stepwise transition to heavy-duty guidewires, tract dilation and placement of catheters over safer, more stable wires and use of real-time ultrasound guidance for needle access. The ductal system is never distended to avoid septic complications.

We would note that the example of 47510 is reflective of the majority of the existing codes for biliary catheter procedures. Simply put, the new codes reflect new thinking and understanding as well as considerable improvements and advances in techniques which render the current values inappropriate for these new codes.

In another example, the existing code 47511, *Introduction of percutaneous transhepatic stent for internal and external biliary drainage*. Current methods utilize a wide range of self-expanding open, as well as covered, metallic stents of various designs designed specifically for biliary pathology and using percutaneous methods as well as plastic and even retrievable metallic stents. These devices were not available when the existing codes were proposed or adopted.

A number of the codes, for example, 47543, *Endoluminal biopsy(ies) of biliary tree, percutaneous, any method(s) (eg, brush, forceps and/or needle),* 47544 *Removal of calculi/debris from biliary duct(s) and/or gallbladder, percutaneous, including destruction of calculi by any method (eg, mechanical, electrohydraulic, lithotripsy),* 47542, *Balloon dilation of biliary duct(s) or of ampulla (sphincteroplasty), percutaneous,* or 47541, *Placement of access through the biliary tree and into small bowel to assist with an endoscopic biliary procedure (eg, rendezvous procedure), percutaneous*, describe procedures which did not exist previously and, thus, are new technology not able to be described at all under the old codes.

Patient Population

SIR/ACR assert that the population of patients treated with the new family of procedures described herein has changed considerably in at least three major ways:

1) Previously the majority of all biliary catheter procedures were used for basic relief of distal ductal biliary obstruction either acutely or chronically often related to pancreatic cancer and/or stone disease. These patients previously drained and stented percutaneously are now largely treated by endoscopic methods. The significant majority of all of the biliary diseases referred for interventional percutaneous treatment now have higher and more complex levels of benign and malignant biliary occlusion, including hilar and segmental obstruction. Treatment of these lesions involves considerably more work, time, effort and risk to achieve satisfactory outcomes.
2) The widespread use of liver transplantation has introduced an entirely different patient population: the postoperative liver transplant patient with ischemic biliary strictures (intrahepatic and/or extrahepatic), which requires major investments of time, skill and effort to obtain access and drain, stent and dilate these complex situations.
3) Hepatic surgery for malignancy has also become far more sophisticated and segmental or lobar resections will frequently result in referrals for drainage of biliary leaks from nondilated ducts. These patients also present challenges in drainage and management.

An example of the change in patient populations can also be seen in the management of biliary stone disease. Previously, patients with distal biliary calculi were referred for external biliary drainage and stone manipulation. These patients are no longer sent for percutaneous treatment. The stone diseases seen currently are intrahepatic lithiasis or extensive stone formation as a result of biliary-enteric anastomoses both of which require far more skill and time to achieve satisfactory initial access but also need much different time-consuming and labor intensive methods to extract or expel the stones.

New Biliary Family

The CPT editorial panel established 14 bundled codes that describe percutaneous biliary procedures including imaging. Below is a table demonstrating the relationship between the new codes:

000 Code Set:

47531: Direct crosswalk to 46611 (work RVU= 1.30)

47532: Recommendation of 25th percentile RVW 4.50 based on survey (N=42) with median intra-service time of 45 and total time of 98 minutes. This recommendation is well supported by the #1 KRS (49407: RVW 4.50 (exactly the same), Intra 45 (exactly the

same), total 110 (slightly higher)). The recommendation is also well bracketed by MPCs 55214 (RVW 3.50, Intra 30, total 79) and 52235 (RVW 5.44, Intra 45 (same as 47532), and total 94 (less than 47532)).

47533: The RUC recommends the survey 25th percentile of 4.50 work RVUs

47534: The RUC recommends the survey 25th percentile of 7.85 work RVUs

47535: Recommendation of 25th percentile RVW 4.20 based on survey (N=42) with median intra-service time of 45 and total time of 93 minutes. The societies feel that the work of 47535 is similar to 47532 and that the survey and our recommendations are therefore also consistent. This recommendation is well bracketed by the #1 and #2 KRS (36247: RVW 6.29, Intra 60, Total 131, and 32550: RVW 4.17, Intra 30, Total 90). The recommendation is also well bracketed by MPCs 52214 (RVW 3.50, Intra 30, Total 79) and 52235 (RVW 5.44, Intra 45, Total 94).

47536: The RUC recommends the survey 25th percentile of 2.86 work RVUs

47537: Recommendation of 25th percentile RVW 1.84 based on survey (N=42) with median intra-service time of 15 and total time of 52 minutes. This work is similar to 47531with the additional work of fluoroscopic drain removal. The societies feel that this extra work is reflective of clinical practice and similarly reflected in the survey median and 25th RVW. This recommendation is well bracketed by the #1 and #2 KRS (49083: RVW 2.00, Intra 25, Total 60, and 49450: RVW 1.36, Intra 10, Total 50).

47538: The RUC recommends the survey 25th percentile of 5.00 work RVUs

47539: Recommendation of 25th percentile RVW 9.00 based on survey (N=41) with median intra-service time of 75 and total time of 136 minutes. This recommendation is well bracketed by MPC 52353 (RVW 7.50, Intra 60, Total 133) and the #1 KRS (37226: RVW 10.49, Intra 90, Total 168).

47540: The RUC recommends the survey 25th percentile of 9.28 work RVUs

47541: Recommendation of 25th percentile RVW 7.00 based on survey (N=42) with median intra-service time of 60 and total time of 121 minutes. The societies feel that the intensity and complexity of this work is in between that of 47533 and 47534 based on magnitude estimation and therefore are recommending a value greater than 47533 but less than 47534. This recommendation is well bracketed by the #1 and #2 KRS (37226: RVW 10.49, Intra 90, Total 168, and 37213: RVW 5.00, Intra 33, Total 99). This recommendation is also supported by MPC 52353 (RVW 7.50, Intra 60, Total 133).

ZZZ Code Set:

47542**:** The RUC recommends the survey 25th percentile of 2.85 work RVUs

47543**:** Recommendation of 25th percentile RVW 3.00 based on survey (N=42) with median intra-service time of 30. This recommendation is well bracketed by MPC 99292 (RVW 2.25, Intra 30) and #1 KRS (37185: RVW 3.28, Intra 40).

47544**:** The RUC recommends a direct crosswalk to 37185 and 92973 (work RVU= 3.28)

PreService Time

We selected pre time package 2B for 47532, 47533, 47534, 47535, 47536, 47541, 47538, 47539, and 47540. For 47531 and 47537, we selected pre time package 2A, because moderate sedation was not inherent in those two procedures. We also added two additional minutes of positioning time to account for positioning patient on angiographic table, as well as optimize lead placement to avoid obscuring imaging.

Relativity

The consensus panel reviewed the survey data for the family this new family of biliary procedures and analyzed the relativity within the family. The consensus panel felt the appropriate recommendations for 47533, 47534, 47538 and 47542 fell between the surveyed 25th percentile and the survey median. As such, we are recommending crosswalk values for those codes.

The consensus panel reviewed the survey data and believe the recommendations compare favorably to (1) the new family of biliary codes, (2) interventional radiology and (3) MPCs. Below is an outline of the comparisons:

	CPT Code	Global Period	Work RVU	Total Time	Pre Time			Intra Time	Post Time	IWPUT
					Eval	Pos	SDW			

reference	49450	000	1.36	50	20	5	5	10	10	0.054
surveyed	47531	000	1.30	54	18	3	6	15	12	0.047
MPC	55876	000	1.73	59	19	10		20	10	0.043
surveyed	47537	000	1.84	52	18	3	6	15	10	0.073
reference	49083	000	2.00	60	15	5	5	25	10	0.052
MPC	31622	000	2.78	65	10	5	5	30	15	0.069
reference	49452	000	2.86	60	20	5	5	20	10	0.102
surveyed	47536	000	2.86	61	20	3	5	20	13	0.111
MPC	52214	000	3.50	79	19	5	5	30	20	0.083
reference	32550	000	4.17	90	15	15	10	30	20	0.099
surveyed	47535	000	4.20	93	25	3	5	45	15	0.071
reference	49407	000	4.50	110	35	5	5	45	20	0.069
surveyed	47532	000	4.50	98	30	3	5	45	15	0.075
reference	37191	000	4.71	83	30	3	5	30	15	0.120
reference	37213	000	5.00	99	33	3	5	33	25	0.109
MPC	52235	000	5.44	94	19	5	5	45	20	0.098
surveyed	47538	000	5.00	106	30	3	5	53	15	0.082
crosswalk	31267	000	5.45	110	30			50	30	0.082
reference	36247	000	6.29	131	33	3	5	60	30	0.080
surveyed	47533	000	5.63	121	33	3	5	60	20	0.083
crosswalk	37197	000	6.29	121	33	3	5	60	20	0.083
surveyed	47541	000	7.00	121	33	3	5	60	20	0.095
MPC	52353	000	7.50	133	33	5	15	60	20	0.101
reference	37211	000	8.00	138	40	3	5	60	30	0.105
surveyed	47534	000	7.85	129	33	3	5	68	20	0.107
crosswalk	43274	000	8.58	139	33	10	5	68	23	0.104
surveyed	47539	000	9.00	136	33	3	5	75	20	0.103
reference	37226	000	10.49	168	40	3	5	90	30	0.098
reference	37228	000	11.00	168	40	3	5	90	30	0.104
surveyed	47540	000	9.28	146	33	3	5	85	20	0.114
reference	37230	000	13.80	198	40	3	5	120	30	0.101
MPC	99292	ZZZ	2.25	30				30		0.075
surveyed	47542	ZZZ	2.85	30				30		0.099
crosswalk	37239	ZZZ	2.97	32	1			30	1	0.098
surveyed	47543	ZZZ	3.00	30				30		0.100
reference	37185	ZZZ	3.28	40				40		0.082
reference	37222	ZZZ	3.73	42	1			40	1	0.092
surveyed	47544	ZZZ	3.28	45				45		0.088
MPC	57267	ZZZ	4.88	45				45		0.108
reference	37235	ZZZ	7.80	82	1			80	1	0.097

Recommendations

The consensus panel reviewed the (1) RUC survey data, (2) the family relationship between the new codes, (2) the relativity to codes within interventional radiology specialty, (3) rank order within the Fee Schedule, (4) compelling evidence, (5) standard packages and (6) RUC guidelines and makes the following physician work recommendations:

CPT	Global	Work	Total	Pre Time			Intra	Post	IWPUT
Code	Period	RVU	Time	Eval	Pos	SDW	Time	Time	
47531	000	1.30	54	18	3	6	15	12	0.047
47532	000	4.50	98	30	3	5	45	15	0.075

47533	000	5.63	121	33	3	5	60	20	0.083
47534	000	7.85	129	33	3	5	68	20	0.107
47535	000	4.20	93	25	3	5	45	15	0.071
47536	000	2.86	61	20	3	5	20	13	0.111
47537	000	1.84	52	18	3	6	15	10	0.073
47538	000	5.00	106	30	3	5	53	15	0.082
47539	000	9.00	136	33	3	5	75	20	0.103
47540	000	9.28	146	33	3	5	85	20	0.114
47541	000	7.00	121	33	3	5	60	20	0.095
47542	ZZZ	2.85	30				30		0.099
47543	ZZZ	3.00	30				30		0.100
47544	ZZZ	3.28	45				45		0.088

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions: No

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☐ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.
   - ☐ Historical precedents.
   - ☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) 47505, 74305, 74363, 47525, 75984 and 47556

How often do physicians <u>in your specialty</u> perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty Interventional Radiology How often? Commonly

Specialty How often?

Specialty How often?

Estimate the number of times this service might be provided nationally in a one-year period?
If the recommendation is from multiple specialties, please provide the frequency and <u>percentage</u> for each specialty. Please explain the rationale for this estimate. A national number is not available.

Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? 0 If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty. Please explain the rationale for this estimate. A national number is not available.

Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%
Specialty	Frequency 0	Percentage 0.00	%

Do many physicians perform this service across the United States? Yes

---

Berenson-Eggers Type of Service (BETOS) Assignment

Please pick the appropriate BETOS classification that best corresponds to the clinical nature of this CPT code. Please select the main BETOS classification and sub-classification to the greatest level of specificity possible.

Main BETOS Classification:
Procedures

BETOS Sub-classification:
Minor procedure

BETOS Sub-classification Level II:
Other

Professional Liability Insurance Information (PLI)

If the surveyed code is an existing code and the specialty believes the specialty utilization mix will not change, enter the surveyed existing CPT code number

If this code is a new/revised code or an existing code in which the specialty utilization mix will change, please select another crosswalk based on a similar specialty mix. 37191

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:47539 Tracking Number U9 Original Specialty Recommended RVU: **9.00**
Presented Recommended RVU: **9.00**
Global Period: 000 RUC Recommended RVU: **9.00**

CPT Descriptor: Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (eg, fluoroscopy and/or ultrasound), balloon dilation, catheter exchange or removal when performed, and all associated radiological supervision and interpretation, each stent; new access, without placement of separate biliary drainage catheter

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A 61-year-old man presents with a new obstructive pancreatic mass, unresectable extra-hepatic metastatic disease, mild jaundice, and hyperbilirubinemia. Percutaneous therapeutic management using an internal biliary stent is performed.

Percentage of Survey Respondents who found Vignette to be Typical: 95%

Site of Service (Complete for 010 and 090 Globals Only)

Percent of survey respondents who stated they perform the procedure; In the hospital 0% , In the ASC 0%, In the office 0%

Percent of survey respondents who stated they typically perform this procedure in the hospital, stated the patient is; Discharged the same day 0% , Overnight stay-less than 24 hours 0% , Overnight stay-more than 24 hours 0%

Percent of survey respondents who stated that if the patient is typically kept overnight also stated that they perform an E&M service later on the same day 0%

Moderate Sedation

Is moderate sedation inherent to this procedure in the Hospital/ASC setting? Yes
Percent of survey respondents who stated moderate sedation is typical in the Hospital/ASC setting? 85%

Is moderate sedation inherent to this procedure in the office setting? Yes
Percent of survey respondents who stated moderate sedation is typical in the office setting? 67%

Description of Pre-Service Work: The patient's medical history, physical exam, and laboratory studies are reviewed and consent is obtained. Relevant preoperative diagnostic imaging studies are retrieved and reviewed. The case is discussed with the referring clinician. A time out is performed. The patient is placed supine on the angiographic table. Moderate conscious sedation is administered. Prophylactic antiobiotics are administered.

Description of Intra-Service Work: Ultrasound and fluoroscopy are used to identify a potential safe tract into a peripheral bile duct in the liver. The abdomen and right flank are prepared and draped in sterile fashion. Under ultrasound and fluoroscopic guidance, a needle is placed into a peripheral bile duct and contrast is injected to ensure biliary placement. Cholangiogram is performed. Multiple radiographs in multiple projections are obtained. A wire is passed through the needle. The tract is dilated with a transitional dilator set and a catheter and wire combination is used to cross the level of obstruction and terminate in the small bowel. A sheath is placed over the wire. A balloon is used to dilate the level of obstruction. A biliary stent is placed through the sheath over the wire, crossing the level of obstruction. A new balloon is then again used to dilate the stent to the appropriate diameter. Cholangiogram is again performed through the sheath to ensure stent patency and appropriate placement. Multiple radiographs in multiple projections are obtained. The wire is removed. The sheath is removed. The tract is embolized.

Description of Post-Service Work: Sterile dressings are applied. The patient is transported to the recovery room for hemodynamic monitoring, sedation recovery, and pain control. The procedure is documented in the permanent record.

Diagnostic cholangiogram results, and patient status are communicated to the patient's family. Permanent surgical procedure and image interpretation reports are created for the medical record and copies of the reports are sent to the patient's referring physician.

SURVEY DATA

RUC Meeting Date (mm/yyyy)	10/2015				
Presenter(s):	Jerry Niedzwiecki, MD, Michael Hall, MD, Bob Vogelzang, MD, Tim Swan, MD, Matt Hawkins, MD, Zeke Silva, MD and Kurt Schoppe, MD				
Specialty(s):	Interventional Radiology				
CPT Code:	47539				
Sample Size:	1730	**Resp N:**	41	**Response:** 2.3 %	
Description of Sample:	Random Sample: SIR 980/ACR 750				

	Low	**25th pctl**	**Median***	**75th pctl**	**High**
Service Performance Rate	0.00	2.00	**5.00**	10.00	25.00
Survey RVW:	3.73	9.00	**10.75**	12.00	15.00
Pre-Service Evaluation Time:			**35.00**		
Pre-Service Positioning Time:			**10.00**		
Pre-Service Scrub, Dress, Wait Time:			**10.00**		
Intra-Service Time:	40.00	65.00	**75.00**	100.00	150.00

Immediate Post Service-Time:	**20.00**	
Post Operative Visits	**Total Min****	**CPT Code and Number of Visits**
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.00** 99239x **0.00** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

**Physician standard total minutes per E/M visit: 99291 (70); 99292 (30); 99231 (20); 99232 (40); 99233 (55); 99238(38); 99239 (55); 99217 (38); 99211 (7); 99212 (16); 99213 (23); 99214 (40); 99215 (55); 99224 (20); 99225 (40); 99226 (55); 99354 (60); 99355 (30); 99356 (60); 99357 (30)

Specialty Society Recommended Data

Please, pick the pre-service time package that best corresponds to the data which was collected in the survey process. (Note: your recommended pre time should not exceed your survey median time for any category)

2b-FAC Diff Pat/Straightfor Proc(w sedation/anes)

CPT Code:	47539	**Recommended Physician Work RVU: 9.00**		
		Specialty Recommended Pre-Service Time	**Specialty Recommended Pre Time Package**	**Adjustments/Recommended Pre-Service Time**
Pre-Service Evaluation Time:		**33.00**	**33.00**	**0.00**
Pre-Service Positioning Time:		**3.00**	**1.00**	**2.00**
Pre-Service Scrub, Dress, Wait Time:		**5.00**	**5.00**	**0.00**
Intra-Service Time:		**75.00**		

Please, pick the post-service time package that best corresponds to the data which was collected in the survey process: (Note: your recommended post time should not exceed your survey median time)

8A IV Sedation/Simple Procedure

	Specialty Recommended Post-Service Time	**Specialty Recommended Post Time Package**	**Adjustments/Recommended Post-Service Time**
Immediate Post Service-Time:	**20.00**	**25.00**	**-5.00**

Post-Operative Visits	Total Min**	CPT Code and Number of Visits
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.0** 99239x **0.0** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

Modifier -51 Exempt Status
Is the recommended value for the new/revised procedure based on its modifier -51 exempt status? No

New Technology/Service:
Is this new/revised procedure considered to be a new technology or service? No

TOP KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
37226	000	10.49	**RUC Time**

CPT Descriptor Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed

SECOND HIGHEST KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
37228	000	11.00	**RUC Time**

CPT Descriptor Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal angioplasty

KEY MPC COMPARISON CODES:
Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU	Time Source	Most Recent Medicare Utilization
52353	000	7.50	**RUC Time**	16,401

CPT Descriptor 1 Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy (ureteral catheterization is included)

MPC CPT Code 2	Global	Work RVU	Time Source	Most Recent Medicare Utilization
		0.00		

CPT Descriptor 2

Other Reference CPT Code	Global	Work RVU	Time Source
		0.00	

CPT Descriptor

RELATIONSHIP OF CODE BEING REVIEWED TO TOP TWO KEY REFERENCE SERVICES:

Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the top two chosen key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Top Key Reference Code: 10 **% of respondents:** 24.3 **%**

Number of respondents who choose 2nd Key Reference Code: 6 **% of respondents:** 14.6 **%**

TIME ESTIMATES (Median)

	CPT Code: 47539	**Top Key Reference CPT Code:** 37226	**2nd Key Reference CPT Code:** **37228**
Median Pre-Service Time	41.00	48.00	48.00
Median Intra-Service Time	75.00	90.00	90.00
Median Immediate Post-service Time	20.00	30.00	30.00
Median Critical Care Time	0.0	0.00	0.00
Median Other Hospital Visit Time	0.0	0.00	0.00
Median Discharge Day Management Time	0.0	0.00	0.00
Median Office Visit Time	0.0	0.00	0.00
Prolonged Services Time	0.0	0.00	0.00
Median Subsequent Observation Care Time	0.0	0.00	0.00
Median Total Time	**136.00**	**168.00**	**168.00**
Other time if appropriate			

INTENSITY/COMPLEXITY MEASURES
(of those that selected Key Reference codes)

Survey respondents are rating the survey code relative to the key reference code.

Intensity & Complexity Rating Scale: (much less= -2.00, somewhat less= -1.00, identical= 0.00, somewhat more= 1.00, much more= 2.00)

	Top Key Ref Code	**2nd Key Ref Code**
Mental Effort and Judgment (Mean)		
The number of possible diagnosis and/or the number of management options that must be considered		
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed		
Urgency of medical decision making		
Technical Skill/Physical Effort (Mean)		
Technical skill required		
Physical effort required		

Psychological Stress (Mean)

The risk of significant complications, morbidity and/or mortality		
Outcome depends on the skill and judgment of physician		
Estimated risk of malpractice suit with poor outcome		

INTENSITY/COMPLEXITY MEASURES	**Top Key Ref Code**	**2nd Key Ref Code**
Time Segment (Mean)		
Overall intensity/complexity	0.60	-0.66

Additional Rationale and Comments

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

The Joint CPT-RUC Workgroup identified (Group 12) codes 47500, 74320-26, 47505, 74305-26, 47510, 75980-26, 47511, 75982-26, 74305-26, 47505, 74320-26, 47500, 75980-26, 47510, 75982-26 as being reported together at least 75% of the time. The specialties updated the percutaneous biliary code family based on the current practice of medicine, and in so doing, deleted 10 percutaneous biliary procedure codes while creating 14 new bundled codes that describe percutaneous biliary procedures including imaging.

This new 'biliary family' was recently surveyed and presented at the April 2015 RUC meeting. However, the RUC and specialty societies agreed that the survey data for this family of services was problematic. Specifically, the RUC noted codes 47532, 47533 and 47534 all had identical median intra-service time of 60 minutes. CPT code 47533 includes the work of 47532 plus the work of an additional access and drain placement. Furthermore, 47534 includes the work of 47533 plus the work of crossing the occlusion and placement of an internal/external drain. Given this time anomaly, the RUC agreed to provide interim recommendations at this meeting, while allowing the specialty societies to re-survey the entire family of codes for October 2015.

The specialty societies worked with the research subcommittee to develop a modified survey tool in an attempt to facilitate gathering more accurate rank order survey data from the surveyed physicians. The entire family of codes was included on one single survey. The research subcommittee approved this survey method, which collected:
• overall complexity/intensity data;
• service performance rates for just the surveyed codes; and
• only whether the vignette is typical or not.
We did not ask for them to provide details if the vignette is not typical.

Compelling Evidence
SIR/ACR believe that the current values for CPT codes now used for the percutaneous, image guided biliary interventional procedures newly described in Tab 4 are no longer rational or appropriate for the detailed, granular and far more accurately descriptive codes in this new group. In our opinion, there have been significant changes in technique, knowledge and technology, patient population and physician time.

Technique, Knowledge and Technology
The codes currently used for this family of biliary procedures no longer reflect the techniques now used for image-guided, catheter-based biliary procedures. Indeed, as can be seen, there are 14 new codes in this family which will henceforth be used to describe a diverse range of procedures. As an index example of these significant changes in technique, one of the most widely used of the current codes, 47510, *Introduction of percutaneous transhepatic catheter for biliary drainage*, was previously performed by a method in which the biliary tree was first opacified and often distended by blind needle puncture (not ultrasound), after which an optimal duct was identified and punctured under fluoroscopy using large sheathed needles or even the trocar technique. These techniques have all changed since this code was introduced and valued as noted below.

Virtually all the medical devices currently used in biliary catheter procedures have been developed since the current codes were adopted. The past twenty years have witnessed major advances in our knowledge base including:
1) using imaging guidance, such as ultrasound, and preoperative mapping to avoid hepatic hilar structures and thus prevent bleeding and bile leaks
2) new insights into how segmental biliary ductal anatomy can help avoid bleeding and septic complications
3) development of much less aggressive and safer guidewire-based methods which involve more steps and more effort, skill and physician time such as micropuncture access with gradual stepwise transition to heavy-duty guidewires, tract dilation and placement of catheters over safer, more stable wires and use of real-time ultrasound guidance for needle access. The ductal system is never distended to avoid septic complications.

We would note that the example of 47510 is reflective of the majority of the existing codes for biliary catheter procedures. Simply put, the new codes reflect new thinking and understanding as well as considerable improvements and advances in techniques which render the current values inappropriate for these new codes.

In another example, the existing code 47511, *Introduction of percutaneous transhepatic stent for internal and external biliary drainage*. Current methods utilize a wide range of self-expanding open, as well as covered, metallic stents of various designs designed specifically for biliary pathology and using percutaneous methods as well as plastic and even retrievable metallic stents. These devices were not available when the existing codes were proposed or adopted.

A number of the codes, for example, 47543, *Endoluminal biopsy(ies) of biliary tree, percutaneous, any method(s) (eg, brush, forceps and/or needle)*, 47544 *Removal of calculi/debris from biliary duct(s) and/or gallbladder, percutaneous, including destruction of calculi by any method (eg, mechanical, electrohydraulic, lithotripsy)*, 47542, *Balloon dilation of biliary duct(s) or of ampulla (sphincteroplasty), percutaneous*, or 47541, *Placement of access through the biliary tree and into small bowel to assist with an endoscopic biliary procedure (eg, rendezvous procedure), percutaneous*, describe procedures which did not exist previously and, thus, are new technology not able to be described at all under the old codes.

Patient Population

SIR/ACR assert that the population of patients treated with the new family of procedures described herein has changed considerably in at least three major ways:

1) Previously the majority of all biliary catheter procedures were used for basic relief of distal ductal biliary obstruction either acutely or chronically often related to pancreatic cancer and/or stone disease. These patients previously drained and stented percutaneously are now largely treated by endoscopic methods. The significant majority of all of the biliary diseases referred for interventional percutaneous treatment now have higher and more complex levels of benign and malignant biliary occlusion, including hilar and segmental obstruction. Treatment of these lesions involves considerably more work, time, effort and risk to achieve satisfactory outcomes.
2) The widespread use of liver transplantation has introduced an entirely different patient population: the postoperative liver transplant patient with ischemic biliary strictures (intrahepatic and/or extrahepatic), which requires major investments of time, skill and effort to obtain access and drain, stent and dilate these complex situations.
3) Hepatic surgery for malignancy has also become far more sophisticated and segmental or lobar resections will frequently result in referrals for drainage of biliary leaks from nondilated ducts. These patients also present challenges in drainage and management.

An example of the change in patient populations can also be seen in the management of biliary stone disease. Previously, patients with distal biliary calculi were referred for external biliary drainage and stone manipulation. These patients are no longer sent for percutaneous treatment. The stone diseases seen currently are intrahepatic lithiasis or extensive stone formation as a result of biliary-enteric anastomoses both of which require far more skill and time to achieve satisfactory initial access but also need much different time-consuming and labor intensive methods to extract or expel the stones.

New Biliary Family

The CPT editorial panel established 14 bundled codes that describe percutaneous biliary procedures including imaging. Below is a table demonstrating the relationship between the new codes:

000 Code Set:

47531: Direct crosswalk to 46611 (work RVU= 1.30)

47532: Recommendation of 25th percentile RVW 4.50 based on survey (N=42) with median intra-service time of 45 and total time of 98 minutes. This recommendation is well supported by the #1 KRS (49407: RVW 4.50 (exactly the same), Intra 45 (exactly the

same), total 110 (slightly higher)). The recommendation is also well bracketed by MPCs 55214 (RVW 3.50, Intra 30, total 79) and 52235 (RVW 5.44, Intra 45 (same as 47532), and total 94 (less than 47532)).

47533: The RUC recommends the survey 25th percentile of 4.50 work RVUs

47534: The RUC recommends the survey 25th percentile of 7.85 work RVUs

47535: Recommendation of 25th percentile RVW 4.20 based on survey (N=42) with median intra-service time of 45 and total time of 93 minutes. The societies feel that the work of 47535 is similar to 47532 and that the survey and our recommendations are therefore also consistent. This recommendation is well bracketed by the #1 and #2 KRS (36247: RVW 6.29, Intra 60, Total 131, and 32550: RVW 4.17, Intra 30, Total 90). The recommendation is also well bracketed by MPCs 52214 (RVW 3.50, Intra 30, Total 79) and 52235 (RVW 5.44, Intra 45, Total 94).

47536: The RUC recommends the survey 25th percentile of 2.86 work RVUs

47537: Recommendation of 25th percentile RVW 1.84 based on survey (N=42) with median intra-service time of 15 and total time of 52 minutes. This work is similar to 47531with the additional work of fluoroscopic drain removal. The societies feel that this extra work is reflective of clinical practice and similarly reflected in the survey median and 25th RVW. This recommendation is well bracketed by the #1 and #2 KRS (49083: RVW 2.00, Intra 25, Total 60, and 49450: RVW 1.36, Intra 10, Total 50).

47538: The RUC recommends the survey 25th percentile of 5.00 work RVUs

47539: Recommendation of 25th percentile RVW 9.00 based on survey (N=41) with median intra-service time of 75 and total time of 136 minutes. This recommendation is well bracketed by MPC 52353 (RVW 7.50, Intra 60, Total 133) and the #1 KRS (37226: RVW 10.49, Intra 90, Total 168).

47540: The RUC recommends the survey 25th percentile of 9.28 work RVUs

47541: Recommendation of 25th percentile RVW 7.00 based on survey (N=42) with median intra-service time of 60 and total time of 121 minutes. The societies feel that the intensity and complexity of this work is in between that of 47533 and 47534 based on magnitude estimation and therefore are recommending a value greater than 47533 but less than 47534. This recommendation is well bracketed by the #1 and #2 KRS (37226: RVW 10.49, Intra 90, Total 168, and 37213: RVW 5.00, Intra 33, Total 99). This recommendation is also supported by MPC 52353 (RVW 7.50, Intra 60, Total 133).

ZZZ Code Set:

47542**:** The RUC recommends the survey 25th percentile of 2.85 work RVUs

47543**:** Recommendation of 25th percentile RVW 3.00 based on survey (N=42) with median intra-service time of 30. This recommendation is well bracketed by MPC 99292 (RVW 2.25, Intra 30) and #1 KRS (37185: RVW 3.28, Intra 40).

47544**:** The RUC recommends a direct crosswalk to 37185 and 92973 (work RVU= 3.28)

PreService Time

We selected pre time package 2B for 47532, 47533, 47534, 47535, 47536, 47541, 47538, 47539, and 47540. For 47531 and 47537, we selected pre time package 2A, because moderate sedation was not inherent in those two procedures. We also added two additional minutes of positioning time to account for positioning patient on angiographic table, as well as optimize lead placement to avoid obscuring imaging.

Relativity

The consensus panel reviewed the survey data for the family this new family of biliary procedures and analyzed the relativity within the family. The consensus panel felt the appropriate recommendations for 47533, 47534, 47538 and 47542 fell between the surveyed 25th percentile and the survey median. As such, we are recommending crosswalk values for those codes.

The consensus panel reviewed the survey data and believe the recommendations compare favorably to (1) the new family of biliary codes, (2) interventional radiology and (3) MPCs. Below is an outline of the comparisons:

	CPT Code	Global Period	Work RVU	Total Time	Pre Time			Intra Time	Post Time	IWPUT
					Eval	Pos	SDW			

reference	49450	000	1.36	50	20	5	5	10	10	0.054
surveyed	47531	000	1.30	54	18	3	6	15	12	0.047
MPC	55876	000	1.73	59	19	10		20	10	0.043
surveyed	47537	000	1.84	52	18	3	6	15	10	0.073
reference	49083	000	2.00	60	15	5	5	25	10	0.052
MPC	31622	000	2.78	65	10	5	5	30	15	0.069
reference	49452	000	2.86	60	20	5	5	20	10	0.102
surveyed	47536	000	2.86	61	20	3	5	20	13	0.111
MPC	52214	000	3.50	79	19	5	5	30	20	0.083
reference	32550	000	4.17	90	15	15	10	30	20	0.099
surveyed	47535	000	4.20	93	25	3	5	45	15	0.071
reference	49407	000	4.50	110	35	5	5	45	20	0.069
surveyed	47532	000	4.50	98	30	3	5	45	15	0.075
reference	37191	000	4.71	83	30	3	5	30	15	0.120
reference	37213	000	5.00	99	33	3	5	33	25	0.109
MPC	52235	000	5.44	94	19	5	5	45	20	0.098
surveyed	47538	000	5.00	106	30	3	5	53	15	0.082
crosswalk	31267	000	5.45	110	30			50	30	0.082
reference	36247	000	6.29	131	33	3	5	60	30	0.080
surveyed	47533	000	5.63	121	33	3	5	60	20	0.083
crosswalk	37197	000	6.29	121	33	3	5	60	20	0.083
surveyed	47541	000	7.00	121	33	3	5	60	20	0.095
MPC	52353	000	7.50	133	33	5	15	60	20	0.101
reference	37211	000	8.00	138	40	3	5	60	30	0.105
surveyed	47534	000	7.85	129	33	3	5	68	20	0.107
crosswalk	43274	000	8.58	139	33	10	5	68	23	0.104
surveyed	47539	000	9.00	136	33	3	5	75	20	0.103
reference	37226	000	10.49	168	40	3	5	90	30	0.098
reference	37228	000	11.00	168	40	3	5	90	30	0.104
surveyed	47540	000	9.28	146	33	3	5	85	20	0.114
reference	37230	000	13.80	198	40	3	5	120	30	0.101
MPC	99292	ZZZ	2.25	30				30		0.075
surveyed	47542	ZZZ	2.85	30				30		0.099
crosswalk	37239	ZZZ	2.97	32	1			30	1	0.098
surveyed	47543	ZZZ	3.00	30				30		0.100
reference	37185	ZZZ	3.28	40				40		0.082
reference	37222	ZZZ	3.73	42	1			40	1	0.092
surveyed	47544	ZZZ	3.28	45				45		0.088
MPC	57267	ZZZ	4.88	45				45		0.108
reference	37235	ZZZ	7.80	82	1			80	1	0.097

Recommendations

The consensus panel reviewed the (1) RUC survey data, (2) the family relationship between the new codes, (2) the relativity to codes within interventional radiology specialty, (3) rank order within the Fee Schedule, (4) compelling evidence, (5) standard packages and (6) RUC guidelines and makes the following physician work recommendations:

CPT	Global	Work	Total	Pre Time			Intra	Post	IWPUT
Code	Period	RVU	Time	Eval	Pos	SDW	Time	Time	
47531	000	1.30	54	18	3	6	15	12	0.047
47532	000	4.50	98	30	3	5	45	15	0.075

47533	000	5.63	121	33	3	5	60	20	0.083
47534	000	7.85	129	33	3	5	68	20	0.107
47535	000	4.20	93	25	3	5	45	15	0.071
47536	000	2.86	61	20	3	5	20	13	0.111
47537	000	1.84	52	18	3	6	15	10	0.073
47538	000	5.00	106	30	3	5	53	15	0.082
47539	000	9.00	136	33	3	5	75	20	0.103
47540	000	9.28	146	33	3	5	85	20	0.114
47541	000	7.00	121	33	3	5	60	20	0.095
47542	ZZZ	2.85	30				30		0.099
47543	ZZZ	3.00	30				30		0.100
47544	ZZZ	3.28	45				45		0.088

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions: No

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☐ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.
   - ☐ Historical precedents.
   - ☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) 76942, 47500, 74320, 74363 and 47556

How often do physicians <u>in your specialty</u> perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty Interventional Radiology How often? Commonly

Specialty How often?

Specialty How often?

Estimate the number of times this service might be provided nationally in a one-year period?
If the recommendation is from multiple specialties, please provide the frequency and <u>percentage</u> for each specialty. Please explain the rationale for this estimate. A national number is not available.

Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? 0 If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty. Please explain the rationale for this estimate. A national number is not available.

Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%
Specialty	Frequency 0	Percentage 0.00	%

Do many physicians perform this service across the United States? Yes

---

Berenson-Eggers Type of Service (BETOS) Assignment

Please pick the appropriate BETOS classification that best corresponds to the clinical nature of this CPT code. Please select the main BETOS classification and sub-classification to the greatest level of specificity possible.

Main BETOS Classification:
Procedures

BETOS Sub-classification:
Minor procedure

BETOS Sub-classification Level II:
Other

Professional Liability Insurance Information (PLI)

If the surveyed code is an existing code and the specialty believes the specialty utilization mix will not change, enter the surveyed existing CPT code number

If this code is a new/revised code or an existing code in which the specialty utilization mix will change, please select another crosswalk based on a similar specialty mix. 37226

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:47540 Tracking Number U10 Original Specialty Recommended RVU: **11.00**
Presented Recommended RVU: **11.00**
Global Period: 000 RUC Recommended RVU: **9.28**

CPT Descriptor: Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (eg, fluoroscopy and/or ultrasound), balloon dilation, catheter exchange or removal when performed, and all associated radiological supervision and interpretation, each stent; new access, with placement of separate biliary drainage catheter (eg, external or internal-external)

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A 61-year-old man presents with a new obstructive pancreatic mass, unresectable extra-hepatic metastatic disease, severe jaundice, and hyperbilirubinemia. Percutaneous therapeutic management using a biliary stent and a biliary drainage catheter is performed.

Percentage of Survey Respondents who found Vignette to be Typical: 100%

Site of Service (Complete for 010 and 090 Globals Only)

Percent of survey respondents who stated they perform the procedure; In the hospital 0% , In the ASC 0%, In the office 0%

Percent of survey respondents who stated they typically perform this procedure in the hospital, stated the patient is; Discharged the same day 0% , Overnight stay-less than 24 hours 0% , Overnight stay-more than 24 hours 0%

Percent of survey respondents who stated that if the patient is typically kept overnight also stated that they perform an E&M service later on the same day 0%

Moderate Sedation

Is moderate sedation inherent to this procedure in the Hospital/ASC setting? Yes
Percent of survey respondents who stated moderate sedation is typical in the Hospital/ASC setting? 85%

Is moderate sedation inherent to this procedure in the office setting? Yes
Percent of survey respondents who stated moderate sedation is typical in the office setting? 69%

Description of Pre-Service Work: The patient's medical history, physical exam, and laboratory studies are reviewed and consent is obtained. Relevant preoperative diagnostic imaging studies are retrieved and reviewed. The case is discussed with the referring clinician. A time out is performed. The patient is placed supine on the angiographic table. Moderate conscious sedation is administered. Prophylactic antiobiotics are administered.

Description of Intra-Service Work: Ultrasound and fluoroscopy are used to identify a potential safe tract into a peripheral bile duct in the liver. The abdomen and right flank are prepared and draped in sterile fashion. Under ultrasound and fluoroscopic guidance, a needle is placed into a peripheral bile duct and contrast is injected to ensure biliary placement. Cholangiogram is performed. Multiple radiographs in multiple projections are obtained. A wire is passed through the needle. The tract is dilated with a transitional dilator set and a catheter and wire combination is used to cross the level of obstruction and terminate in the small bowel. A sheath is placed over the wire. A balloon is placed over the wire to dilate the level of obstruction. A biliary stent is placed through the sheath over the wire, crossing the level of obstruction. A new balloon is then used to dilate the stent to the appropriate diameter. Cholangiogram is again performed through the sheath to ensure stent patency. Multiple radiographs in multiple projections are obtained. The sheath is exchanged over the wire for an external biliary drainage catheter. The catheter is capped and anchored at the skin surface with a retention suture.

Description of Post-Service Work: Sterile dressings are applied. The patient is transported to the recovery room for hemodynamic monitoring, sedation recovery, and pain control. The procedure is documented in the permanent record.

Diagnostic cholangiogram results, and patient status are communicated to the patient's family. Permanent surgical procedure and image interpretation reports are created for the medical record and copies of the reports are sent to the patient's referring physician.

SURVEY DATA

RUC Meeting Date (mm/yyyy)	10/2015				
Presenter(s):	Jerry Niedzwiecki, MD, Michael Hall, MD, Bob Vogelzang, MD, Tim Swan, MD, Matt Hawkins, MD, Zeke Silva, MD and Kurt Schoppe, MD				
Specialty(s):	Interventional Radiology				
CPT Code:	47540				
Sample Size:	1730	**Resp N:**	42	**Response:** 2.4 %	
Description of Sample:	Random Sample: SIR 980/ACR 750				

	Low	**25th pctl**	**Median***	**75th pctl**	**High**
Service Performance Rate	0.00	2.00	**5.00**	10.00	40.00
Survey RVW:	4.25	9.28	**11.00**	13.80	16.00
Pre-Service Evaluation Time:			**33.00**		
Pre-Service Positioning Time:			**10.00**		
Pre-Service Scrub, Dress, Wait Time:			**10.00**		
Intra-Service Time:	40.00	70.00	**85.00**	120.00	180.00

Immediate Post Service-Time:	**20.00**	
Post Operative Visits	**Total Min****	**CPT Code and Number of Visits**
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.00** 99239x **0.00** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

**Physician standard total minutes per E/M visit: 99291 (70); 99292 (30); 99231 (20); 99232 (40); 99233 (55); 99238(38); 99239 (55); 99217 (38); 99211 (7); 99212 (16); 99213 (23); 99214 (40); 99215 (55); 99224 (20); 99225 (40); 99226 (55); 99354 (60); 99355 (30); 99356 (60); 99357 (30)

Specialty Society Recommended Data

Please, pick the pre-service time package that best corresponds to the data which was collected in the survey process. (Note: your recommended pre time should not exceed your survey median time for any category)

2b-FAC Diff Pat/Straightfor Proc(w sedation/anes)

CPT Code:	47540	**Recommended Physician Work RVU: 9.28**		
		Specialty Recommended Pre-Service Time	**Specialty Recommended Pre Time Package**	**Adjustments/Recommended Pre-Service Time**
Pre-Service Evaluation Time:		**33.00**	**33.00**	**0.00**
Pre-Service Positioning Time:		**3.00**	**1.00**	**2.00**
Pre-Service Scrub, Dress, Wait Time:		**5.00**	**5.00**	**0.00**
Intra-Service Time:		**85.00**		

Please, pick the post-service time package that best corresponds to the data which was collected in the survey process: (Note: your recommended post time should not exceed your survey median time)

8A IV Sedation/Simple Procedure

	Specialty Recommended Post-Service Time	**Specialty Recommended Post Time Package**	**Adjustments/Recommended Post-Service Time**
Immediate Post Service-Time:	**20.00**	**25.00**	**-5.00**

Post-Operative Visits	Total Min**	CPT Code and Number of Visits
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.0** 99239x **0.0** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

Modifier -51 Exempt Status

Is the recommended value for the new/revised procedure based on its modifier -51 exempt status? No

New Technology/Service:

Is this new/revised procedure considered to be a new technology or service? No

TOP KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
37230	000	13.80	**RUC Time**

CPT Descriptor Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed

SECOND HIGHEST KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
37228	000	11.00	**RUC Time**

CPT Descriptor Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal angioplasty

KEY MPC COMPARISON CODES:

Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU	Time Source	Most Recent Medicare Utilization
52353	000	7.50	**RUC Time**	16,401

CPT Descriptor 1 Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy (ureteral catheterization is included)

MPC CPT Code 2	Global	Work RVU	Time Source	Most Recent Medicare Utilization
		0.00		

CPT Descriptor 2

Other Reference CPT Code	Global	Work RVU	Time Source
		0.00	

CPT Descriptor

RELATIONSHIP OF CODE BEING REVIEWED TO TOP TWO KEY REFERENCE SERVICES:

Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the top two chosen key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Top Key Reference Code: 8 **% of respondents:** 19.0 **%**

Number of respondents who choose 2nd Key Reference Code: 7 **% of respondents:** 16.6 **%**

TIME ESTIMATES (Median)

	CPT Code: 47540	**Top Key Reference CPT Code:** 37230	**2nd Key Reference CPT Code:** **37228**
Median Pre-Service Time	41.00	48.00	48.00
Median Intra-Service Time	85.00	120.00	90.00
Median Immediate Post-service Time	20.00	30.00	30.00
Median Critical Care Time	0.0	0.00	0.00
Median Other Hospital Visit Time	0.0	0.00	0.00
Median Discharge Day Management Time	0.0	0.00	0.00
Median Office Visit Time	0.0	0.00	0.00
Prolonged Services Time	0.0	0.00	0.00
Median Subsequent Observation Care Time	0.0	0.00	0.00
Median Total Time	**146.00**	**198.00**	**168.00**
Other time if appropriate			

INTENSITY/COMPLEXITY MEASURES
(of those that selected Key Reference codes)

Survey respondents are rating the survey code relative to the key reference code.

Intensity & Complexity Rating Scale: (much less= -2.00, somewhat less= -1.00, identical= 0.00, somewhat more= 1.00, much more= 2.00)

	Top Key Ref Code	**2nd Key Ref Code**
Mental Effort and Judgment (Mean)		
The number of possible diagnosis and/or the number of management options that must be considered		
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed		
Urgency of medical decision making		
Technical Skill/Physical Effort (Mean)		
Technical skill required		
Physical effort required		

Psychological Stress (Mean)

The risk of significant complications, morbidity and/or mortality		
Outcome depends on the skill and judgment of physician		
Estimated risk of malpractice suit with poor outcome		

INTENSITY/COMPLEXITY MEASURES	**Top Key Ref Code**	**2nd Key Ref Code**
Time Segment (Mean)		
Overall intensity/complexity	0.25	0.14

Additional Rationale and Comments

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

The Joint CPT-RUC Workgroup identified (Group 12) codes 47500, 74320-26, 47505, 74305-26, 47510, 75980-26, 47511, 75982-26, 74305-26, 47505, 74320-26, 47500, 75980-26, 47510, 75982-26 as being reported together at least 75% of the time. The specialties updated the percutaneous biliary code family based on the current practice of medicine, and in so doing, deleted 10 percutaneous biliary procedure codes while creating 14 new bundled codes that describe percutaneous biliary procedures including imaging.

This new 'biliary family' was recently surveyed and presented at the April 2015 RUC meeting. However, the RUC and specialty societies agreed that the survey data for this family of services was problematic. Specifically, the RUC noted codes 47532, 47533 and 47534 all had identical median intra-service time of 60 minutes. CPT code 47533 includes the work of 47532 plus the work of an additional access and drain placement. Furthermore, 47534 includes the work of 47533 plus the work of crossing the occlusion and placement of an internal/external drain. Given this time anomaly, the RUC agreed to provide interim recommendations at this meeting, while allowing the specialty societies to re-survey the entire family of codes for October 2015.

The specialty societies worked with the research subcommittee to develop a modified survey tool in an attempt to facilitate gathering more accurate rank order survey data from the surveyed physicians. The entire family of codes was included on one single survey. The research subcommittee approved this survey method, which collected:
• overall complexity/intensity data;
• service performance rates for just the surveyed codes; and
• only whether the vignette is typical or not.
We did not ask for them to provide details if the vignette is not typical.

Compelling Evidence
SIR/ACR believe that the current values for CPT codes now used for the percutaneous, image guided biliary interventional procedures newly described in Tab 4 are no longer rational or appropriate for the detailed, granular and far more accurately descriptive codes in this new group. In our opinion, there have been significant changes in technique, knowledge and technology, patient population and physician time.

Technique, Knowledge and Technology
The codes currently used for this family of biliary procedures no longer reflect the techniques now used for image-guided, catheter-based biliary procedures. Indeed, as can be seen, there are 14 new codes in this family which will henceforth be used to describe a diverse range of procedures. As an index example of these significant changes in technique, one of the most widely used of the current codes, 47510, *Introduction of percutaneous transhepatic catheter for biliary drainage*, was previously performed by a method in which the biliary tree was first opacified and often distended by blind needle puncture (not ultrasound), after which an optimal duct was identified and punctured under fluoroscopy using large sheathed needles or even the trocar technique. These techniques have all changed since this code was introduced and valued as noted below.

Virtually all the medical devices currently used in biliary catheter procedures have been developed since the current codes were adopted. The past twenty years have witnessed major advances in our knowledge base including:
1) using imaging guidance, such as ultrasound, and preoperative mapping to avoid hepatic hilar structures and thus prevent bleeding and bile leaks
2) new insights into how segmental biliary ductal anatomy can help avoid bleeding and septic complications
3) development of much less aggressive and safer guidewire-based methods which involve more steps and more effort, skill and physician time such as micropuncture access with gradual stepwise transition to heavy-duty guidewires, tract dilation and placement of catheters over safer, more stable wires and use of real-time ultrasound guidance for needle access. The ductal system is never distended to avoid septic complications.

We would note that the example of 47510 is reflective of the majority of the existing codes for biliary catheter procedures. Simply put, the new codes reflect new thinking and understanding as well as considerable improvements and advances in techniques which render the current values inappropriate for these new codes.

In another example, the existing code 47511, *Introduction of percutaneous transhepatic stent for internal and external biliary drainage*. Current methods utilize a wide range of self-expanding open, as well as covered, metallic stents of various designs designed specifically for biliary pathology and using percutaneous methods as well as plastic and even retrievable metallic stents. These devices were not available when the existing codes were proposed or adopted.

A number of the codes, for example, 47543, *Endoluminal biopsy(ies) of biliary tree, percutaneous, any method(s) (eg, brush, forceps and/or needle)*, 47544 *Removal of calculi/debris from biliary duct(s) and/or gallbladder, percutaneous, including destruction of calculi by any method (eg, mechanical, electrohydraulic, lithotripsy)*, 47542, *Balloon dilation of biliary duct(s) or of ampulla (sphincteroplasty), percutaneous*, or 47541, *Placement of access through the biliary tree and into small bowel to assist with an endoscopic biliary procedure (eg, rendezvous procedure), percutaneous*, describe procedures which did not exist previously and, thus, are new technology not able to be described at all under the old codes.

Patient Population

SIR/ACR assert that the population of patients treated with the new family of procedures described herein has changed considerably in at least three major ways:

1) Previously the majority of all biliary catheter procedures were used for basic relief of distal ductal biliary obstruction either acutely or chronically often related to pancreatic cancer and/or stone disease. These patients previously drained and stented percutaneously are now largely treated by endoscopic methods. The significant majority of all of the biliary diseases referred for interventional percutaneous treatment now have higher and more complex levels of benign and malignant biliary occlusion, including hilar and segmental obstruction. Treatment of these lesions involves considerably more work, time, effort and risk to achieve satisfactory outcomes.
2) The widespread use of liver transplantation has introduced an entirely different patient population: the postoperative liver transplant patient with ischemic biliary strictures (intrahepatic and/or extrahepatic), which requires major investments of time, skill and effort to obtain access and drain, stent and dilate these complex situations.
3) Hepatic surgery for malignancy has also become far more sophisticated and segmental or lobar resections will frequently result in referrals for drainage of biliary leaks from nondilated ducts. These patients also present challenges in drainage and management.

An example of the change in patient populations can also be seen in the management of biliary stone disease. Previously, patients with distal biliary calculi were referred for external biliary drainage and stone manipulation. These patients are no longer sent for percutaneous treatment. The stone diseases seen currently are intrahepatic lithiasis or extensive stone formation as a result of biliary-enteric anastomoses both of which require far more skill and time to achieve satisfactory initial access but also need much different time-consuming and labor intensive methods to extract or expel the stones.

New Biliary Family

The CPT editorial panel established 14 bundled codes that describe percutaneous biliary procedures including imaging. Below is a table demonstrating the relationship between the new codes:

000 Code Set:

47531: Direct crosswalk to 46611 (work RVU= 1.30)

47532: Recommendation of 25th percentile RVW 4.50 based on survey (N=42) with median intra-service time of 45 and total time of 98 minutes. This recommendation is well supported by the #1 KRS (49407: RVW 4.50 (exactly the same), Intra 45 (exactly the

same), total 110 (slightly higher)). The recommendation is also well bracketed by MPCs 55214 (RVW 3.50, Intra 30, total 79) and 52235 (RVW 5.44, Intra 45 (same as 47532), and total 94 (less than 47532)).

47533: The RUC recommends the survey 25th percentile of 4.50 work RVUs

47534: The RUC recommends the survey 25th percentile of 7.85 work RVUs

47535: Recommendation of 25th percentile RVW 4.20 based on survey (N=42) with median intra-service time of 45 and total time of 93 minutes. The societies feel that the work of 47535 is similar to 47532 and that the survey and our recommendations are therefore also consistent. This recommendation is well bracketed by the #1 and #2 KRS (36247: RVW 6.29, Intra 60, Total 131, and 32550: RVW 4.17, Intra 30, Total 90). The recommendation is also well bracketed by MPCs 52214 (RVW 3.50, Intra 30, Total 79) and 52235 (RVW 5.44, Intra 45, Total 94).

47536: The RUC recommends the survey 25th percentile of 2.86 work RVUs

47537: Recommendation of 25th percentile RVW 1.84 based on survey (N=42) with median intra-service time of 15 and total time of 52 minutes. This work is similar to 47531with the additional work of fluoroscopic drain removal. The societies feel that this extra work is reflective of clinical practice and similarly reflected in the survey median and 25th RVW. This recommendation is well bracketed by the #1 and #2 KRS (49083: RVW 2.00, Intra 25, Total 60, and 49450: RVW 1.36, Intra 10, Total 50).

47538: The RUC recommends the survey 25th percentile of 5.00 work RVUs

47539: Recommendation of 25th percentile RVW 9.00 based on survey (N=41) with median intra-service time of 75 and total time of 136 minutes. This recommendation is well bracketed by MPC 52353 (RVW 7.50, Intra 60, Total 133) and the #1 KRS (37226: RVW 10.49, Intra 90, Total 168).

47540: The RUC recommends the survey 25th percentile of 9.28 work RVUs

47541: Recommendation of 25th percentile RVW 7.00 based on survey (N=42) with median intra-service time of 60 and total time of 121 minutes. The societies feel that the intensity and complexity of this work is in between that of 47533 and 47534 based on magnitude estimation and therefore are recommending a value greater than 47533 but less than 47534. This recommendation is well bracketed by the #1 and #2 KRS (37226: RVW 10.49, Intra 90, Total 168, and 37213: RVW 5.00, Intra 33, Total 99). This recommendation is also supported by MPC 52353 (RVW 7.50, Intra 60, Total 133).

ZZZ Code Set:

47542**:** The RUC recommends the survey 25th percentile of 2.85 work RVUs

47543**:** Recommendation of 25th percentile RVW 3.00 based on survey (N=42) with median intra-service time of 30. This recommendation is well bracketed by MPC 99292 (RVW 2.25, Intra 30) and #1 KRS (37185: RVW 3.28, Intra 40).

47544**:** The RUC recommends a direct crosswalk to 37185 and 92973 (work RVU= 3.28)

PreService Time

We selected pre time package 2B for 47532, 47533, 47534, 47535, 47536, 47541, 47538, 47539, and 47540. For 47531 and 47537, we selected pre time package 2A, because moderate sedation was not inherent in those two procedures. We also added two additional minutes of positioning time to account for positioning patient on angiographic table, as well as optimize lead placement to avoid obscuring imaging.

Relativity

The consensus panel reviewed the survey data for the family this new family of biliary procedures and analyzed the relativity within the family. The consensus panel felt the appropriate recommendations for 47533, 47534, 47538 and 47542 fell between the surveyed 25th percentile and the survey median. As such, we are recommending crosswalk values for those codes.

The consensus panel reviewed the survey data and believe the recommendations compare favorably to (1) the new family of biliary codes, (2) interventional radiology and (3) MPCs. Below is an outline of the comparisons:

	CPT Code	Global Period	Work RVU	Total Time	Pre Time			Intra Time	Post Time	IWPUT
					Eval	Pos	SDW			

reference	49450	000	1.36	50	20	5	5	10	10	0.054
surveyed	47531	000	1.30	54	18	3	6	15	12	0.047
MPC	55876	000	1.73	59	19	10		20	10	0.043
surveyed	47537	000	1.84	52	18	3	6	15	10	0.073
reference	49083	000	2.00	60	15	5	5	25	10	0.052
MPC	31622	000	2.78	65	10	5	5	30	15	0.069
reference	49452	000	2.86	60	20	5	5	20	10	0.102
surveyed	47536	000	2.86	61	20	3	5	20	13	0.111
MPC	52214	000	3.50	79	19	5	5	30	20	0.083
reference	32550	000	4.17	90	15	15	10	30	20	0.099
surveyed	47535	000	4.20	93	25	3	5	45	15	0.071
reference	49407	000	4.50	110	35	5	5	45	20	0.069
surveyed	47532	000	4.50	98	30	3	5	45	15	0.075
reference	37191	000	4.71	83	30	3	5	30	15	0.120
reference	37213	000	5.00	99	33	3	5	33	25	0.109
MPC	52235	000	5.44	94	19	5	5	45	20	0.098
surveyed	47538	000	5.00	106	30	3	5	53	15	0.082
crosswalk	31267	000	5.45	110	30			50	30	0.082
reference	36247	000	6.29	131	33	3	5	60	30	0.080
surveyed	47533	000	5.63	121	33	3	5	60	20	0.083
crosswalk	37197	000	6.29	121	33	3	5	60	20	0.083
surveyed	47541	000	7.00	121	33	3	5	60	20	0.095
MPC	52353	000	7.50	133	33	5	15	60	20	0.101
reference	37211	000	8.00	138	40	3	5	60	30	0.105
surveyed	47534	000	7.85	129	33	3	5	68	20	0.107
crosswalk	43274	000	8.58	139	33	10	5	68	23	0.104
surveyed	47539	000	9.00	136	33	3	5	75	20	0.103
reference	37226	000	10.49	168	40	3	5	90	30	0.098
reference	37228	000	11.00	168	40	3	5	90	30	0.104
surveyed	47540	000	9.28	146	33	3	5	85	20	0.114
reference	37230	000	13.80	198	40	3	5	120	30	0.101
MPC	99292	ZZZ	2.25	30				30		0.075
surveyed	47542	ZZZ	2.85	30				30		0.099
crosswalk	37239	ZZZ	2.97	32	1			30	1	0.098
surveyed	47543	ZZZ	3.00	30				30		0.100
reference	37185	ZZZ	3.28	40				40		0.082
reference	37222	ZZZ	3.73	42	1			40	1	0.092
surveyed	47544	ZZZ	3.28	45				45		0.088
MPC	57267	ZZZ	4.88	45				45		0.108
reference	37235	ZZZ	7.80	82	1			80	1	0.097

Recommendations

The consensus panel reviewed the (1) RUC survey data, (2) the family relationship between the new codes, (2) the relativity to codes within interventional radiology specialty, (3) rank order within the Fee Schedule, (4) compelling evidence, (5) standard packages and (6) RUC guidelines and makes the following physician work recommendations:

CPT	Global	Work	Total	Pre Time			Intra	Post	IWPUT
Code	Period	RVU	Time	Eval	Pos	SDW	Time	Time	
47531	000	1.30	54	18	3	6	15	12	0.047
47532	000	4.50	98	30	3	5	45	15	0.075

47533	000	5.63	121	33	3	5	60	20	0.083
47534	000	7.85	129	33	3	5	68	20	0.107
47535	000	4.20	93	25	3	5	45	15	0.071
47536	000	2.86	61	20	3	5	20	13	0.111
47537	000	1.84	52	18	3	6	15	10	0.073
47538	000	5.00	106	30	3	5	53	15	0.082
47539	000	9.00	136	33	3	5	75	20	0.103
47540	000	9.28	146	33	3	5	85	20	0.114
47541	000	7.00	121	33	3	5	60	20	0.095
47542	ZZZ	2.85	30				30		0.099
47543	ZZZ	3.00	30				30		0.100
47544	ZZZ	3.28	45				45		0.088

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions: No

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☐ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.
   - ☐ Historical precedents.
   - ☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) 76942, 47500, 74320, 47510, 75980, 74363 and 47556

How often do physicians in your specialty perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty Interventional Radiology How often? Commonly

Specialty How often?

Specialty How often?

Estimate the number of times this service might be provided nationally in a one-year period?
If the recommendation is from multiple specialties, please provide the frequency and percentage for each specialty. Please explain the rationale for this estimate. A national number is not available.

Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? 0 If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty. Please explain the rationale for this estimate. A national number is not available.

Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%
Specialty	Frequency 0	Percentage 0.00	%

Do many physicians perform this service across the United States? Yes

---

Berenson-Eggers Type of Service (BETOS) Assignment

Please pick the appropriate BETOS classification that best corresponds to the clinical nature of this CPT code. Please select the main BETOS classification and sub-classification to the greatest level of specificity possible.

Main BETOS Classification:
Procedures

BETOS Sub-classification:
Minor procedure

BETOS Sub-classification Level II:
Other

Professional Liability Insurance Information (PLI)

If the surveyed code is an existing code and the specialty believes the specialty utilization mix will not change, enter the surveyed existing CPT code number

If this code is a new/revised code or an existing code in which the specialty utilization mix will change, please select another crosswalk based on a similar specialty mix. 37226

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:47541 Tracking Number U11 Original Specialty Recommended RVU: **7.00**
Presented Recommended RVU: **7.00**
Global Period: 000 RUC Recommended RVU: **7.00**

CPT Descriptor: Placement of access through the biliary tree and into small bowel to assist with an endoscopic biliary procedure (eg, rendezvous procedure), percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; new access

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A 61-year-old man presents with a new obstructive pancreatic mass. ERCP was unsuccessful, and the gastroenterology service has asked for percutaneous wire placement through the bile ducts into the small bowel, so that access can be used for access into the biliary system for subsequent endoscopically guided interventions.

Percentage of Survey Respondents who found Vignette to be Typical: 90%

Site of Service (Complete for 010 and 090 Globals Only)

Percent of survey respondents who stated they perform the procedure; In the hospital 0% , In the ASC 0%, In the office 0%

Percent of survey respondents who stated they typically perform this procedure in the hospital, stated the patient is; Discharged the same day 0% , Overnight stay-less than 24 hours 0% , Overnight stay-more than 24 hours 0%

Percent of survey respondents who stated that if the patient is typically kept overnight also stated that they perform an E&M service later on the same day 0%

Moderate Sedation

Is moderate sedation inherent to this procedure in the Hospital/ASC setting? Yes
Percent of survey respondents who stated moderate sedation is typical in the Hospital/ASC setting? 82%

Is moderate sedation inherent to this procedure in the office setting? Yes
Percent of survey respondents who stated moderate sedation is typical in the office setting? 75%

Description of Pre-Service Work: The patient's medical history, physical exam, and laboratory studies are reviewed and consent is obtained. Relevant preoperative diagnostic imaging studies are retrieved and reviewed. The case is discussed with the referring clinician. A time out is performed. The patient is placed supine on the angiographic table. Moderate conscious sedation is administered. Prophylactic antiobiotics are administered.

Description of Intra-Service Work: Ultrasound and fluoroscopy are used to identify a potential safe tract into a peripheral bile duct in the liver. The abdomen and right flank are prepared and draped in sterile fashion. Under ultrasound and fluoroscopic guidance, a needle is placed into a peripheral bile duct and contrast is injected to ensure biliary placement. Cholangiogram is performed. Multiple radiographs in multiple projections are obtained. A wire is passed through the needle. The tract is dilated with a transitional dilator set. A catheter and 0.035 wire is then used to cross the level of obstruction and successfully place a wire that extends into the small bowel from the percutaneous access site.

Description of Post-Service Work: A sterile dressing is placed over the wire to maintain biliary access for the patients subsequent endoscopic procedure. The patient is transported to the recovery room for hemodynamic monitoring, sedation recovery, and pain control. The procedure is documented in the permanent record. Diagnostic cholangiogram results, and patient status are communicated to the patient's family. Permanent surgical procedure and image interpretation reports are created for the medical record and copies of the reports are sent to the patient's referring physician.

SURVEY DATA

RUC Meeting Date (mm/yyyy)	10/2015				
Presenter(s):	Jerry Niedzwiecki, MD, Michael Hall, MD, Bob Vogelzang, MD, Tim Swan, MD, Matt Hawkins, MD, Zeke Silva, MD and Kurt Schoppe, MD				
Specialty(s):	Interventional Radiology				
CPT Code:	47541				
Sample Size:	1730	**Resp N:**	42	**Response:** 2.4 %	
Description of Sample:	Random Sample: SIR 980/ACR 750				

	Low	**25th pctl**	**Median***	**75th pctl**	**High**
Service Performance Rate	0.00	1.00	**3.00**	5.00	40.00
Survey RVW:	4.25	7.00	**8.60**	10.50	18.00
Pre-Service Evaluation Time:			**35.00**		
Pre-Service Positioning Time:			**10.00**		
Pre-Service Scrub, Dress, Wait Time:			**10.00**		
Intra-Service Time:	25.00	45.00	**60.00**	80.00	195.00

Immediate Post Service-Time:	**20.00**	
Post Operative Visits	**Total Min****	**CPT Code and Number of Visits**
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.00** 99239x **0.00** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

**Physician standard total minutes per E/M visit: 99291 (70); 99292 (30); 99231 (20); 99232 (40); 99233 (55); 99238(38); 99239 (55); 99217 (38); 99211 (7); 99212 (16); 99213 (23); 99214 (40); 99215 (55); 99224 (20); 99225 (40); 99226 (55); 99354 (60); 99355 (30); 99356 (60); 99357 (30)

Specialty Society Recommended Data

Please, pick the pre-service time package that best corresponds to the data which was collected in the survey process. (Note: your recommended pre time should not exceed your survey median time for any category)

2b-FAC Diff Pat/Straightfor Proc(w sedation/anes)

CPT Code:	47541	**Recommended Physician Work RVU: 7.00**		
		Specialty Recommended Pre-Service Time	**Specialty Recommended Pre Time Package**	**Adjustments/Recommended Pre-Service Time**
Pre-Service Evaluation Time:		**33.00**	**33.00**	**0.00**
Pre-Service Positioning Time:		**3.00**	**1.00**	**2.00**
Pre-Service Scrub, Dress, Wait Time:		**5.00**	**5.00**	**0.00**
Intra-Service Time:		**60.00**		

Please, pick the post-service time package that best corresponds to the data which was collected in the survey process: (Note: your recommended post time should not exceed your survey median time)

8A IV Sedation/Simple Procedure

	Specialty Recommended Post-Service Time	**Specialty Recommended Post Time Package**	**Adjustments/Recommended Post-Service Time**
Immediate Post Service-Time:	**20.00**	**25.00**	**-5.00**

Post-Operative Visits	Total Min**	CPT Code and Number of Visits
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.0** 99239x **0.0** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

Modifier -51 Exempt Status

Is the recommended value for the new/revised procedure based on its modifier -51 exempt status? No

New Technology/Service:

Is this new/revised procedure considered to be a new technology or service? No

TOP KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
37226	000	10.49	**RUC Time**

CPT Descriptor Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed

SECOND HIGHEST KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
37213	000	5.00	**RUC Time**

CPT Descriptor Transcatheter therapy, arterial or venous infusion for thrombolysis other than coronary, any method, including radiological supervision and interpretation, continued treatment on subsequent day during course of thrombolytic therapy, including follow-up catheter contrast injection, position change, or exchange, when performed;

KEY MPC COMPARISON CODES:

Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU	Time Source	Most Recent Medicare Utilization
52353	000	7.50	**RUC Time**	16,401

CPT Descriptor 1 Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy (ureteral catheterization is included)

MPC CPT Code 2	Global	Work RVU	Time Source	Most Recent Medicare Utilization
		0.00		

CPT Descriptor 2

Other Reference CPT Code	Global	Work RVU	Time Source
		0.00	

CPT Descriptor

RELATIONSHIP OF CODE BEING REVIEWED TO TOP TWO KEY REFERENCE SERVICES:

Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the top two chosen key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Top Key Reference Code: 10 **% of respondents:** 23.8 **%**

Number of respondents who choose 2nd Key Reference Code: 4 **% of respondents:** 9.5 **%**

TIME ESTIMATES (Median)

	CPT Code: 47541	**Top Key Reference CPT Code:** 37226	**2nd Key Reference CPT Code:** **37213**
Median Pre-Service Time	41.00	48.00	41.00
Median Intra-Service Time	60.00	90.00	33.00
Median Immediate Post-service Time	20.00	30.00	25.00
Median Critical Care Time	0.0	0.00	0.00
Median Other Hospital Visit Time	0.0	0.00	0.00
Median Discharge Day Management Time	0.0	0.00	0.00
Median Office Visit Time	0.0	0.00	0.00
Prolonged Services Time	0.0	0.00	0.00
Median Subsequent Observation Care Time	0.0	0.00	0.00
Median Total Time	**121.00**	**168.00**	**99.00**
Other time if appropriate			

INTENSITY/COMPLEXITY MEASURES
(of those that selected Key Reference codes)

Survey respondents are rating the survey code relative to the key reference code.

Intensity & Complexity Rating Scale: (much less= -2.00, somewhat less= -1.00, identical= 0.00, somewhat more= 1.00, much more= 2.00)

	Top Key Ref Code	**2nd Key Ref Code**
Mental Effort and Judgment (Mean)		
The number of possible diagnosis and/or the number of management options that must be considered		
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed		
Urgency of medical decision making		
Technical Skill/Physical Effort (Mean)		
Technical skill required		
Physical effort required		

Psychological Stress (Mean)

The risk of significant complications, morbidity and/or mortality		
Outcome depends on the skill and judgment of physician		
Estimated risk of malpractice suit with poor outcome		

INTENSITY/COMPLEXITY MEASURES	**Top Key Ref Code**	**2nd Key Ref Code**
Time Segment (Mean)		
Overall intensity/complexity	-0.10	0.25

Additional Rationale and Comments

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

The Joint CPT-RUC Workgroup identified (Group 12) codes 47500, 74320-26, 47505, 74305-26, 47510, 75980-26, 47511, 75982-26, 74305-26, 47505, 74320-26, 47500, 75980-26, 47510, 75982-26 as being reported together at least 75% of the time. The specialties updated the percutaneous biliary code family based on the current practice of medicine, and in so doing, deleted 10 percutaneous biliary procedure codes while creating 14 new bundled codes that describe percutaneous biliary procedures including imaging.

This new 'biliary family' was recently surveyed and presented at the April 2015 RUC meeting. However, the RUC and specialty societies agreed that the survey data for this family of services was problematic. Specifically, the RUC noted codes 47532, 47533 and 47534 all had identical median intra-service time of 60 minutes. CPT code 47533 includes the work of 47532 plus the work of an additional access and drain placement. Furthermore, 47534 includes the work of 47533 plus the work of crossing the occlusion and placement of an internal/external drain. Given this time anomaly, the RUC agreed to provide interim recommendations at this meeting, while allowing the specialty societies to re-survey the entire family of codes for October 2015.

The specialty societies worked with the research subcommittee to develop a modified survey tool in an attempt to facilitate gathering more accurate rank order survey data from the surveyed physicians. The entire family of codes was included on one single survey. The research subcommittee approved this survey method, which collected:
• overall complexity/intensity data;
• service performance rates for just the surveyed codes; and
• only whether the vignette is typical or not.
We did not ask for them to provide details if the vignette is not typical.

Compelling Evidence
SIR/ACR believe that the current values for CPT codes now used for the percutaneous, image guided biliary interventional procedures newly described in Tab 4 are no longer rational or appropriate for the detailed, granular and far more accurately descriptive codes in this new group. In our opinion, there have been significant changes in technique, knowledge and technology, patient population and physician time.

Technique, Knowledge and Technology
The codes currently used for this family of biliary procedures no longer reflect the techniques now used for image-guided, catheter-based biliary procedures. Indeed, as can be seen, there are 14 new codes in this family which will henceforth be used to describe a diverse range of procedures. As an index example of these significant changes in technique, one of the most widely used of the current codes, 47510, *Introduction of percutaneous transhepatic catheter for biliary drainage*, was previously performed by a method in which the biliary tree was first opacified and often distended by blind needle puncture (not ultrasound), after which an optimal duct was identified and punctured under fluoroscopy using large sheathed needles or even the trocar technique. These techniques have all changed since this code was introduced and valued as noted below.

Virtually all the medical devices currently used in biliary catheter procedures have been developed since the current codes were adopted. The past twenty years have witnessed major advances in our knowledge base including:
1) using imaging guidance, such as ultrasound, and preoperative mapping to avoid hepatic hilar structures and thus prevent bleeding and bile leaks
2) new insights into how segmental biliary ductal anatomy can help avoid bleeding and septic complications
3) development of much less aggressive and safer guidewire-based methods which involve more steps and more effort, skill and physician time such as micropuncture access with gradual stepwise transition to heavy-duty guidewires, tract dilation and placement of catheters over safer, more stable wires and use of real-time ultrasound guidance for needle access. The ductal system is never distended to avoid septic complications.

We would note that the example of 47510 is reflective of the majority of the existing codes for biliary catheter procedures. Simply put, the new codes reflect new thinking and understanding as well as considerable improvements and advances in techniques which render the current values inappropriate for these new codes.

In another example, the existing code 47511, *Introduction of percutaneous transhepatic stent for internal and external biliary drainage*. Current methods utilize a wide range of self-expanding open, as well as covered, metallic stents of various designs designed specifically for biliary pathology and using percutaneous methods as well as plastic and even retrievable metallic stents. These devices were not available when the existing codes were proposed or adopted.

A number of the codes, for example, 47543, *Endoluminal biopsy(ies) of biliary tree, percutaneous, any method(s) (eg, brush, forceps and/or needle)*, 47544 *Removal of calculi/debris from biliary duct(s) and/or gallbladder, percutaneous, including destruction of calculi by any method (eg, mechanical, electrohydraulic, lithotripsy)*, 47542, *Balloon dilation of biliary duct(s) or of ampulla (sphincteroplasty), percutaneous*, or 47541, *Placement of access through the biliary tree and into small bowel to assist with an endoscopic biliary procedure (eg, rendezvous procedure), percutaneous*, describe procedures which did not exist previously and, thus, are new technology not able to be described at all under the old codes.

Patient Population

SIR/ACR assert that the population of patients treated with the new family of procedures described herein has changed considerably in at least three major ways:

1) Previously the majority of all biliary catheter procedures were used for basic relief of distal ductal biliary obstruction either acutely or chronically often related to pancreatic cancer and/or stone disease. These patients previously drained and stented percutaneously are now largely treated by endoscopic methods. The significant majority of all of the biliary diseases referred for interventional percutaneous treatment now have higher and more complex levels of benign and malignant biliary occlusion, including hilar and segmental obstruction. Treatment of these lesions involves considerably more work, time, effort and risk to achieve satisfactory outcomes.
2) The widespread use of liver transplantation has introduced an entirely different patient population: the postoperative liver transplant patient with ischemic biliary strictures (intrahepatic and/or extrahepatic), which requires major investments of time, skill and effort to obtain access and drain, stent and dilate these complex situations.
3) Hepatic surgery for malignancy has also become far more sophisticated and segmental or lobar resections will frequently result in referrals for drainage of biliary leaks from nondilated ducts. These patients also present challenges in drainage and management.

An example of the change in patient populations can also be seen in the management of biliary stone disease. Previously, patients with distal biliary calculi were referred for external biliary drainage and stone manipulation. These patients are no longer sent for percutaneous treatment. The stone diseases seen currently are intrahepatic lithiasis or extensive stone formation as a result of biliary-enteric anastomoses both of which require far more skill and time to achieve satisfactory initial access but also need much different time-consuming and labor intensive methods to extract or expel the stones.

New Biliary Family

The CPT editorial panel established 14 bundled codes that describe percutaneous biliary procedures including imaging. Below is a table demonstrating the relationship between the new codes:

000 Code Set:

47531: Direct crosswalk to 46611 (work RVU= 1.30)

47532: Recommendation of 25th percentile RVW 4.50 based on survey (N=42) with median intra-service time of 45 and total time of 98 minutes. This recommendation is well supported by the #1 KRS (49407: RVW 4.50 (exactly the same), Intra 45 (exactly the

same), total 110 (slightly higher)). The recommendation is also well bracketed by MPCs 55214 (RVW 3.50, Intra 30, total 79) and 52235 (RVW 5.44, Intra 45 (same as 47532), and total 94 (less than 47532)).

47533: The RUC recommends the survey 25th percentile of 4.50 work RVUs

47534: The RUC recommends the survey 25th percentile of 7.85 work RVUs

47535: Recommendation of 25th percentile RVW 4.20 based on survey (N=42) with median intra-service time of 45 and total time of 93 minutes. The societies feel that the work of 47535 is similar to 47532 and that the survey and our recommendations are therefore also consistent. This recommendation is well bracketed by the #1 and #2 KRS (36247: RVW 6.29, Intra 60, Total 131, and 32550: RVW 4.17, Intra 30, Total 90). The recommendation is also well bracketed by MPCs 52214 (RVW 3.50, Intra 30, Total 79) and 52235 (RVW 5.44, Intra 45, Total 94).

47536: The RUC recommends the survey 25th percentile of 2.86 work RVUs

47537: Recommendation of 25th percentile RVW 1.84 based on survey (N=42) with median intra-service time of 15 and total time of 52 minutes. This work is similar to 47531with the additional work of fluoroscopic drain removal. The societies feel that this extra work is reflective of clinical practice and similarly reflected in the survey median and 25th RVW. This recommendation is well bracketed by the #1 and #2 KRS (49083: RVW 2.00, Intra 25, Total 60, and 49450: RVW 1.36, Intra 10, Total 50).

47538: The RUC recommends the survey 25th percentile of 5.00 work RVUs

47539: Recommendation of 25th percentile RVW 9.00 based on survey (N=41) with median intra-service time of 75 and total time of 136 minutes. This recommendation is well bracketed by MPC 52353 (RVW 7.50, Intra 60, Total 133) and the #1 KRS (37226: RVW 10.49, Intra 90, Total 168).

47540: The RUC recommends the survey 25th percentile of 9.28 work RVUs

47541: Recommendation of 25th percentile RVW 7.00 based on survey (N=42) with median intra-service time of 60 and total time of 121 minutes. The societies feel that the intensity and complexity of this work is in between that of 47533 and 47534 based on magnitude estimation and therefore are recommending a value greater than 47533 but less than 47534. This recommendation is well bracketed by the #1 and #2 KRS (37226: RVW 10.49, Intra 90, Total 168, and 37213: RVW 5.00, Intra 33, Total 99). This recommendation is also supported by MPC 52353 (RVW 7.50, Intra 60, Total 133).

ZZZ Code Set:

47542**:** The RUC recommends the survey 25th percentile of 2.85 work RVUs

47543**:** Recommendation of 25th percentile RVW 3.00 based on survey (N=42) with median intra-service time of 30. This recommendation is well bracketed by MPC 99292 (RVW 2.25, Intra 30) and #1 KRS (37185: RVW 3.28, Intra 40).

47544**:** The RUC recommends a direct crosswalk to 37185 and 92973 (work RVU= 3.28)

PreService Time

We selected pre time package 2B for 47532, 47533, 47534, 47535, 47536, 47541, 47538, 47539, and 47540. For 47531 and 47537, we selected pre time package 2A, because moderate sedation was not inherent in those two procedures. We also added two additional minutes of positioning time to account for positioning patient on angiographic table, as well as optimize lead placement to avoid obscuring imaging.

Relativity

The consensus panel reviewed the survey data for the family this new family of biliary procedures and analyzed the relativity within the family. The consensus panel felt the appropriate recommendations for 47533, 47534, 47538 and 47542 fell between the surveyed 25th percentile and the survey median. As such, we are recommending crosswalk values for those codes.

The consensus panel reviewed the survey data and believe the recommendations compare favorably to (1) the new family of biliary codes, (2) interventional radiology and (3) MPCs. Below is an outline of the comparisons:

	CPT Code	Global Period	Work RVU	Total Time	Pre Time			Intra Time	Post Time	IWPUT
					Eval	Pos	SDW			

reference	49450	000	1.36	50	20	5	5	10	10	0.054
surveyed	47531	000	1.30	54	18	3	6	15	12	0.047
MPC	55876	000	1.73	59	19	10		20	10	0.043
surveyed	47537	000	1.84	52	18	3	6	15	10	0.073
reference	49083	000	2.00	60	15	5	5	25	10	0.052
MPC	31622	000	2.78	65	10	5	5	30	15	0.069
reference	49452	000	2.86	60	20	5	5	20	10	0.102
surveyed	47536	000	2.86	61	20	3	5	20	13	0.111
MPC	52214	000	3.50	79	19	5	5	30	20	0.083
reference	32550	000	4.17	90	15	15	10	30	20	0.099
surveyed	47535	000	4.20	93	25	3	5	45	15	0.071
reference	49407	000	4.50	110	35	5	5	45	20	0.069
surveyed	47532	000	4.50	98	30	3	5	45	15	0.075
reference	37191	000	4.71	83	30	3	5	30	15	0.120
reference	37213	000	5.00	99	33	3	5	33	25	0.109
MPC	52235	000	5.44	94	19	5	5	45	20	0.098
surveyed	47538	000	5.00	106	30	3	5	53	15	0.082
crosswalk	31267	000	5.45	110	30			50	30	0.082
reference	36247	000	6.29	131	33	3	5	60	30	0.080
surveyed	47533	000	5.63	121	33	3	5	60	20	0.083
crosswalk	37197	000	6.29	121	33	3	5	60	20	0.083
surveyed	47541	000	7.00	121	33	3	5	60	20	0.095
MPC	52353	000	7.50	133	33	5	15	60	20	0.101
reference	37211	000	8.00	138	40	3	5	60	30	0.105
surveyed	47534	000	7.85	129	33	3	5	68	20	0.107
crosswalk	43274	000	8.58	139	33	10	5	68	23	0.104
surveyed	47539	000	9.00	136	33	3	5	75	20	0.103
reference	37226	000	10.49	168	40	3	5	90	30	0.098
reference	37228	000	11.00	168	40	3	5	90	30	0.104
surveyed	47540	000	9.28	146	33	3	5	85	20	0.114
reference	37230	000	13.80	198	40	3	5	120	30	0.101
MPC	99292	ZZZ	2.25	30				30		0.075
surveyed	47542	ZZZ	2.85	30				30		0.099
crosswalk	37239	ZZZ	2.97	32	1			30	1	0.098
surveyed	47543	ZZZ	3.00	30				30		0.100
reference	37185	ZZZ	3.28	40				40		0.082
reference	37222	ZZZ	3.73	42	1			40	1	0.092
surveyed	47544	ZZZ	3.28	45				45		0.088
MPC	57267	ZZZ	4.88	45				45		0.108
reference	37235	ZZZ	7.80	82	1			80	1	0.097

Recommendations

The consensus panel reviewed the (1) RUC survey data, (2) the family relationship between the new codes, (2) the relativity to codes within interventional radiology specialty, (3) rank order within the Fee Schedule, (4) compelling evidence, (5) standard packages and (6) RUC guidelines and makes the following physician work recommendations:

CPT	Global	Work	Total	Pre Time			Intra	Post	IWPUT
Code	Period	RVU	Time	Eval	Pos	SDW	Time	Time	
47531	000	1.30	54	18	3	6	15	12	0.047
47532	000	4.50	98	30	3	5	45	15	0.075

47533	000	5.63	121	33	3	5	60	20	0.083
47534	000	7.85	129	33	3	5	68	20	0.107
47535	000	4.20	93	25	3	5	45	15	0.071
47536	000	2.86	61	20	3	5	20	13	0.111
47537	000	1.84	52	18	3	6	15	10	0.073
47538	000	5.00	106	30	3	5	53	15	0.082
47539	000	9.00	136	33	3	5	75	20	0.103
47540	000	9.28	146	33	3	5	85	20	0.114
47541	000	7.00	121	33	3	5	60	20	0.095
47542	ZZZ	2.85	30				30		0.099
47543	ZZZ	3.00	30				30		0.100
47544	ZZZ	3.28	45				45		0.088

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions: No

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☐ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.
   - ☐ Historical precedents.
   - ☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) 76942, 47500 and 74320

How often do physicians in your specialty perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty Interventional Radiology How often? Commonly

Specialty How often?

Specialty How often?

Estimate the number of times this service might be provided nationally in a one-year period?
If the recommendation is from multiple specialties, please provide the frequency and percentage for each specialty. Please explain the rationale for this estimate. A national number is not available.

Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? 0 If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty. Please explain the rationale for this estimate. A national number is not available.

Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%
Specialty	Frequency 0	Percentage 0.00	%

Do many physicians perform this service across the United States? Yes

---

Berenson-Eggers Type of Service (BETOS) Assignment

Please pick the appropriate BETOS classification that best corresponds to the clinical nature of this CPT code. Please select the main BETOS classification and sub-classification to the greatest level of specificity possible.

Main BETOS Classification:
Procedures

BETOS Sub-classification:
Minor procedure

BETOS Sub-classification Level II:
Other

Professional Liability Insurance Information (PLI)

If the surveyed code is an existing code and the specialty believes the specialty utilization mix will not change, enter the surveyed existing CPT code number

If this code is a new/revised code or an existing code in which the specialty utilization mix will change, please select another crosswalk based on a similar specialty mix. 36247

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:47542 Tracking Number U12 Original Specialty Recommended RVU: **2.97**
Presented Recommended RVU: **2.97**
Global Period: ZZZ RUC Recommended RVU: **2.85**

CPT Descriptor: Balloon dilation of biliary duct(s) or of ampulla (sphincteroplasty), percutaneous, including imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation, each duct (List separately in addition to code for primary procedure)

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A 41-year-old female presents with hyperbilirubinemia 6 months following cholecystectomy. Magnetic resonance cholangiopancreatography (MRCP) demonstrates biliary strictures in the right hepatic duct with consequent biliary ductal dilation throughout the right hepatic lobe. Percutaneous therapeutic management is performed.

Percentage of Survey Respondents who found Vignette to be Typical: 95%

Site of Service (Complete for 010 and 090 Globals Only)

Percent of survey respondents who stated they perform the procedure; In the hospital 0% , In the ASC 0%, In the office 0%

Percent of survey respondents who stated they typically perform this procedure in the hospital, stated the patient is; Discharged the same day 0% , Overnight stay-less than 24 hours 0% , Overnight stay-more than 24 hours 0%

Percent of survey respondents who stated that if the patient is typically kept overnight also stated that they perform an E&M service later on the same day 0%

Moderate Sedation

Is moderate sedation inherent to this procedure in the Hospital/ASC setting? Yes
Percent of survey respondents who stated moderate sedation is typical in the Hospital/ASC setting? 93%

Is moderate sedation inherent to this procedure in the office setting? Yes
Percent of survey respondents who stated moderate sedation is typical in the office setting? 100%

Description of Pre-Service Work:

Description of Intra-Service Work: Separately reportable access to the biliary tree is acquired and a transitional dilator is placed. A wire and catheter combination is used to pass the wire across the biliary stricture. The transitional dilator set is exchanged for a sheath. A balloon is placed through the sheath over the wire, and used to dilate the biliary stricture. The balloon is removed. Cholangiography is performed through the sheath to assess adequacy of dilation. An 8F internal/external biliary drain is placed over the wire, terminating in the small bowel (separately reportable).

Description of Post-Service Work:

SURVEY DATA

RUC Meeting Date (mm/yyyy)	10/2015				
Presenter(s):	Jerry Niedzwiecki, MD, Michael Hall, MD, Bob Vogelzang, MD, Tim Swan, MD, Matt Hawkins, MD, Zeke Silva, MD and Kurt Schoppe, MD				
Specialty(s):	Interventional Radiology				
CPT Code:	47542				
Sample Size:	1730	**Resp N:**	42	**Response:** 2.4 %	
Description of Sample:	Random Sample: SIR 980/ACR 750				

	Low	**25th pctl**	**Median***	**75th pctl**	**High**
Service Performance Rate	1.00	3.00	**6.00**	15.00	33.00
Survey RVW:	1.00	2.85	**3.74**	4.00	12.00
Pre-Service Evaluation Time:			**0.00**		
Pre-Service Positioning Time:			**0.00**		
Pre-Service Scrub, Dress, Wait Time:			**0.00**		
Intra-Service Time:	10.00	15.00	**30.00**	50.00	150.00

Immediate Post Service-Time:	**0.00**	
Post Operative Visits	**Total Min****	**CPT Code and Number of Visits**
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.00** 99239x **0.00** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

**Physician standard total minutes per E/M visit: 99291 (70); 99292 (30); 99231 (20); 99232 (40); 99233 (55); 99238(38); 99239 (55); 99217 (38); 99211 (7); 99212 (16); 99213 (23); 99214 (40); 99215 (55); 99224 (20); 99225 (40); 99226 (55); 99354 (60); 99355 (30); 99356 (60); 99357 (30)

Specialty Society Recommended Data

Please, pick the pre-service time package that best corresponds to the data which was collected in the survey process. (Note: your recommended pre time should not exceed your survey median time for any category)

ZZZ Global Code

CPT Code:	47542	**Recommended Physician Work RVU: 2.85**		
		Specialty Recommended Pre-Service Time	**Specialty Recommended Pre Time Package**	**Adjustments/Recommended Pre-Service Time**
Pre-Service Evaluation Time:		**0.00**	**0.00**	**0.00**
Pre-Service Positioning Time:		**0.00**	**0.00**	**0.00**
Pre-Service Scrub, Dress, Wait Time:		**0.00**	**0.00**	**0.00**
Intra-Service Time:		**30.00**		

Please, pick the post-service time package that best corresponds to the data which was collected in the survey process: (Note: your recommended post time should not exceed your survey median time)

ZZZ Global Code

	Specialty Recommended Post-Service Time	**Specialty Recommended Post Time Package**	**Adjustments/Recommended Post-Service Time**
Immediate Post Service-Time:	**0.00**	**0.00**	**0.00**

Post-Operative Visits	Total Min**	CPT Code and Number of Visits
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.0** 99239x **0.0** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

Modifier -51 Exempt Status
Is the recommended value for the new/revised procedure based on its modifier -51 exempt status? No

New Technology/Service:
Is this new/revised procedure considered to be a new technology or service? No

TOP KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
37222	ZZZ	3.73	**RUC Time**

CPT Descriptor Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal angioplasty (List separately in addition to code for primary procedure)

SECOND HIGHEST KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
37185	ZZZ	3.28	**RUC Time**

CPT Descriptor Primary percutaneous transluminal mechanical thrombectomy, noncoronary, arterial or arterial bypass graft, including fluoroscopic guidance and intraprocedural pharmacological thrombolytic injection(s); second and all subsequent vessel(s) within the same vascular family (List separately in addition to code for primary mechanical thrombectomy procedure)

KEY MPC COMPARISON CODES:
Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU	Time Source	Most Recent Medicare Utilization
99292	ZZZ	2.25	**RUC Time**	456,453

CPT Descriptor 1 Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes (List separately in addition to code for primary service)

MPC CPT Code 2	Global	Work RVU	Time Source	Most Recent Medicare Utilization
57267	ZZZ	4.88	**RUC Time**	8,063

CPT Descriptor 2 Insertion of mesh or other prosthesis for repair of pelvic floor defect, each site (anterior, posterior compartment), vaginal approach (List separately in addition to code for primary procedure)

Other Reference CPT Code	Global	Work RVU	Time Source
		0.00	

CPT Descriptor

RELATIONSHIP OF CODE BEING REVIEWED TO TOP TWO KEY REFERENCE SERVICES:
Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the top two chosen key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Top Key Reference Code: 10 **% of respondents:** 9.0 **%**

Number of respondents who choose 2nd Key Reference Code: 9 **% of respondents:** 21.4 **%**

TIME ESTIMATES (Median)

	CPT Code: 47542	**Top Key Reference CPT Code:** 37222	**2nd Key Reference CPT Code:** **37185**
Median Pre-Service Time	0.00	1.00	0.00
Median Intra-Service Time	30.00	40.00	40.00
Median Immediate Post-service Time	0.00	1.00	0.00
Median Critical Care Time	0.0	0.00	0.00
Median Other Hospital Visit Time	0.0	0.00	0.00
Median Discharge Day Management Time	0.0	0.00	0.00
Median Office Visit Time	0.0	0.00	0.00
Prolonged Services Time	0.0	0.00	0.00
Median Subsequent Observation Care Time	0.0	0.00	0.00
Median Total Time	**30.00**	**42.00**	**40.00**
Other time if appropriate			

INTENSITY/COMPLEXITY MEASURES
(of those that selected Key Reference codes)

Survey respondents are rating the survey code relative to the key reference code.

Intensity & Complexity Rating Scale: (much less= -2.00, somewhat less= -1.00, identical= 0.00, somewhat more= 1.00, much more= 2.00)

	Top Key Ref Code	**2nd Key Ref Code**
Mental Effort and Judgment (Mean)		
The number of possible diagnosis and/or the number of management options that must be considered		
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed		
Urgency of medical decision making		
Technical Skill/Physical Effort (Mean)		
Technical skill required		

Physical effort required		

Psychological Stress (Mean)

The risk of significant complications, morbidity and/or mortality		
Outcome depends on the skill and judgment of physician		
Estimated risk of malpractice suit with poor outcome		

INTENSITY/COMPLEXITY MEASURES	**Top Key Ref Code**	**2nd Key Ref Code**
Time Segment (Mean)		
Overall intensity/complexity	-0.20	-0.44

Additional Rationale and Comments

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

The Joint CPT-RUC Workgroup identified (Group 12) codes 47500, 74320-26, 47505, 74305-26, 47510, 75980-26, 47511, 75982-26, 74305-26, 47505, 74320-26, 47500, 75980-26, 47510, 75982-26 as being reported together at least 75% of the time. The specialties updated the percutaneous biliary code family based on the current practice of medicine, and in so doing, deleted 10 percutaneous biliary procedure codes while creating 14 new bundled codes that describe percutaneous biliary procedures including imaging.

This new 'biliary family' was recently surveyed and presented at the April 2015 RUC meeting. However, the RUC and specialty societies agreed that the survey data for this family of services was problematic. Specifically, the RUC noted codes 47532, 47533 and 47534 all had identical median intra-service time of 60 minutes. CPT code 47533 includes the work of 47532 plus the work of an additional access and drain placement. Furthermore, 47534 includes the work of 47533 plus the work of crossing the occlusion and placement of an internal/external drain. Given this time anomaly, the RUC agreed to provide interim recommendations at this meeting, while allowing the specialty societies to re-survey the entire family of codes for October 2015.

The specialty societies worked with the research subcommittee to develop a modified survey tool in an attempt to facilitate gathering more accurate rank order survey data from the surveyed physicians. The entire family of codes was included on one single survey. The research subcommittee approved this survey method, which collected:
• overall complexity/intensity data;
• service performance rates for just the surveyed codes; and
• only whether the vignette is typical or not.
We did not ask for them to provide details if the vignette is not typical.

Compelling Evidence
SIR/ACR believe that the current values for CPT codes now used for the percutaneous, image guided biliary interventional procedures newly described in Tab 4 are no longer rational or appropriate for the detailed, granular and far more accurately descriptive codes in this new group. In our opinion, there have been significant changes in technique, knowledge and technology, patient population and physician time.

Technique, Knowledge and Technology
The codes currently used for this family of biliary procedures no longer reflect the techniques now used for image-guided, catheter-based biliary procedures. Indeed, as can be seen, there are 14 new codes in this family which will henceforth be used to describe a diverse range of procedures. As an index example of these significant changes in technique, one of the most widely used of the current codes, 47510, *Introduction of percutaneous transhepatic catheter for biliary drainage*, was previously performed by a method in which the biliary tree was first opacified and often distended by blind needle puncture (not ultrasound), after which an optimal duct was identified and punctured under fluoroscopy using large sheathed needles or even the trocar technique. These techniques have all changed since this code was introduced and valued as noted below.

Virtually all the medical devices currently used in biliary catheter procedures have been developed since the current codes were adopted. The past twenty years have witnessed major advances in our knowledge base including:
1) using imaging guidance, such as ultrasound, and preoperative mapping to avoid hepatic hilar structures and thus prevent bleeding and bile leaks
2) new insights into how segmental biliary ductal anatomy can help avoid bleeding and septic complications
3) development of much less aggressive and safer guidewire-based methods which involve more steps and more effort, skill and physician time such as micropuncture access with gradual stepwise transition to heavy-duty guidewires, tract dilation and placement of catheters over safer, more stable wires and use of real-time ultrasound guidance for needle access. The ductal system is never distended to avoid septic complications.

We would note that the example of 47510 is reflective of the majority of the existing codes for biliary catheter procedures. Simply put, the new codes reflect new thinking and understanding as well as considerable improvements and advances in techniques which render the current values inappropriate for these new codes.

In another example, the existing code 47511, *Introduction of percutaneous transhepatic stent for internal and external biliary drainage*. Current methods utilize a wide range of self-expanding open, as well as covered, metallic stents of various designs designed specifically for biliary pathology and using percutaneous methods as well as plastic and even retrievable metallic stents. These devices were not available when the existing codes were proposed or adopted.

A number of the codes, for example, 47543, *Endoluminal biopsy(ies) of biliary tree, percutaneous, any method(s) (eg, brush, forceps and/or needle)*, 47544 *Removal of calculi/debris from biliary duct(s) and/or gallbladder, percutaneous, including destruction of calculi by any method (eg, mechanical, electrohydraulic, lithotripsy)*, 47542, *Balloon dilation of biliary duct(s) or of ampulla (sphincteroplasty), percutaneous*, or 47541, *Placement of access through the biliary tree and into small bowel to assist with an endoscopic biliary procedure (eg, rendezvous procedure), percutaneous*, describe procedures which did not exist previously and, thus, are new technology not able to be described at all under the old codes.

Patient Population

SIR/ACR assert that the population of patients treated with the new family of procedures described herein has changed considerably in at least three major ways:

1) Previously the majority of all biliary catheter procedures were used for basic relief of distal ductal biliary obstruction either acutely or chronically often related to pancreatic cancer and/or stone disease. These patients previously drained and stented percutaneously are now largely treated by endoscopic methods. The significant majority of all of the biliary diseases referred for interventional percutaneous treatment now have higher and more complex levels of benign and malignant biliary occlusion, including hilar and segmental obstruction. Treatment of these lesions involves considerably more work, time, effort and risk to achieve satisfactory outcomes.
2) The widespread use of liver transplantation has introduced an entirely different patient population: the postoperative liver transplant patient with ischemic biliary strictures (intrahepatic and/or extrahepatic), which requires major investments of time, skill and effort to obtain access and drain, stent and dilate these complex situations.
3) Hepatic surgery for malignancy has also become far more sophisticated and segmental or lobar resections will frequently result in referrals for drainage of biliary leaks from nondilated ducts. These patients also present challenges in drainage and management.

An example of the change in patient populations can also be seen in the management of biliary stone disease. Previously, patients with distal biliary calculi were referred for external biliary drainage and stone manipulation. These patients are no longer sent for percutaneous treatment. The stone diseases seen currently are intrahepatic lithiasis or extensive stone formation as a result of biliary-enteric anastomoses both of which require far more skill and time to achieve satisfactory initial access but also need much different time-consuming and labor intensive methods to extract or expel the stones.

New Biliary Family

The CPT editorial panel established 14 bundled codes that describe percutaneous biliary procedures including imaging. Below is a table demonstrating the relationship between the new codes:

000 Code Set:

47531: Direct crosswalk to 46611 (work RVU= 1.30)

47532: Recommendation of 25th percentile RVW 4.50 based on survey (N=42) with median intra-service time of 45 and total time of 98 minutes. This recommendation is well supported by the #1 KRS (49407: RVW 4.50 (exactly the same), Intra 45 (exactly the

same), total 110 (slightly higher)). The recommendation is also well bracketed by MPCs 55214 (RVW 3.50, Intra 30, total 79) and 52235 (RVW 5.44, Intra 45 (same as 47532), and total 94 (less than 47532)).

47533: The RUC recommends the survey 25th percentile of 4.50 work RVUs

47534: The RUC recommends the survey 25th percentile of 7.85 work RVUs

47535: Recommendation of 25th percentile RVW 4.20 based on survey (N=42) with median intra-service time of 45 and total time of 93 minutes. The societies feel that the work of 47535 is similar to 47532 and that the survey and our recommendations are therefore also consistent. This recommendation is well bracketed by the #1 and #2 KRS (36247: RVW 6.29, Intra 60, Total 131, and 32550: RVW 4.17, Intra 30, Total 90). The recommendation is also well bracketed by MPCs 52214 (RVW 3.50, Intra 30, Total 79) and 52235 (RVW 5.44, Intra 45, Total 94).

47536: The RUC recommends the survey 25th percentile of 2.86 work RVUs

47537: Recommendation of 25th percentile RVW 1.84 based on survey (N=42) with median intra-service time of 15 and total time of 52 minutes. This work is similar to 47531with the additional work of fluoroscopic drain removal. The societies feel that this extra work is reflective of clinical practice and similarly reflected in the survey median and 25th RVW. This recommendation is well bracketed by the #1 and #2 KRS (49083: RVW 2.00, Intra 25, Total 60, and 49450: RVW 1.36, Intra 10, Total 50).

47538: The RUC recommends the survey 25th percentile of 5.00 work RVUs

47539: Recommendation of 25th percentile RVW 9.00 based on survey (N=41) with median intra-service time of 75 and total time of 136 minutes. This recommendation is well bracketed by MPC 52353 (RVW 7.50, Intra 60, Total 133) and the #1 KRS (37226: RVW 10.49, Intra 90, Total 168).

47540: The RUC recommends the survey 25th percentile of 9.28 work RVUs

47541: Recommendation of 25th percentile RVW 7.00 based on survey (N=42) with median intra-service time of 60 and total time of 121 minutes. The societies feel that the intensity and complexity of this work is in between that of 47533 and 47534 based on magnitude estimation and therefore are recommending a value greater than 47533 but less than 47534. This recommendation is well bracketed by the #1 and #2 KRS (37226: RVW 10.49, Intra 90, Total 168, and 37213: RVW 5.00, Intra 33, Total 99). This recommendation is also supported by MPC 52353 (RVW 7.50, Intra 60, Total 133).

ZZZ Code Set:

47542**:** The RUC recommends the survey 25th percentile of 2.85 work RVUs

47543**:** Recommendation of 25th percentile RVW 3.00 based on survey (N=42) with median intra-service time of 30. This recommendation is well bracketed by MPC 99292 (RVW 2.25, Intra 30) and #1 KRS (37185: RVW 3.28, Intra 40).

47544**:** The RUC recommends a direct crosswalk to 37185 and 92973 (work RVU= 3.28)

PreService Time

We selected pre time package 2B for 47532, 47533, 47534, 47535, 47536, 47541, 47538, 47539, and 47540. For 47531 and 47537, we selected pre time package 2A, because moderate sedation was not inherent in those two procedures. We also added two additional minutes of positioning time to account for positioning patient on angiographic table, as well as optimize lead placement to avoid obscuring imaging.

Relativity

The consensus panel reviewed the survey data for the family this new family of biliary procedures and analyzed the relativity within the family. The consensus panel felt the appropriate recommendations for 47533, 47534, 47538 and 47542 fell between the surveyed 25th percentile and the survey median. As such, we are recommending crosswalk values for those codes.

The consensus panel reviewed the survey data and believe the recommendations compare favorably to (1) the new family of biliary codes, (2) interventional radiology and (3) MPCs. Below is an outline of the comparisons:

	CPT Code	Global Period	Work RVU	Total Time	Pre Time			Intra Time	Post Time	IWPUT
					Eval	Pos	SDW			

reference	49450	000	1.36	50	20	5	5	10	10	0.054
surveyed	47531	000	1.30	54	18	3	6	15	12	0.047
MPC	55876	000	1.73	59	19	10		20	10	0.043
surveyed	47537	000	1.84	52	18	3	6	15	10	0.073
reference	49083	000	2.00	60	15	5	5	25	10	0.052
MPC	31622	000	2.78	65	10	5	5	30	15	0.069
reference	49452	000	2.86	60	20	5	5	20	10	0.102
surveyed	47536	000	2.86	61	20	3	5	20	13	0.111
MPC	52214	000	3.50	79	19	5	5	30	20	0.083
reference	32550	000	4.17	90	15	15	10	30	20	0.099
surveyed	47535	000	4.20	93	25	3	5	45	15	0.071
reference	49407	000	4.50	110	35	5	5	45	20	0.069
surveyed	47532	000	4.50	98	30	3	5	45	15	0.075
reference	37191	000	4.71	83	30	3	5	30	15	0.120
reference	37213	000	5.00	99	33	3	5	33	25	0.109
MPC	52235	000	5.44	94	19	5	5	45	20	0.098
surveyed	47538	000	5.00	106	30	3	5	53	15	0.082
crosswalk	31267	000	5.45	110	30			50	30	0.082
reference	36247	000	6.29	131	33	3	5	60	30	0.080
surveyed	47533	000	5.63	121	33	3	5	60	20	0.083
crosswalk	37197	000	6.29	121	33	3	5	60	20	0.083
surveyed	47541	000	7.00	121	33	3	5	60	20	0.095
MPC	52353	000	7.50	133	33	5	15	60	20	0.101
reference	37211	000	8.00	138	40	3	5	60	30	0.105
surveyed	47534	000	7.85	129	33	3	5	68	20	0.107
crosswalk	43274	000	8.58	139	33	10	5	68	23	0.104
surveyed	47539	000	9.00	136	33	3	5	75	20	0.103
reference	37226	000	10.49	168	40	3	5	90	30	0.098
reference	37228	000	11.00	168	40	3	5	90	30	0.104
surveyed	47540	000	9.28	146	33	3	5	85	20	0.114
reference	37230	000	13.80	198	40	3	5	120	30	0.101
MPC	99292	ZZZ	2.25	30				30		0.075
surveyed	47542	ZZZ	2.85	30				30		0.099
crosswalk	37239	ZZZ	2.97	32	1			30	1	0.098
surveyed	47543	ZZZ	3.00	30				30		0.100
reference	37185	ZZZ	3.28	40				40		0.082
reference	37222	ZZZ	3.73	42	1			40	1	0.092
surveyed	47544	ZZZ	3.28	45				45		0.088
MPC	57267	ZZZ	4.88	45				45		0.108
reference	37235	ZZZ	7.80	82	1			80	1	0.097

Recommendations

The consensus panel reviewed the (1) RUC survey data, (2) the family relationship between the new codes, (2) the relativity to codes within interventional radiology specialty, (3) rank order within the Fee Schedule, (4) compelling evidence, (5) standard packages and (6) RUC guidelines and makes the following physician work recommendations:

CPT	Global	Work	Total	Pre Time			Intra	Post	IWPUT
Code	Period	RVU	Time	Eval	Pos	SDW	Time	Time	
47531	000	1.30	54	18	3	6	15	12	0.047
47532	000	4.50	98	30	3	5	45	15	0.075

47533	000	5.63	121	33	3	5	60	20	0.083
47534	000	7.85	129	33	3	5	68	20	0.107
47535	000	4.20	93	25	3	5	45	15	0.071
47536	000	2.86	61	20	3	5	20	13	0.111
47537	000	1.84	52	18	3	6	15	10	0.073
47538	000	5.00	106	30	3	5	53	15	0.082
47539	000	9.00	136	33	3	5	75	20	0.103
47540	000	9.28	146	33	3	5	85	20	0.114
47541	000	7.00	121	33	3	5	60	20	0.095
47542	ZZZ	2.85	30				30		0.099
47543	ZZZ	3.00	30				30		0.100
47544	ZZZ	3.28	45				45		0.088

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions: Yes

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☒ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.
   - ☐ Historical precedents.
   - ☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) 74363 and 47555

How often do physicians in your specialty perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty Interventional Radiology How often? Commonly

Specialty How often?

Specialty How often?

Estimate the number of times this service might be provided nationally in a one-year period?
If the recommendation is from multiple specialties, please provide the frequency and percentage for each specialty. Please explain the rationale for this estimate. A national number is not available.

Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? 0 If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty. Please explain the rationale for this estimate. A national number is not available.

Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%
Specialty	Frequency 0	Percentage 0.00	%

Do many physicians perform this service across the United States? Yes

---

Berenson-Eggers Type of Service (BETOS) Assignment

Please pick the appropriate BETOS classification that best corresponds to the clinical nature of this CPT code. Please select the main BETOS classification and sub-classification to the greatest level of specificity possible.

Main BETOS Classification:
Procedures

BETOS Sub-classification:
Minor procedure

BETOS Sub-classification Level II:
Other

Professional Liability Insurance Information (PLI)

If the surveyed code is an existing code and the specialty believes the specialty utilization mix will not change, enter the surveyed existing CPT code number

If this code is a new/revised code or an existing code in which the specialty utilization mix will change, please select another crosswalk based on a similar specialty mix. 37222

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:47543 Tracking Number U13 Original Specialty Recommended RVU: **3.00**
Presented Recommended RVU: **3.00**
Global Period: ZZZ RUC Recommended RVU: **3.00**

CPT Descriptor: Endoluminal biopsy(ies) of biliary tree, percutaneous, any method(s) (eg, brush, forceps and/or needle), including imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation, single or multiple (List separately in addition to code for primary procedure)

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A 61-year-old man presents following placement of an internal-external drain placed in the setting of cholangitis, sepsis, and a new pancreatic head mass. The patient's sepsis/cholangitis has resolved, and endoluminal biopsy is now appropriate to assess for metastatic disease

Percentage of Survey Respondents who found Vignette to be Typical: 98%

Site of Service (Complete for 010 and 090 Globals Only)

Percent of survey respondents who stated they perform the procedure; In the hospital 0% , In the ASC 0%, In the office 0%

Percent of survey respondents who stated they typically perform this procedure in the hospital, stated the patient is; Discharged the same day 0% , Overnight stay-less than 24 hours 0% , Overnight stay-more than 24 hours 0%

Percent of survey respondents who stated that if the patient is typically kept overnight also stated that they perform an E&M service later on the same day 0%

Moderate Sedation

Is moderate sedation inherent to this procedure in the Hospital/ASC setting? Yes
Percent of survey respondents who stated moderate sedation is typical in the Hospital/ASC setting? 95%

Is moderate sedation inherent to this procedure in the office setting? Yes
Percent of survey respondents who stated moderate sedation is typical in the office setting? 93%

Description of Pre-Service Work:

Description of Intra-Service Work: Separately reportable removal of the existing drainage catheter over a wire is performed. A sheath is placed. Through the sheath, a biopsy device is placed to obtain biopsies from the ipsilateral hepatic duct, common hepatic duct, and common bile duct. Using a new guidewire and catheter combination, the sheath is manipulated into the contralateral hepatic duct. The biopsy device is again placed and specimens are obtained. The biopsy specimens are sent to the lab for analysis. A catheter and wire combination is then used to obtain access into the small bowel. The sheath is exchanged over the wire for a new internal/external biliary drainage catheter (separately reportable).

Description of Post-Service Work:

SURVEY DATA

RUC Meeting Date (mm/yyyy)	10/2015				
Presenter(s):	Jerry Niedzwiecki, MD, Michael Hall, MD, Bob Vogelzang, MD, Tim Swan, MD, Matt Hawkins, MD, Zeke Silva, MD and Kurt Schoppe, MD				
Specialty(s):	Interventional Radiology				
CPT Code:	47543				
Sample Size:	1730	**Resp N:**	42	**Response:** 2.4 %	
Description of Sample:	Random Sample: SIR 980/ACR 750				

	Low	**25th pctl**	**Median***	**75th pctl**	**High**
Service Performance Rate	0.00	2.00	**5.00**	13.00	40.00
Survey RVW:	1.50	3.00	**3.80**	4.00	12.00
Pre-Service Evaluation Time:			**0.00**		
Pre-Service Positioning Time:			**0.00**		
Pre-Service Scrub, Dress, Wait Time:			**0.00**		
Intra-Service Time:	10.00	15.00	**30.00**	45.00	150.00

Immediate Post Service-Time:	**0.00**	
Post Operative Visits	**Total Min****	**CPT Code and Number of Visits**
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.00** 99239x **0.00** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

**Physician standard total minutes per E/M visit: 99291 (70); 99292 (30); 99231 (20); 99232 (40); 99233 (55); 99238(38); 99239 (55); 99217 (38); 99211 (7); 99212 (16); 99213 (23); 99214 (40); 99215 (55); 99224 (20); 99225 (40); 99226 (55); 99354 (60); 99355 (30); 99356 (60); 99357 (30)

Specialty Society Recommended Data

Please, pick the pre-service time package that best corresponds to the data which was collected in the survey process. (Note: your recommended pre time should not exceed your survey median time for any category)

ZZZ Global Code

CPT Code:	47543	**Recommended Physician Work RVU: 3.00**		
		Specialty Recommended Pre-Service Time	**Specialty Recommended Pre Time Package**	**Adjustments/Recommended Pre-Service Time**
Pre-Service Evaluation Time:		**0.00**	**0.00**	**0.00**
Pre-Service Positioning Time:		**0.00**	**0.00**	**0.00**
Pre-Service Scrub, Dress, Wait Time:		**0.00**	**0.00**	**0.00**
Intra-Service Time:		**30.00**		

Please, pick the post-service time package that best corresponds to the data which was collected in the survey process: (Note: your recommended post time should not exceed your survey median time)

ZZZ Global Code

	Specialty Recommended Post-Service Time	**Specialty Recommended Post Time Package**	**Adjustments/Recommended Post-Service Time**
Immediate Post Service-Time:	**0.00**	**0.00**	**0.00**

Post-Operative Visits	Total Min**	CPT Code and Number of Visits
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.0** 99239x **0.0** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

Modifier -51 Exempt Status
Is the recommended value for the new/revised procedure based on its modifier -51 exempt status? No

New Technology/Service:
Is this new/revised procedure considered to be a new technology or service? No

TOP KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
37185	ZZZ	3.28	**RUC Time**

CPT Descriptor Primary percutaneous transluminal mechanical thrombectomy, noncoronary, arterial or arterial bypass graft, including fluoroscopic guidance and intraprocedural pharmacological thrombolytic injection(s); second and all subsequent vessel(s) within the same vascular family (List separately in addition to code for primary mechanical thrombectomy procedure)

SECOND HIGHEST KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
37222	ZZZ	3.73	**RUC Time**

CPT Descriptor Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal angioplasty (List separately in addition to code for primary procedure)

KEY MPC COMPARISON CODES:
Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU	Time Source	Most Recent Medicare Utilization
99292	ZZZ	2.25	**RUC Time**	456,453

CPT Descriptor 1 Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes (List separately in addition to code for primary service)

MPC CPT Code 2	Global	Work RVU	Time Source	Most Recent Medicare Utilization
57267	ZZZ	4.88	**RUC Time**	8,063

CPT Descriptor 2 Insertion of mesh or other prosthesis for repair of pelvic floor defect, each site (anterior, posterior compartment), vaginal approach (List separately in addition to code for primary procedure)

Other Reference CPT Code	Global	Work RVU	Time Source
		0.00	

CPT Descriptor

RELATIONSHIP OF CODE BEING REVIEWED TO TOP TWO KEY REFERENCE SERVICES:
Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the top two chosen key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Top Key Reference Code: 13 **% of respondents:** 30.9 **%**

Number of respondents who choose 2nd Key Reference Code: 9 **% of respondents:** 21.4 **%**

TIME ESTIMATES (Median)

	CPT Code: 47543	**Top Key Reference CPT Code:** 37185	**2nd Key Reference CPT Code:** **37222**
Median Pre-Service Time	0.00	0.00	1.00
Median Intra-Service Time	30.00	40.00	40.00
Median Immediate Post-service Time	0.00	0.00	1.00
Median Critical Care Time	0.0	0.00	0.00
Median Other Hospital Visit Time	0.0	0.00	0.00
Median Discharge Day Management Time	0.0	0.00	0.00
Median Office Visit Time	0.0	0.00	0.00
Prolonged Services Time	0.0	0.00	0.00
Median Subsequent Observation Care Time	0.0	0.00	0.00
Median Total Time	**30.00**	**40.00**	**42.00**
Other time if appropriate			

INTENSITY/COMPLEXITY MEASURES
(of those that selected Key Reference codes)

Survey respondents are rating the survey code relative to the key reference code.

Intensity & Complexity Rating Scale: (much less= -2.00, somewhat less= -1.00, identical= 0.00, somewhat more= 1.00, much more= 2.00)

	Top Key Ref Code	**2nd Key Ref Code**
Mental Effort and Judgment (Mean)		
The number of possible diagnosis and/or the number of management options that must be considered		
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed		
Urgency of medical decision making		
Technical Skill/Physical Effort (Mean)		
Technical skill required		

Physical effort required		

Psychological Stress (Mean)

The risk of significant complications, morbidity and/or mortality		
Outcome depends on the skill and judgment of physician		
Estimated risk of malpractice suit with poor outcome		

INTENSITY/COMPLEXITY MEASURES	**Top Key Ref Code**	**2nd Key Ref Code**
Time Segment (Mean)		
Overall intensity/complexity	-0.38	-0.44

Additional Rationale and Comments

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

The Joint CPT-RUC Workgroup identified (Group 12) codes 47500, 74320-26, 47505, 74305-26, 47510, 75980-26, 47511, 75982-26, 74305-26, 47505, 74320-26, 47500, 75980-26, 47510, 75982-26 as being reported together at least 75% of the time. The specialties updated the percutaneous biliary code family based on the current practice of medicine, and in so doing, deleted 10 percutaneous biliary procedure codes while creating 14 new bundled codes that describe percutaneous biliary procedures including imaging.

This new 'biliary family' was recently surveyed and presented at the April 2015 RUC meeting. However, the RUC and specialty societies agreed that the survey data for this family of services was problematic. Specifically, the RUC noted codes 47532, 47533 and 47534 all had identical median intra-service time of 60 minutes. CPT code 47533 includes the work of 47532 plus the work of an additional access and drain placement. Furthermore, 47534 includes the work of 47533 plus the work of crossing the occlusion and placement of an internal/external drain. Given this time anomaly, the RUC agreed to provide interim recommendations at this meeting, while allowing the specialty societies to re-survey the entire family of codes for October 2015.

The specialty societies worked with the research subcommittee to develop a modified survey tool in an attempt to facilitate gathering more accurate rank order survey data from the surveyed physicians. The entire family of codes was included on one single survey. The research subcommittee approved this survey method, which collected:
• overall complexity/intensity data;
• service performance rates for just the surveyed codes; and
• only whether the vignette is typical or not.
We did not ask for them to provide details if the vignette is not typical.

Compelling Evidence
SIR/ACR believe that the current values for CPT codes now used for the percutaneous, image guided biliary interventional procedures newly described in Tab 4 are no longer rational or appropriate for the detailed, granular and far more accurately descriptive codes in this new group. In our opinion, there have been significant changes in technique, knowledge and technology, patient population and physician time.

Technique, Knowledge and Technology
The codes currently used for this family of biliary procedures no longer reflect the techniques now used for image-guided, catheter-based biliary procedures. Indeed, as can be seen, there are 14 new codes in this family which will henceforth be used to describe a diverse range of procedures. As an index example of these significant changes in technique, one of the most widely used of the current codes, 47510, *Introduction of percutaneous transhepatic catheter for biliary drainage*, was previously performed by a method in which the biliary tree was first opacified and often distended by blind needle puncture (not ultrasound), after which an optimal duct was identified and punctured under fluoroscopy using large sheathed needles or even the trocar technique. These techniques have all changed since this code was introduced and valued as noted below.

Virtually all the medical devices currently used in biliary catheter procedures have been developed since the current codes were adopted. The past twenty years have witnessed major advances in our knowledge base including:
1) using imaging guidance, such as ultrasound, and preoperative mapping to avoid hepatic hilar structures and thus prevent bleeding and bile leaks
2) new insights into how segmental biliary ductal anatomy can help avoid bleeding and septic complications
3) development of much less aggressive and safer guidewire-based methods which involve more steps and more effort, skill and physician time such as micropuncture access with gradual stepwise transition to heavy-duty guidewires, tract dilation and placement of catheters over safer, more stable wires and use of real-time ultrasound guidance for needle access. The ductal system is never distended to avoid septic complications.

We would note that the example of 47510 is reflective of the majority of the existing codes for biliary catheter procedures. Simply put, the new codes reflect new thinking and understanding as well as considerable improvements and advances in techniques which render the current values inappropriate for these new codes.

In another example, the existing code 47511, *Introduction of percutaneous transhepatic stent for internal and external biliary drainage*. Current methods utilize a wide range of self-expanding open, as well as covered, metallic stents of various designs designed specifically for biliary pathology and using percutaneous methods as well as plastic and even retrievable metallic stents. These devices were not available when the existing codes were proposed or adopted.

A number of the codes, for example, 47543, *Endoluminal biopsy(ies) of biliary tree, percutaneous, any method(s) (eg, brush, forceps and/or needle)*, 47544 *Removal of calculi/debris from biliary duct(s) and/or gallbladder, percutaneous, including destruction of calculi by any method (eg, mechanical, electrohydraulic, lithotripsy)*, 47542, *Balloon dilation of biliary duct(s) or of ampulla (sphincteroplasty), percutaneous*, or 47541, *Placement of access through the biliary tree and into small bowel to assist with an endoscopic biliary procedure (eg, rendezvous procedure), percutaneous*, describe procedures which did not exist previously and, thus, are new technology not able to be described at all under the old codes.

Patient Population

SIR/ACR assert that the population of patients treated with the new family of procedures described herein has changed considerably in at least three major ways:

1) Previously the majority of all biliary catheter procedures were used for basic relief of distal ductal biliary obstruction either acutely or chronically often related to pancreatic cancer and/or stone disease. These patients previously drained and stented percutaneously are now largely treated by endoscopic methods. The significant majority of all of the biliary diseases referred for interventional percutaneous treatment now have higher and more complex levels of benign and malignant biliary occlusion, including hilar and segmental obstruction. Treatment of these lesions involves considerably more work, time, effort and risk to achieve satisfactory outcomes.
2) The widespread use of liver transplantation has introduced an entirely different patient population: the postoperative liver transplant patient with ischemic biliary strictures (intrahepatic and/or extrahepatic), which requires major investments of time, skill and effort to obtain access and drain, stent and dilate these complex situations.
3) Hepatic surgery for malignancy has also become far more sophisticated and segmental or lobar resections will frequently result in referrals for drainage of biliary leaks from nondilated ducts. These patients also present challenges in drainage and management.

An example of the change in patient populations can also be seen in the management of biliary stone disease. Previously, patients with distal biliary calculi were referred for external biliary drainage and stone manipulation. These patients are no longer sent for percutaneous treatment. The stone diseases seen currently are intrahepatic lithiasis or extensive stone formation as a result of biliary-enteric anastomoses both of which require far more skill and time to achieve satisfactory initial access but also need much different time-consuming and labor intensive methods to extract or expel the stones.

New Biliary Family

The CPT editorial panel established 14 bundled codes that describe percutaneous biliary procedures including imaging. Below is a table demonstrating the relationship between the new codes:

000 Code Set:

47531: Direct crosswalk to 46611 (work RVU= 1.30)

47532: Recommendation of 25th percentile RVW 4.50 based on survey (N=42) with median intra-service time of 45 and total time of 98 minutes. This recommendation is well supported by the #1 KRS (49407: RVW 4.50 (exactly the same), Intra 45 (exactly the

same), total 110 (slightly higher)). The recommendation is also well bracketed by MPCs 55214 (RVW 3.50, Intra 30, total 79) and 52235 (RVW 5.44, Intra 45 (same as 47532), and total 94 (less than 47532)).

47533: The RUC recommends the survey 25th percentile of 4.50 work RVUs

47534: The RUC recommends the survey 25th percentile of 7.85 work RVUs

47535: Recommendation of 25th percentile RVW 4.20 based on survey (N=42) with median intra-service time of 45 and total time of 93 minutes. The societies feel that the work of 47535 is similar to 47532 and that the survey and our recommendations are therefore also consistent. This recommendation is well bracketed by the #1 and #2 KRS (36247: RVW 6.29, Intra 60, Total 131, and 32550: RVW 4.17, Intra 30, Total 90). The recommendation is also well bracketed by MPCs 52214 (RVW 3.50, Intra 30, Total 79) and 52235 (RVW 5.44, Intra 45, Total 94).

47536: The RUC recommends the survey 25th percentile of 2.86 work RVUs

47537: Recommendation of 25th percentile RVW 1.84 based on survey (N=42) with median intra-service time of 15 and total time of 52 minutes. This work is similar to 47531with the additional work of fluoroscopic drain removal. The societies feel that this extra work is reflective of clinical practice and similarly reflected in the survey median and 25th RVW. This recommendation is well bracketed by the #1 and #2 KRS (49083: RVW 2.00, Intra 25, Total 60, and 49450: RVW 1.36, Intra 10, Total 50).

47538: The RUC recommends the survey 25th percentile of 5.00 work RVUs

47539: Recommendation of 25th percentile RVW 9.00 based on survey (N=41) with median intra-service time of 75 and total time of 136 minutes. This recommendation is well bracketed by MPC 52353 (RVW 7.50, Intra 60, Total 133) and the #1 KRS (37226: RVW 10.49, Intra 90, Total 168).

47540: The RUC recommends the survey 25th percentile of 9.28 work RVUs

47541: Recommendation of 25th percentile RVW 7.00 based on survey (N=42) with median intra-service time of 60 and total time of 121 minutes. The societies feel that the intensity and complexity of this work is in between that of 47533 and 47534 based on magnitude estimation and therefore are recommending a value greater than 47533 but less than 47534. This recommendation is well bracketed by the #1 and #2 KRS (37226: RVW 10.49, Intra 90, Total 168, and 37213: RVW 5.00, Intra 33, Total 99). This recommendation is also supported by MPC 52353 (RVW 7.50, Intra 60, Total 133).

ZZZ Code Set:

47542**:** The RUC recommends the survey 25th percentile of 2.85 work RVUs

47543**:** Recommendation of 25th percentile RVW 3.00 based on survey (N=42) with median intra-service time of 30. This recommendation is well bracketed by MPC 99292 (RVW 2.25, Intra 30) and #1 KRS (37185: RVW 3.28, Intra 40).

47544**:** The RUC recommends a direct crosswalk to 37185 and 92973 (work RVU= 3.28)

PreService Time

We selected pre time package 2B for 47532, 47533, 47534, 47535, 47536, 47541, 47538, 47539, and 47540. For 47531 and 47537, we selected pre time package 2A, because moderate sedation was not inherent in those two procedures. We also added two additional minutes of positioning time to account for positioning patient on angiographic table, as well as optimize lead placement to avoid obscuring imaging.

Relativity

The consensus panel reviewed the survey data for the family this new family of biliary procedures and analyzed the relativity within the family. The consensus panel felt the appropriate recommendations for 47533, 47534, 47538 and 47542 fell between the surveyed 25th percentile and the survey median. As such, we are recommending crosswalk values for those codes.

The consensus panel reviewed the survey data and believe the recommendations compare favorably to (1) the new family of biliary codes, (2) interventional radiology and (3) MPCs. Below is an outline of the comparisons:

	CPT Code	Global Period	Work RVU	Total Time	Pre Time			Intra Time	Post Time	IWPUT
					Eval	Pos	SDW			

reference	49450	000	1.36	50	20	5	5	10	10	0.054
surveyed	47531	000	1.30	54	18	3	6	15	12	0.047
MPC	55876	000	1.73	59	19	10		20	10	0.043
surveyed	47537	000	1.84	52	18	3	6	15	10	0.073
reference	49083	000	2.00	60	15	5	5	25	10	0.052
MPC	31622	000	2.78	65	10	5	5	30	15	0.069
reference	49452	000	2.86	60	20	5	5	20	10	0.102
surveyed	47536	000	2.86	61	20	3	5	20	13	0.111
MPC	52214	000	3.50	79	19	5	5	30	20	0.083
reference	32550	000	4.17	90	15	15	10	30	20	0.099
surveyed	47535	000	4.20	93	25	3	5	45	15	0.071
reference	49407	000	4.50	110	35	5	5	45	20	0.069
surveyed	47532	000	4.50	98	30	3	5	45	15	0.075
reference	37191	000	4.71	83	30	3	5	30	15	0.120
reference	37213	000	5.00	99	33	3	5	33	25	0.109
MPC	52235	000	5.44	94	19	5	5	45	20	0.098
surveyed	47538	000	5.00	106	30	3	5	53	15	0.082
crosswalk	31267	000	5.45	110	30			50	30	0.082
reference	36247	000	6.29	131	33	3	5	60	30	0.080
surveyed	47533	000	5.63	121	33	3	5	60	20	0.083
crosswalk	37197	000	6.29	121	33	3	5	60	20	0.083
surveyed	47541	000	7.00	121	33	3	5	60	20	0.095
MPC	52353	000	7.50	133	33	5	15	60	20	0.101
reference	37211	000	8.00	138	40	3	5	60	30	0.105
surveyed	47534	000	7.85	129	33	3	5	68	20	0.107
crosswalk	43274	000	8.58	139	33	10	5	68	23	0.104
surveyed	47539	000	9.00	136	33	3	5	75	20	0.103
reference	37226	000	10.49	168	40	3	5	90	30	0.098
reference	37228	000	11.00	168	40	3	5	90	30	0.104
surveyed	47540	000	9.28	146	33	3	5	85	20	0.114
reference	37230	000	13.80	198	40	3	5	120	30	0.101
MPC	99292	ZZZ	2.25	30				30		0.075
surveyed	47542	ZZZ	2.85	30				30		0.099
crosswalk	37239	ZZZ	2.97	32	1			30	1	0.098
surveyed	47543	ZZZ	3.00	30				30		0.100
reference	37185	ZZZ	3.28	40				40		0.082
reference	37222	ZZZ	3.73	42	1			40	1	0.092
surveyed	47544	ZZZ	3.28	45				45		0.088
MPC	57267	ZZZ	4.88	45				45		0.108
reference	37235	ZZZ	7.80	82	1			80	1	0.097

Recommendations

The consensus panel reviewed the (1) RUC survey data, (2) the family relationship between the new codes, (2) the relativity to codes within interventional radiology specialty, (3) rank order within the Fee Schedule, (4) compelling evidence, (5) standard packages and (6) RUC guidelines and makes the following physician work recommendations:

CPT	Global	Work	Total	Pre Time			Intra	Post	IWPUT
Code	Period	RVU	Time	Eval	Pos	SDW	Time	Time	
47531	000	1.30	54	18	3	6	15	12	0.047
47532	000	4.50	98	30	3	5	45	15	0.075

47533	000	5.63	121	33	3	5	60	20	0.083
47534	000	7.85	129	33	3	5	68	20	0.107
47535	000	4.20	93	25	3	5	45	15	0.071
47536	000	2.86	61	20	3	5	20	13	0.111
47537	000	1.84	52	18	3	6	15	10	0.073
47538	000	5.00	106	30	3	5	53	15	0.082
47539	000	9.00	136	33	3	5	75	20	0.103
47540	000	9.28	146	33	3	5	85	20	0.114
47541	000	7.00	121	33	3	5	60	20	0.095
47542	ZZZ	2.85	30				30		0.099
47543	ZZZ	3.00	30				30		0.100
47544	ZZZ	3.28	45				45		0.088

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions: Yes

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☒ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.
   - ☐ Historical precedents.
   - ☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) 47553 and 76000

How often do physicians in your specialty perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty Interventional Radiology How often? Commonly

Specialty How often?

Specialty How often?

Estimate the number of times this service might be provided nationally in a one-year period?
If the recommendation is from multiple specialties, please provide the frequency and percentage for each specialty. Please explain the rationale for this estimate. A national number is not available.

Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? 0 If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty. Please explain the rationale for this estimate. A national number is not available.

Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%
Specialty	Frequency 0	Percentage 0.00	%

Do many physicians perform this service across the United States? Yes

---

Berenson-Eggers Type of Service (BETOS) Assignment

Please pick the appropriate BETOS classification that best corresponds to the clinical nature of this CPT code. Please select the main BETOS classification and sub-classification to the greatest level of specificity possible.

Main BETOS Classification:
Procedures

BETOS Sub-classification:
Minor procedure

BETOS Sub-classification Level II:
Other

Professional Liability Insurance Information (PLI)

If the surveyed code is an existing code and the specialty believes the specialty utilization mix will not change, enter the surveyed existing CPT code number

If this code is a new/revised code or an existing code in which the specialty utilization mix will change, please select another crosswalk based on a similar specialty mix. 22515

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:47544 Tracking Number U14 Original Specialty Recommended RVU: **3.95**
Presented Recommended RVU: **3.95**
Global Period: ZZZ RUC Recommended RVU: **3.28**

CPT Descriptor: Removal of calculi/debris from biliary duct(s) and/or gallbladder, percutaneous, including destruction of calculi by any method (eg, mechanical, electrohydraulic, lithotripsy) when performed, imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation (List separately in addition to code for primary procedure)

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A 61-year-old man presents following placement of an internal-external drain placed in the setting of cholangitis. Cholangiogram performed at the time of catheter placement demonstrated multiple filling defects in the common bile duct consistent with cholelithiasis. Calculi are consequently removed via percutaneous access during the procedure.

Percentage of Survey Respondents who found Vignette to be Typical: 94%

Site of Service (Complete for 010 and 090 Globals Only)

Percent of survey respondents who stated they perform the procedure; In the hospital 0% , In the ASC 0%, In the office 0%

Percent of survey respondents who stated they typically perform this procedure in the hospital, stated the patient is; Discharged the same day 0% , Overnight stay-less than 24 hours 0% , Overnight stay-more than 24 hours 0%

Percent of survey respondents who stated that if the patient is typically kept overnight also stated that they perform an E&M service later on the same day 0%

Moderate Sedation

Is moderate sedation inherent to this procedure in the Hospital/ASC setting? Yes
Percent of survey respondents who stated moderate sedation is typical in the Hospital/ASC setting? 94%

Is moderate sedation inherent to this procedure in the office setting? Yes
Percent of survey respondents who stated moderate sedation is typical in the office setting? 93%

Description of Pre-Service Work:

Description of Intra-Service Work: Separately reportable removal of the existing tube is performed over a wire (tip in small bowel). A sheath is placed over the wire. Cholangiogram is performed. Through the sheath, a balloon catheter is placed and the balloon inflated. The balloon catheter is advanced over the wire and through the ampulla multiple times, clearing the bile ducts of cholelithiases. The balloon catheter is removed. Cholangiography is performed through the sheath to assess adequacy of stone removal. The sheath is exchanged over the wire and a separately reportable internal/external biliary drainage catheter is placed.

Description of Post-Service Work:

SURVEY DATA

RUC Meeting Date (mm/yyyy)	10/2015				
Presenter(s):	Jerry Niedzwiecki, MD, Michael Hall, MD, Bob Vogelzang, MD, Tim Swan, MD, Matt Hawkins, MD, Zeke Silva, MD and Kurt Schoppe, MD				
Specialty(s):	Interventional Radiology				
CPT Code:	47544				
Sample Size:	1730	**Resp N:**	32	**Response:** 1.8 %	
Description of Sample:	Random Sample: SIR 980/ACR 750				

	Low	25th pctl	Median*	75th pctl	High
Service Performance Rate	0.00	2.00	**3.00**	5.00	35.00
Survey RVW:	2.00	3.95	**5.50**	8.00	16.40
Pre-Service Evaluation Time:			**0.00**		
Pre-Service Positioning Time:			**0.00**		
Pre-Service Scrub, Dress, Wait Time:			**0.00**		
Intra-Service Time:	10.00	25.00	**45.00**	75.00	200.00

Immediate Post Service-Time:	**0.00**	
Post Operative Visits	**Total Min****	**CPT Code and Number of Visits**
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.00** 99239x **0.00** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

**Physician standard total minutes per E/M visit: 99291 (70); 99292 (30); 99231 (20); 99232 (40); 99233 (55); 99238(38); 99239 (55); 99217 (38); 99211 (7); 99212 (16); 99213 (23); 99214 (40); 99215 (55); 99224 (20); 99225 (40); 99226 (55); 99354 (60); 99355 (30); 99356 (60); 99357 (30)

Specialty Society Recommended Data

Please, pick the pre-service time package that best corresponds to the data which was collected in the survey process. (Note: your recommended pre time should not exceed your survey median time for any category)

ZZZ Global Code

CPT Code:	47544	**Recommended Physician Work RVU: 3.28**		
		Specialty Recommended Pre-Service Time	**Specialty Recommended Pre Time Package**	**Adjustments/Recommended Pre-Service Time**
Pre-Service Evaluation Time:		**0.00**	**0.00**	**0.00**
Pre-Service Positioning Time:		**0.00**	**0.00**	**0.00**
Pre-Service Scrub, Dress, Wait Time:		**0.00**	**0.00**	**0.00**
Intra-Service Time:		**45.00**		

Please, pick the post-service time package that best corresponds to the data which was collected in the survey process: (Note: your recommended post time should not exceed your survey median time)

ZZZ Global Code

	Specialty Recommended Post-Service Time	**Specialty Recommended Post Time Package**	**Adjustments/Recommended Post-Service Time**
Immediate Post Service-Time:	**0.00**	**0.00**	**0.00**

Post-Operative Visits	Total Min**	CPT Code and Number of Visits
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.0** 99239x **0.0** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

Modifier -51 Exempt Status

Is the recommended value for the new/revised procedure based on its modifier -51 exempt status? No

New Technology/Service:

Is this new/revised procedure considered to be a new technology or service? No

TOP KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
37185	ZZZ	3.28	**RUC Time**

CPT Descriptor Primary percutaneous transluminal mechanical thrombectomy, noncoronary, arterial or arterial bypass graft, including fluoroscopic guidance and intraprocedural pharmacological thrombolytic injection(s); second and all subsequent vessel(s) within the same vascular family (List separately in addition to code for primary mechanical thrombectomy procedure)

SECOND HIGHEST KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
37235	ZZZ	7.80	**RUC Time**

CPT Descriptor Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)

KEY MPC COMPARISON CODES:

Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU	Time Source	Most Recent Medicare Utilization
57267	ZZZ	4.88	**RUC Time**	8,063

CPT Descriptor 1 Insertion of mesh or other prosthesis for repair of pelvic floor defect, each site (anterior, posterior compartment), vaginal approach (List separately in addition to code for primary procedure)

MPC CPT Code 2	Global	Work RVU	Time Source	Most Recent Medicare Utilization
		0.00		

CPT Descriptor 2

Other Reference CPT Code	Global	Work RVU	Time Source
		0.00	

CPT Descriptor

RELATIONSHIP OF CODE BEING REVIEWED TO TOP TWO KEY REFERENCE SERVICES:
Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the top two chosen key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Top Key Reference Code: 9 **% of respondents:** 28.1 **%**

Number of respondents who choose 2nd Key Reference Code: 8 **% of respondents:** 25.0 **%**

TIME ESTIMATES (Median)

	CPT Code: 47544	**Top Key Reference CPT Code:** 37185	**2nd Key Reference CPT Code:** **37235**
Median Pre-Service Time	0.00	0.00	1.00
Median Intra-Service Time	45.00	40.00	80.00
Median Immediate Post-service Time	0.00	0.00	1.00
Median Critical Care Time	0.0	0.00	0.00
Median Other Hospital Visit Time	0.0	0.00	0.00
Median Discharge Day Management Time	0.0	0.00	0.00
Median Office Visit Time	0.0	0.00	0.00
Prolonged Services Time	0.0	0.00	0.00
Median Subsequent Observation Care Time	0.0	0.00	0.00
Median Total Time	**45.00**	**40.00**	**82.00**
Other time if appropriate			

INTENSITY/COMPLEXITY MEASURES
(of those that selected Key Reference codes)

Survey respondents are rating the survey code relative to the key reference code.

Intensity & Complexity Rating Scale: (much less= -2.00, somewhat less= -1.00, identical= 0.00, somewhat more= 1.00, much more= 2.00)

	Top Key Ref Code	**2nd Key Ref Code**
Mental Effort and Judgment (Mean)		
The number of possible diagnosis and/or the number of management options that must be considered		
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed		
Urgency of medical decision making		
Technical Skill/Physical Effort (Mean)		
Technical skill required		

Physical effort required		

Psychological Stress (Mean)

The risk of significant complications, morbidity and/or mortality		
Outcome depends on the skill and judgment of physician		
Estimated risk of malpractice suit with poor outcome		

INTENSITY/COMPLEXITY MEASURES	**Top Key Ref Code**	**2nd Key Ref Code**
Time Segment (Mean)		
Overall intensity/complexity	0.22	0.50

Additional Rationale and Comments

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

The Joint CPT-RUC Workgroup identified (Group 12) codes 47500, 74320-26, 47505, 74305-26, 47510, 75980-26, 47511, 75982-26, 74305-26, 47505, 74320-26, 47500, 75980-26, 47510, 75982-26 as being reported together at least 75% of the time. The specialties updated the percutaneous biliary code family based on the current practice of medicine, and in so doing, deleted 10 percutaneous biliary procedure codes while creating 14 new bundled codes that describe percutaneous biliary procedures including imaging.

This new 'biliary family' was recently surveyed and presented at the April 2015 RUC meeting. However, the RUC and specialty societies agreed that the survey data for this family of services was problematic. Specifically, the RUC noted codes 47532, 47533 and 47534 all had identical median intra-service time of 60 minutes. CPT code 47533 includes the work of 47532 plus the work of an additional access and drain placement. Furthermore, 47534 includes the work of 47533 plus the work of crossing the occlusion and placement of an internal/external drain. Given this time anomaly, the RUC agreed to provide interim recommendations at this meeting, while allowing the specialty societies to re-survey the entire family of codes for October 2015.

The specialty societies worked with the research subcommittee to develop a modified survey tool in an attempt to facilitate gathering more accurate rank order survey data from the surveyed physicians. The entire family of codes was included on one single survey. The research subcommittee approved this survey method, which collected:
• overall complexity/intensity data;
• service performance rates for just the surveyed codes; and
• only whether the vignette is typical or not.
We did not ask for them to provide details if the vignette is not typical.

Compelling Evidence
SIR/ACR believe that the current values for CPT codes now used for the percutaneous, image guided biliary interventional procedures newly described in Tab 4 are no longer rational or appropriate for the detailed, granular and far more accurately descriptive codes in this new group. In our opinion, there have been significant changes in technique, knowledge and technology, patient population and physician time.

Technique, Knowledge and Technology
The codes currently used for this family of biliary procedures no longer reflect the techniques now used for image-guided, catheter-based biliary procedures. Indeed, as can be seen, there are 14 new codes in this family which will henceforth be used to describe a diverse range of procedures. As an index example of these significant changes in technique, one of the most widely used of the current codes, 47510, *Introduction of percutaneous transhepatic catheter for biliary drainage*, was previously performed by a method in which the biliary tree was first opacified and often distended by blind needle puncture (not ultrasound), after which an optimal duct was identified and punctured under fluoroscopy using large sheathed needles or even the trocar technique. These techniques have all changed since this code was introduced and valued as noted below.

Virtually all the medical devices currently used in biliary catheter procedures have been developed since the current codes were adopted. The past twenty years have witnessed major advances in our knowledge base including:
1) using imaging guidance, such as ultrasound, and preoperative mapping to avoid hepatic hilar structures and thus prevent bleeding and bile leaks
2) new insights into how segmental biliary ductal anatomy can help avoid bleeding and septic complications
3) development of much less aggressive and safer guidewire-based methods which involve more steps and more effort, skill and physician time such as micropuncture access with gradual stepwise transition to heavy-duty guidewires, tract dilation and placement of catheters over safer, more stable wires and use of real-time ultrasound guidance for needle access. The ductal system is never distended to avoid septic complications.

We would note that the example of 47510 is reflective of the majority of the existing codes for biliary catheter procedures. Simply put, the new codes reflect new thinking and understanding as well as considerable improvements and advances in techniques which render the current values inappropriate for these new codes.

In another example, the existing code 47511, *Introduction of percutaneous transhepatic stent for internal and external biliary drainage*. Current methods utilize a wide range of self-expanding open, as well as covered, metallic stents of various designs designed specifically for biliary pathology and using percutaneous methods as well as plastic and even retrievable metallic stents. These devices were not available when the existing codes were proposed or adopted.

A number of the codes, for example, 47543, *Endoluminal biopsy(ies) of biliary tree, percutaneous, any method(s) (eg, brush, forceps and/or needle)*, 47544 *Removal of calculi/debris from biliary duct(s) and/or gallbladder, percutaneous, including destruction of calculi by any method (eg, mechanical, electrohydraulic, lithotripsy)*, 47542, *Balloon dilation of biliary duct(s) or of ampulla (sphincteroplasty), percutaneous*, or 47541, *Placement of access through the biliary tree and into small bowel to assist with an endoscopic biliary procedure (eg, rendezvous procedure), percutaneous*, describe procedures which did not exist previously and, thus, are new technology not able to be described at all under the old codes.

Patient Population

SIR/ACR assert that the population of patients treated with the new family of procedures described herein has changed considerably in at least three major ways:

1) Previously the majority of all biliary catheter procedures were used for basic relief of distal ductal biliary obstruction either acutely or chronically often related to pancreatic cancer and/or stone disease. These patients previously drained and stented percutaneously are now largely treated by endoscopic methods. The significant majority of all of the biliary diseases referred for interventional percutaneous treatment now have higher and more complex levels of benign and malignant biliary occlusion, including hilar and segmental obstruction. Treatment of these lesions involves considerably more work, time, effort and risk to achieve satisfactory outcomes.
2) The widespread use of liver transplantation has introduced an entirely different patient population: the postoperative liver transplant patient with ischemic biliary strictures (intrahepatic and/or extrahepatic), which requires major investments of time, skill and effort to obtain access and drain, stent and dilate these complex situations.
3) Hepatic surgery for malignancy has also become far more sophisticated and segmental or lobar resections will frequently result in referrals for drainage of biliary leaks from nondilated ducts. These patients also present challenges in drainage and management.

An example of the change in patient populations can also be seen in the management of biliary stone disease. Previously, patients with distal biliary calculi were referred for external biliary drainage and stone manipulation. These patients are no longer sent for percutaneous treatment. The stone diseases seen currently are intrahepatic lithiasis or extensive stone formation as a result of biliary-enteric anastomoses both of which require far more skill and time to achieve satisfactory initial access but also need much different time-consuming and labor intensive methods to extract or expel the stones.

New Biliary Family

The CPT editorial panel established 14 bundled codes that describe percutaneous biliary procedures including imaging. Below is a table demonstrating the relationship between the new codes:

000 Code Set:

47531: Direct crosswalk to 46611 (work RVU= 1.30)

47532: Recommendation of 25th percentile RVW 4.50 based on survey (N=42) with median intra-service time of 45 and total time of 98 minutes. This recommendation is well supported by the #1 KRS (49407: RVW 4.50 (exactly the same), Intra 45 (exactly the

same), total 110 (slightly higher)). The recommendation is also well bracketed by MPCs 55214 (RVW 3.50, Intra 30, total 79) and 52235 (RVW 5.44, Intra 45 (same as 47532), and total 94 (less than 47532)).

47533: The RUC recommends the survey 25th percentile of 4.50 work RVUs

47534: The RUC recommends the survey 25th percentile of 7.85 work RVUs

47535: Recommendation of 25th percentile RVW 4.20 based on survey (N=42) with median intra-service time of 45 and total time of 93 minutes. The societies feel that the work of 47535 is similar to 47532 and that the survey and our recommendations are therefore also consistent. This recommendation is well bracketed by the #1 and #2 KRS (36247: RVW 6.29, Intra 60, Total 131, and 32550: RVW 4.17, Intra 30, Total 90). The recommendation is also well bracketed by MPCs 52214 (RVW 3.50, Intra 30, Total 79) and 52235 (RVW 5.44, Intra 45, Total 94).

47536: The RUC recommends the survey 25th percentile of 2.86 work RVUs

47537: Recommendation of 25th percentile RVW 1.84 based on survey (N=42) with median intra-service time of 15 and total time of 52 minutes. This work is similar to 47531with the additional work of fluoroscopic drain removal. The societies feel that this extra work is reflective of clinical practice and similarly reflected in the survey median and 25th RVW. This recommendation is well bracketed by the #1 and #2 KRS (49083: RVW 2.00, Intra 25, Total 60, and 49450: RVW 1.36, Intra 10, Total 50).

47538: The RUC recommends the survey 25th percentile of 5.00 work RVUs

47539: Recommendation of 25th percentile RVW 9.00 based on survey (N=41) with median intra-service time of 75 and total time of 136 minutes. This recommendation is well bracketed by MPC 52353 (RVW 7.50, Intra 60, Total 133) and the #1 KRS (37226: RVW 10.49, Intra 90, Total 168).

47540: The RUC recommends the survey 25th percentile of 9.28 work RVUs

47541: Recommendation of 25th percentile RVW 7.00 based on survey (N=42) with median intra-service time of 60 and total time of 121 minutes. The societies feel that the intensity and complexity of this work is in between that of 47533 and 47534 based on magnitude estimation and therefore are recommending a value greater than 47533 but less than 47534. This recommendation is well bracketed by the #1 and #2 KRS (37226: RVW 10.49, Intra 90, Total 168, and 37213: RVW 5.00, Intra 33, Total 99). This recommendation is also supported by MPC 52353 (RVW 7.50, Intra 60, Total 133).

ZZZ Code Set:

47542**:** The RUC recommends the survey 25th percentile of 2.85 work RVUs

47543**:** Recommendation of 25th percentile RVW 3.00 based on survey (N=42) with median intra-service time of 30. This recommendation is well bracketed by MPC 99292 (RVW 2.25, Intra 30) and #1 KRS (37185: RVW 3.28, Intra 40).

47544**:** The RUC recommends a direct crosswalk to 37185 and 92973 (work RVU= 3.28)

PreService Time

We selected pre time package 2B for 47532, 47533, 47534, 47535, 47536, 47541, 47538, 47539, and 47540. For 47531 and 47537, we selected pre time package 2A, because moderate sedation was not inherent in those two procedures. We also added two additional minutes of positioning time to account for positioning patient on angiographic table, as well as optimize lead placement to avoid obscuring imaging.

Relativity

The consensus panel reviewed the survey data for the family this new family of biliary procedures and analyzed the relativity within the family. The consensus panel felt the appropriate recommendations for 47533, 47534, 47538 and 47542 fell between the surveyed 25th percentile and the survey median. As such, we are recommending crosswalk values for those codes.

The consensus panel reviewed the survey data and believe the recommendations compare favorably to (1) the new family of biliary codes, (2) interventional radiology and (3) MPCs. Below is an outline of the comparisons:

	CPT Code	Global Period	Work RVU	Total Time	Pre Time			Intra Time	Post Time	IWPUT
					Eval	Pos	SDW			

reference	49450	000	1.36	50	20	5	5	10	10	0.054
surveyed	47531	000	1.30	54	18	3	6	15	12	0.047
MPC	55876	000	1.73	59	19	10		20	10	0.043
surveyed	47537	000	1.84	52	18	3	6	15	10	0.073
reference	49083	000	2.00	60	15	5	5	25	10	0.052
MPC	31622	000	2.78	65	10	5	5	30	15	0.069
reference	49452	000	2.86	60	20	5	5	20	10	0.102
surveyed	47536	000	2.86	61	20	3	5	20	13	0.111
MPC	52214	000	3.50	79	19	5	5	30	20	0.083
reference	32550	000	4.17	90	15	15	10	30	20	0.099
surveyed	47535	000	4.20	93	25	3	5	45	15	0.071
reference	49407	000	4.50	110	35	5	5	45	20	0.069
surveyed	47532	000	4.50	98	30	3	5	45	15	0.075
reference	37191	000	4.71	83	30	3	5	30	15	0.120
reference	37213	000	5.00	99	33	3	5	33	25	0.109
MPC	52235	000	5.44	94	19	5	5	45	20	0.098
surveyed	47538	000	5.00	106	30	3	5	53	15	0.082
crosswalk	31267	000	5.45	110	30			50	30	0.082
reference	36247	000	6.29	131	33	3	5	60	30	0.080
surveyed	47533	000	5.63	121	33	3	5	60	20	0.083
crosswalk	37197	000	6.29	121	33	3	5	60	20	0.083
surveyed	47541	000	7.00	121	33	3	5	60	20	0.095
MPC	52353	000	7.50	133	33	5	15	60	20	0.101
reference	37211	000	8.00	138	40	3	5	60	30	0.105
surveyed	47534	000	7.85	129	33	3	5	68	20	0.107
crosswalk	43274	000	8.58	139	33	10	5	68	23	0.104
surveyed	47539	000	9.00	136	33	3	5	75	20	0.103
reference	37226	000	10.49	168	40	3	5	90	30	0.098
reference	37228	000	11.00	168	40	3	5	90	30	0.104
surveyed	47540	000	9.28	146	33	3	5	85	20	0.114
reference	37230	000	13.80	198	40	3	5	120	30	0.101
MPC	99292	ZZZ	2.25	30				30		0.075
surveyed	47542	ZZZ	2.85	30				30		0.099
crosswalk	37239	ZZZ	2.97	32	1			30	1	0.098
surveyed	47543	ZZZ	3.00	30				30		0.100
reference	37185	ZZZ	3.28	40				40		0.082
reference	37222	ZZZ	3.73	42	1			40	1	0.092
surveyed	47544	ZZZ	3.28	45				45		0.088
MPC	57267	ZZZ	4.88	45				45		0.108
reference	37235	ZZZ	7.80	82	1			80	1	0.097

Recommendations

The consensus panel reviewed the (1) RUC survey data, (2) the family relationship between the new codes, (2) the relativity to codes within interventional radiology specialty, (3) rank order within the Fee Schedule, (4) compelling evidence, (5) standard packages and (6) RUC guidelines and makes the following physician work recommendations:

CPT	Global	Work	Total	Pre Time			Intra	Post	IWPUT
Code	Period	RVU	Time	Eval	Pos	SDW	Time	Time	
47531	000	1.30	54	18	3	6	15	12	0.047
47532	000	4.50	98	30	3	5	45	15	0.075

47533	000	5.63	121	33	3	5	60	20	0.083
47534	000	7.85	129	33	3	5	68	20	0.107
47535	000	4.20	93	25	3	5	45	15	0.071
47536	000	2.86	61	20	3	5	20	13	0.111
47537	000	1.84	52	18	3	6	15	10	0.073
47538	000	5.00	106	30	3	5	53	15	0.082
47539	000	9.00	136	33	3	5	75	20	0.103
47540	000	9.28	146	33	3	5	85	20	0.114
47541	000	7.00	121	33	3	5	60	20	0.095
47542	ZZZ	2.85	30				30		0.099
47543	ZZZ	3.00	30				30		0.100
47544	ZZZ	3.28	45				45		0.088

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions: Yes

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☒ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.
   - ☐ Historical precedents.
   - ☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) 47630 and 74327

How often do physicians in your specialty perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty Interventional Radiology How often? Commonly

Specialty How often?

Specialty How often?

Estimate the number of times this service might be provided nationally in a one-year period?
If the recommendation is from multiple specialties, please provide the frequency and percentage for each specialty. Please explain the rationale for this estimate. A national number is not available.

Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? 0 If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty. Please explain the rationale for this estimate. A national number is not available.

Specialty	Frequency	Percentage	%
Specialty	Frequency	Percentage	%
Specialty	Frequency 0	Percentage 0.00	%

Do many physicians perform this service across the United States? Yes

---

Berenson-Eggers Type of Service (BETOS) Assignment

Please pick the appropriate BETOS classification that best corresponds to the clinical nature of this CPT code. Please select the main BETOS classification and sub-classification to the greatest level of specificity possible.

Main BETOS Classification:
Procedures

BETOS Sub-classification:
Minor procedure

BETOS Sub-classification Level II:
Other

Professional Liability Insurance Information (PLI)

If the surveyed code is an existing code and the specialty believes the specialty utilization mix will not change, enter the surveyed existing CPT code number

If this code is a new/revised code or an existing code in which the specialty utilization mix will change, please select another crosswalk based on a similar specialty mix. 37235

SS Rec Summary

ISSUE: Percutaneous Biliary Procedures Bundling

TAB: 4

Source	CPT	DESC	Resp	IWPUT	RVW MIN	RVW 25th	RVW MED	RVW 75th	RVW MAX	Total Time	PRE-TIME EVAL	PRE-TIME POSIT	PRE-TIME SDW	INTRA-TIME MIN	INTRA-TIME 25th	INTRA-TIME MED	INTRA-TIME 75th	INTRA-TIME MAX	IMMD POST	SURVEY EXPERIENCE MIN	SURVEY EXPERIENCE 25th	SURVEY EXPERIENCE MED	SURVEY EXPERIENCE 75th	SURVEY EXPERIENCE MAX
REF	37222	Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal angioplasty (List separately in addition to code for primary procedure)	10	0.092			3.73			42	1					40			1					
REF	37185	Primary percutaneous transluminal mechanical thrombectomy, noncoronary, arterial or arterial bypass graft, including fluoroscopic guidance and intraprocedural pharmacological thrombolytic injection(s); second and all subsequent vessel(s) within the same vascular family (List separately in addition to code for primary mechanical thrombectomy procedure)	9	0.082			3.28			40						40								
CURRENT	74363	Percutaneous transhepatic dilation of biliary duct stricture with or without					0.88			18														
CURRENT	47555	Biliary endoscopy, percutaneous via T-tube or other tract;with dilation of biliary		0.094			7.55	8.43		135	21		25			68			21					
SVY	47531	Balloon dilation of biliary duct(s) or of ampulla (sphincteroplasty), percutaneous, including imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation, each duct (List separately in addition to code for primary procedure)	42	0.125	1.00	2.85	3.74	4.00	12.00	30				10	15	30	50	150		1	3	6	15	33
REC	47542			0.099			2.85			30						30								

SS Rec Summary

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	AO	AP	AQ	AR	AS
14						RVW					Total	PRE-TIME			INTRA-TIME					IMMD	SURVEY EXPERIENCE				
15	Source	CPT	DESC	Resp	IWPUT	MIN	25th	MED	75th	MAX	Time	EVAL	POSIT	SDW	MIN	25th	MED	75th	MAX	POST	MIN	25th	MED	75th	MAX
22																									
23																									
24																									
25						RVW					Total	PRE-TIME			INTRA-TIME					IMMD	SURVEY EXPERIENCE				
26	Source	CPT	DESC	Resp	IWPUT	MIN	25th	MED	75th	MAX	Time	EVAL	POSIT	SDW	MIN	25th	MED	75th	MAX	POST	MIN	25th	MED	75th	MAX
27	REF	37185	Primary percutaneous transluminal mechanical thrombectomy, noncoronary, arterial or arterial bypass graft, including fluoroscopic guidance and intraprocedural pharmacological thrombolytic injection(s); second and all subsequent vessel(s) within the same vascular family (List separately in addition to code for primary mechanical thrombectomy procedure)	13	0.082			3.28			40						40									
28	REF	37222	Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal angioplasty (List separately in addition to code for primary procedure)	9	0.092			3.73			42	1					40			1					
29	CURRENT	47553	Biliary endoscopy, percutaneous via T-tube or other tract; with biopsy, single or		0.110			6.34			111	19		25			48			19					
30	CURRENT	76000	Fluoroscopy (separate procedure), up to 1 hour physician or other qualified health					0.17			5														
31	SVY	47543	Endoluminal biopsy(ies) of biliary tree, percutaneous, any method(s) (eg, brush, forceps and/or needle), including imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation, single or multiple (List separately in addition to code for primary procedure)	42	0.127	1.50	3.00	3.80	4.00	12.00	30				10	15	30	45	150		0	2	5	13	40
32	REC	47543			0.100			3.00			30						30								

SS Rec Summary

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	AO	AP	AQ	AR	AS
14						RVW					Total	PRE-TIME			INTRA-TIME					IMMD	SURVEY EXPERIENCE				
15	Source	CPT	DESC	Resp	IWPUT	MIN	25th	MED	75th	MAX	Time	EVAL	POSIT	SDW	MIN	25th	MED	75th	MAX	POST	MIN	25th	MED	75th	MAX
33																									
34																									
35						RVW					Total	PRE-TIME			INTRA-TIME					IMMD	SURVEY EXPERIENCE				
36	Source	CPT	DESC	Resp	IWPUT	MIN	25th	MED	75th	MAX	Time	EVAL	POSIT	SDW	MIN	25th	MED	75th	MAX	POST	MIN	25th	MED	75th	MAX
37	REF	37185	Primary percutaneous transluminal mechanical thrombectomy, noncoronary, arterial or arterial bypass graft, including fluoroscopic guidance and intraprocedural pharmacological thrombolytic injection(s); second and all subsequent vessel(s) within the same vascular family (List separately in addition to code for primary mechanical thrombectomy procedure)	9	0.082			3.28			40						40									
38	REF	37235	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)	8	0.097			7.80			82	1					80			1					
39	CURRENT	47630	Biliary duct stone extraction, percutaneous via T-tube tract, basket, or		-0.037			4.51			274	27		25			52			22					
40	CURRENT	74327	Postoperative biliary duct calculus removal, percutaneous via T-tube tract,					0.70			14														
41	SVY	47544	Removal of calculi/debris from biliary duct(s) and/or gallbladder, percutaneous, including destruction of calculi by any method (eg, mechanical, electrohydraulic, lithotripsy) when performed, imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation (List separately in addition to code for primary procedure)	32	0.122	2.00	3.95	5.50	8.00	16.40	45				10	25	45	75	200		0	2	3	5	35
42	REC	47544	direct crosswalk to 37185 and 92973		0.073			3.28			45						45								
43																									
44																									
45																									
46																									

SS Rec Summary

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	AO	AP	AQ	AR	AS
14						RVW					Total	PRE-TIME			INTRA-TIME					IMMD	SURVEY EXPERIENCE				
15	**Source**	**CPT**	**DESC**	**Resp**	**IWPUT**	MIN	25th	MED	75th	MAX	Time	EVAL	POSIT	SDW	MIN	25th	MED	75th	MAX	**POST**	**MIN**	**25th**	**MED**	**75th**	**MAX**
47																									

4
5
12
13
14
Tab Number

Percutaneous Biliary Procedures Bundling
Intracranial Endovascular Intervention
Abdominal Aorta Ultrasound Screening
Fluoroscopic Guidance
Moderate Sedation Services
Issue

475XX1-475XX14
61640-61642
767X1
77001-77003
991X1X-991X2X
Code Range

Attestation Statement

This form needs to be completed by any **RUC Advisor** whose specialty society is developing a recommendation to be reviewed by the RUC.

As a RUC Advisor, I attest that the integrity of the RUC survey, summary of recommendation forms and practice expense recommendations are based on accurate and complete data to the best of my knowledge. As a RUC advisor, I acknowledge that violations would be addressed by the executive committee (i.e., RUC Chair, AMA Representative and Alternate AMA Representative.)

Signature

Kurt A. Schoppe, MD
Printed Signature

American College of Radiology
Specialty Society

September 8, 2015
Date

4
5
12
13
14
Tab Number

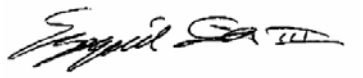
Percutaneous Biliary Procedures Bundling
Intracranial Endovascular Intervention
Abdominal Aorta Ultrasound Screening
Fluoroscopic Guidance
Moderate Sedation Services
Issue

475XX1-475XX14
61640-61642
767X1
77001-77003
991X1X-991X2X
Code Range

Attestation Statement

This form needs to be completed by any **RUC Advisor** whose specialty society is developing a recommendation to be reviewed by the RUC.

As a RUC Advisor, I attest that the integrity of the RUC survey, summary of recommendation forms and practice expense recommendations are based on accurate and complete data to the best of my knowledge. As a RUC advisor, I acknowledge that violations would be addressed by the executive committee (i.e., RUC Chair, AMA Representative and Alternate AMA Representative.)



Signature

Ezequiel Silva, III, MD, FACR
Printed Signature

American College of Radiology
Specialty Society

September 8, 2015
Date

Tab 4 Percutaneous Biliary Procedures Bundling (47531-47544)
Tab 5 Intracranial Endovascular Intervention (61460 – 61462)
Tab 12 Abdominal Aorta Ultrasound Screening (767X1)
Tab 13 Fluoroscopic Guidance (77001-77003)
Tab 14 Moderate Sedation Services (991X1X-991X4X)

Attestation Statement

This form needs to be completed by any **RUC Advisor** whose specialty society is developing a recommendation to be reviewed by the RUC.

As a RUC Advisor, I attest that the integrity of the RUC survey, summary of recommendation forms and practice expense recommendations are based on accurate and complete data to the best of my knowledge. As a RUC advisor, I acknowledge that violations would be addressed by the executive committee (i.e., RUC Chair , AMA Representative and Alternate AMA Representative.)

Signature

Michael Hall, MD
Printed Signature

The Society of Interventional Radiology (SIR)
Specialty Society

9/04/2015
Date

CPT Code: 47531-47544
Specialty Society('s): SIR and ACR

AMA/Specialty Society Update Process
Practice Expense Summary of Recommendation
Non Facility Direct Inputs

Global Period: 000 **Meeting Date:** 10/2015

CPT Long Descriptor:
47531 Injection procedure for cholangiography, percutaneous, complete diagnostic procedure including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; existing access

47532 Injection procedure for cholangiography, percutaneous, complete diagnostic procedure including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; new access (eg, percutaneous transhepatic cholangiogram)

47533 Placement of biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; external

47534 Placement of biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; internal-external

47535 Conversion of external biliary drainage catheter to internal-external biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation

47536 Exchange of biliary drainage catheter (eg. external, internal-external , or conversion of internal-external to external only), percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation

47537 Removal of biliary drainage catheter, percutaneous, requiring fluoroscopic guidance (eg, with concurrent indwelling biliary stents), including diagnostic cholangiography when performed, imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation

47541 Placement of access through the biliary tree and into small bowel to assist with an endoscopic biliary procedure (eg, rendezvous procedure), percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; new access

47538 Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (eg, fluoroscopy and/or ultrasound), balloon dilation, catheter exchange or removal when performed, and all associated radiological supervision and interpretation, each stent; existing access

47539 Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (eg, fluoroscopy and/or ultrasound), balloon dilation, catheter exchange or removal when performed, and all associated radiological supervision and interpretation, each stent; new access, without placement of separate biliary drainage catheter

47540 Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (eg, fluoroscopy and/or ultrasound), balloon dilation, catheter exchange or removal when performed, and all associated radiological supervision and interpretation, each stent; new access, with placement of separate biliary drainage catheter (eg, external or internal-external)

Global Period: ZZZ **Meeting Date:** 10/2015

47542 Balloon dilation of biliary duct(s) or of ampulla (sphincteroplasty), percutaneous, including imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation, each duct (List separately in addition to code for primary procedure)

47543 Endoluminal biopsy(ies) of biliary tree, percutaneous, any method(s) (eg, brush, forceps and/or needle), including imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation, single or multiple (List separately in addition to code for primary procedure)

47544 Removal of calculi/debris from biliary duct(s) and/or gallbladder, percutaneous, including destruction of calculi by any method (eg, mechanical, electrohydraulic, lithotripsy) when performed, imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation (List separately in addition to code for primary procedure)

---

1. Please provide a brief description of the process used to develop your recommendation and the composition of your Specialty Society Practice Expense Committee:

SIR and ACR convened a panel that included a number of experts familiar with these services to evaluate the direct practice expense inputs for this newly created CPT code.

2. You must provide reference code(s) for comparison on your spreadsheet. If the code you are making recommendations on is a revised code you must use the current PE direct inputs for the code as your comparison. You must provide an explanation for the selection of reference codes. Reference Code Rationale:

We included the practice expense inputs for CPT code 47525, one of the components of the currently coded scenarios that is priced in the office. We also included the recently passed practice expense inputs for a comparable GU code, 5039X4, *Placement of nephroureteral catheter, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; new access,* from the February 2015 PE meeting. We believe using both sets of data provides a good framework for our recommendations.

3. If you are recommending more minutes than the PE Subcommittee standards you must provide evidence to justify the time:

We are including pre service minutes for completing diagnostic forms. We believe our recommendation appropriately reflects the minimal use of clinical staff for that activity.

We are also requesting 6 minutes for cleaning the room, 3 minutes above the standard. These additional minutes are necessary considering these procedures generate external fluids, which require additional cleaning time. The clinical staff also needs time to clean the imaging equipment (in addition to the standard time to clean the angio room/equipment).

4. If you are requesting an increase over the current inputs in clinical staff time, supplies or equipment you must provide compelling evidence:

N/A

5. Please describe in detail the clinical activities of your staff:

Pre-Service Clinical Labor Activities:

Complete pre-service diagnostic & referral forms
Availability of prior images confirmed and reviewed
Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist

Intra-Service Clinical Labor Activities:

Prepare room, equipment, supplies
Patient is greeted, gowned and escorted into procedure room
Prepare and position patient prone on table / obtain vitals / set up IV / monitor patient
Sterile prep performed and draping of target site
Nurse administers conscious sedation and pre-procedure prophylactic antibiotics (as noted)
Assist physician in performing procedure
Assist in specimen collection processing. (x3, x4)
Monitor pt. following service/check tubes, monitors, drains not related to moderate sedation
Clean room/equipment by physician staff
Complete diagnostic forms, lab & X-ray requisitions
Check dressings & wound/ home care instructions /coordinate office visits /prescriptions
Technologist archives and QC's images to/in PACS, checking for all images and dose page
Review examination with interpreting MD
Exam documents scanned into PACS. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue

Post-Service Clinical Labor Activities:

Conduct phone calls/call in prescriptions

CPT Code: 47531-47544
Specialty Society('s): SIR and ACR

AMA/Specialty Society Update Process
Practice Expense Summary of Recommendation
Facility Direct Inputs

Global Period: 000 **Meeting Date:** 010/2015

CPT Long Descriptor:
47531 Injection procedure for cholangiography, percutaneous, complete diagnostic procedure including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; existing access

47532 Injection procedure for cholangiography, percutaneous, complete diagnostic procedure including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; new access (eg, percutaneous transhepatic cholangiogram)

47533 Placement of biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; external

47534 Placement of biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; internal-external

47535 Conversion of external biliary drainage catheter to internal-external biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation

47536 Exchange of biliary drainage catheter (eg. external, internal-external , or conversion of internal-external to external only), percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation

47537 Removal of biliary drainage catheter, percutaneous, requiring fluoroscopic guidance (eg, with concurrent indwelling biliary stents), including diagnostic cholangiography when performed, imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation

47541 Placement of access through the biliary tree and into small bowel to assist with an endoscopic biliary procedure (eg, rendezvous procedure), percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; new access

47538 Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (eg, fluoroscopy and/or ultrasound), balloon dilation, catheter exchange or removal when performed, and all associated radiological supervision and interpretation, each stent; existing access

47539 Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (eg, fluoroscopy and/or ultrasound), balloon dilation, catheter exchange or removal when performed, and all associated radiological supervision and interpretation, each stent; new access, without placement of separate biliary drainage catheter

47540 Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (eg, fluoroscopy and/or ultrasound), balloon dilation, catheter exchange or removal when performed, and all associated radiological supervision and interpretation, each stent; new access, with placement of separate biliary drainage catheter (eg, external or internal-external)

Global Period: ZZZ **Meeting Date:** 10/2015

47542 Balloon dilation of biliary duct(s) or of ampulla (sphincteroplasty), percutaneous, including imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation, each duct (List separately in addition to code for primary procedure)

47543 Endoluminal biopsy(ies) of biliary tree, percutaneous, any method(s) (eg, brush, forceps and/or needle), including imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation, single or multiple (List separately in addition to code for primary procedure)

47544 Removal of calculi/debris from biliary duct(s) and/or gallbladder, percutaneous, including destruction of calculi by any method (eg, mechanical, electrohydraulic, lithotripsy) when performed, imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation (List separately in addition to code for primary procedure)

---

1. Please provide a brief description of the process used to develop your recommendation and the composition of your Specialty Society Practice Expense Committee:

SIR and ACR convened a panel that included a number of experts familiar with these services to evaluate the direct practice expense inputs for this newly created CPT code.

2. You must provide reference code(s) for comparison on your spreadsheet. If the code you are making recommendations on is a revised code you must use the current PE direct inputs for the code as your comparison. You must provide an explanation for the selection of reference codes. Reference Code Rationale:

We included the practice expense inputs for CPT code 47525, one of the components of the currently coded scenarios that is priced in the office. We also included the recently passed practice expense inputs for a comparable GU code, X4 *Placement of nephroureteral catheter, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; new access* from the February 2015 PE meeting. We believe using both sets of data provides a good framework for our recommendations.

3. If you are recommending more minutes than the PE Subcommittee standards you must provide evidence to justify the time:

We are including pre service minutes for several activities. We believe our recommendation appropriately reflects the extensive use of clinical staff for these activities.

4. If you are requesting an increase over the current inputs in clinical staff time, supplies or equipment you must provide compelling evidence:

N/A

5. Please describe in detail the clinical activities of your staff:

Pre-Service Clinical Labor Activities:

Complete pre-service diagnostic & referral forms
Coordinate pre-surgery services
Schedule space and equipment in facility
Provide pre-service education/obtain consent
Follow-up phone calls & prescriptions

Intra-Service Clinical Labor Activities:

N/A

Post-Service Clinical Labor Activities:

	A	B	C	D	E	F	G	H	I
1	**REVISED/APPROVED AT 04/2015 MEETING**			**Current Inputs**				**REFERENCE CODE Feb 2015**	
2	***Please note: If a supply has a purchase price of $100 or more please bold the item name and CMS code.**			**47525**		**75984**		**5039X4**	
3				*Change of percutaneous biliary drainage catheter*		*Change of percutaneous tube or drainage catheter with contrast monitoring (eg, genitourinary system, abscess), radiological supervision and interpretation*		*Placement of nephroureteral catheter, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (g, ultrasound and/or fluoroscopy) and all associated radiological*	
4	**Meeting Date: October** 2015 **Tab:** 6 Biliary Procedures Bundling **Specialty:** SIR, ACR	**CMS Code**	**Staff Type**						
5	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**
6	**GLOBAL PERIOD**			**000**	**000**	**000**	**000**	**000**	**000**
7	**TOTAL CLINICAL LABOR TIME**			**86**	**23**	**31**	**0**	**286**	**30**
8	**TOTAL PRE-SERV CLINICAL LABOR TIME**			**0**	**23**	**3**	**0**	**7**	**30**
9		*L037D*	*RN/LPN/MTA*	*0*	*23*	*0*	*0*	*3*	*30*
10		*L041B*	*RadTech*	*0*		*3*		*4*	
11	**TOTAL SERVICE PERIOD CLINICAL LABOR TIME**			**86**	**0**	**28**	**0**	**276**	**0**
12		*L037D*	*RN/LPN/MTA*	*34*		*0*		*34*	
13		*L041B*	*RadTech*	*6*		*28*		*120*	
14		*L051A*	*RN*	*46*		*0*		*122*	
15	**TOTAL POST-SERV CLINICAL LABOR TIME**	L037D	RN/LPN/MTA	**0**	**0**	**0**	**0**	**3**	**0**
16	**PRE-SERVICE**								
17	**Start: Following visit when decision for surgery or procedure made**								
18	Complete pre-service diagnostic & referral forms	L037D	RN/LPN/MTA		5			3	5
19	Coordinate pre-surgery services	L037D	RN/LPN/MTA		10				10
20	Schedule space and equipment in facility	L037D	RN/LPN/MTA		5				5
21	Provide pre-service education/obtain consent	L037D	RN/LPN/MTA						7
22	Follow-up phone calls & prescriptions	L037D	RN/LPN/MTA		3				3
23	Availability of prior images confirmed	L041B	RadTech			3		2	
24	Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist	L041B	RadTech					2	
25	Other Clinical Activity - *specify:*								
26	**End: When patient enters office/facility for surgery/procedure**								
27	**SERVICE PERIOD**								
28	**Start: When patient enters office/facility for surgery/procedure:**								
29	Greet patient, provide gowning, ensure appropriate medical records are available	L037D	RN/LPN/MTA	3				3	
30	Obtain vital signs	L037D	RN/LPN/MTA	3				5	
31	Provide pre-service education/obtain consent	L037D	RN/LPN/MTA	5				5	
32	Prepare room, equipment, supplies	L041B	RT	1		1		2	
33	Setup scope (non facility setting only)								
34	Prepare and position patient/ monitor patient/ set up IV	L041B	RT	2		1		2	
35	Sedate/apply anesthesia	L051A	RN	1				2	
36	Other Clinical Activity - specify:								
37	Intra-service								
38	Assist Physician in Performing Procedure (CS)	L051A	RN	20				60	
39	Assist Physician in Performing Procedure	L037D	RN/LPN/MTA	20					
40	Assist Physician in Performing Procedure	L041B	RT			12		60	
41	Acquire images (75%)	L041B	RT			9		45	
42	Circulator (25%)	L037D	RN/LPN/MTA					15	
43									
44	Post-Service								
45	Monitor pt. following moderate sedation	L051A	RN	15				15	
46	Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation)	L051A	RN	10				45	
47	Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation)	L037D	RN/LPN/MTA						
48	Clean room/equipment by physician staff	L041B	RT	3		3		6	
49	Clean Scope								
50	Clean Surgical Instrument Package								
51	Complete diagnostic forms, lab & X-ray requisitions	L037D	RN/LPN/MTA					3	

	A	B	C	D	E	F	G	H	I
1	**REVISED/APPROVED AT 04/2015 MEETING**			**Current Inputs**				**REFERENCE CODE Feb 2015**	
2	***Please note: If a supply has a purchase price of $100 or more please bold the item name and CMS code.**			**47525**		**75984**		**5039X4**	
3				*Change of percutaneous biliary drainage catheter*		*Change of percutaneous tube or drainage catheter with contrast monitoring (eg, genitourinary system, abscess), radiological supervision and interpretation*		*Placement of nephroureteral catheter, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological*	
4	**Meeting Date: October** 2015 **Tab:** 6 Biliary Procedures Bundling **Specialty:** SIR, ACR	**CMS Code**	**Staff Type**						
5	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**
6	**GLOBAL PERIOD**			**000**	**000**	**000**	**000**	**000**	**000**
52	Review/read X-ray, lab, and pathology reports								
53	Check dressings & wound/ home care instructions /coordinate office visits /prescriptions	L037D	RN/LPN/MTA	3				3	
54	Technologist QC's images in PACS, checking for all images, reformats, and dose page	L041B	RT			2		2	
55	Review examination with interpreting MD	L041B	RT					2	
56	Exam documents scanned into PACS. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue	L041B	RT					1	
57	Other Clinical Activity - *specify:*								
61	**End: Patient leaves office**								

	A	B	C	D	E	F	G	H	I
1	**REVISED/APPROVED AT 04/2015 MEETING**			**Current Inputs**				**REFERENCE CODE Feb 2015**	
2	***Please note: If a supply has a purchase price of $100 or more please bold the item name and CMS code.**			**47525**		**75984**		**5039X4**	
3									
4	**Meeting Date: October** 2015 **Tab:** 6 Biliary Procedures Bundling **Specialty:** SIR, ACR	**CMS Code**	**Staff Type**	*Change of percutaneous biliary drainage catheter*		*Change of percutaneous tube or drainage catheter with contrast monitoring (eg, genitourinary system, abscess), radiological supervision and interpretation*		*Placement of nephroureteral catheter, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological*	
5	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**
6	**GLOBAL PERIOD**			**000**	**000**	**000**	**000**	**000**	**000**
62	**POST-SERVICE Period**								
63	**Start: Patient leaves office/facility**								
64	Conduct phone calls/call in prescriptions	L037D	RN/LPN/MTA					3	
65	***Office visits: List Number and Level of Office Visits***			**# visits**	**# visits**	**# visits**	**# visits**	**# visits**	**# visits**
71	**Total Office Visit Time**			**0**	**0**	**0**	**0**	**0**	**0**
72	Other Clinical Activity - *specify:*								
73	**End: with last office visit before end of global period**								
74	**MEDICAL SUPPLIES***	**CODE**	**UNIT**						
75	pack, minimum multi-specialty visit	SA048	pack					1	
76	pack, conscious sedation	SA044	pack					1	
77	**Nephroureteral Catheter**	**NEW**	**item**					**1**	
78	**catheter, balloon, PTA**	**SD152**	**item**						
79	**Viabil covered biliary stent**	**NEW**	**item**						
80	**internal/external biliary catheter**	**NEW**	**item**						
81	**stone basket**	**NEW**							
82	Radial Jaw	NEW	item						
83	kit, iv starter	SA019	kit					1	
84	kit, suture removal	SA031	kit						
85	pack, cleaning and disinfecting, endoscope	SA042	pack					1	
86	tray, shave prep	SA067	tray					1	
87	kit, AccuStick II Introducer System with RO Marker	SA071	kit					1	
88	cap, surgical	SB001	item					4	
89	cover-condom, transducer or ultrasound probe	SB005	item					1	
90	drape, sterile, femoral	SB009	item					1	
91	drape-towel, sterile 18inx26in	SB019	item					2	
92	gloves, non-sterile	SB022	pair						
93	gloves, sterile	SB024	pair					2	
94	gown, surgical, sterile	SB028	item					2	
95	mask, surgical	SB033	item					2	
96	mask, surgical, with face shield	SB034	item					2	
97	shoe covers, surgical	SB039	pair					4	
98	underpad 2ftx3ft (Chux)	SB044	item					1	
99	closed flush system, angiography	SC010	item					1	
100	needle, Chiba	SC035	item					1	
101	3 way stop cock (for irrigation)	SC049	item					1	
102	syringe 10-12ml	SC051	item					2	
103	syringe 60ml (for irrigation)	SC056	item					2	
104	syringe w-needle, OSHA compliant (SafetyGlide)	SC058	item					2	
105	dilator, vessel, angiographic	SD043	item					2	
106	guidewire, hydrophilic	SD089	item					1	
107	guidewire, STIFF	SD090	item					1	
108	vascular sheath	SD136	item						
109	percutaneous catheter fastener (Percu-Stay)	SD146	item					1	
110	catheter, (Glide)	SD147	item					1	
111	catheter, balloon inflation device	SD149	item						
112	drainage catheter, all purpose	SD161	item					1	
113	pouch, nephrostomy-biliary drainage	SD163	item					1	
114	guidewire bowl w-lid, sterile	SD171	item					1	
115	blade, surgical (Bard-Parker)	SF007	item					1	
116	applicator, sponge-tipped	SG009	item					4	
117	dressing, 12-7mm (Gelfoam)	SG033	item						
118	gauze, sterile 4in x 4in	SG055	item					6	
119	tape, surgical paper 1in (Micropore)	SG079	item					12	
120	lidocaine 1%-2% inj (Xylocaine)	SH047	ml					10	
121	sodium chloride 0.9% flush syringe	SH065	item					2	

	A	B	C	D	E	F	G	H	I
1	**REVISED/APPROVED AT 04/2015 MEETING**			**Current Inputs**				**REFERENCE CODE Feb 2015**	
2	***Please note: If a supply has a purchase price of $100 or more please bold the item name and CMS code.**			**47525**		**75984**		**5039X4**	
3									
4	**Meeting Date: October** 2015 **Tab:** 6 Biliary Procedures Bundling **Specialty:** SIR, ACR	**CMS Code**	**Staff Type**	*Change of percutaneous biliary drainage catheter*		*Change of percutaneous tube or drainage catheter with contrast monitoring (eg, genitourinary system, abscess), radiological supervision and interpretation*		*Placement of nephroureteral catheter, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological*	
5	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**
6	**GLOBAL PERIOD**			**000**	**000**	**000**	**000**	**000**	**000**
122	sodium chloride 0.9% irrigation (500-1000ml uou)	SH069	item					1	
123	povidone soln (Betadine)	SJ041	ml					60	
124	cup, biopsy-specimen sterile 4oz	SL036	item					1	
125	disinfectant, surface (Envirocide, Sanizide)	SM013	oz			1		1	
126	sanitizing cloth-wipe (surface, instruments, equipment)	SM022	item						
127	**EQUIPMENT**	**CODE**							
128	angiographic room	EL011		34		9		72	
129	portable ultrasound	EQ250						72	
130	light, exam	EQ168						72	
131	PACS Workstation Proxy	ED050				28		72	
132	table, instrument, mobile	EF027		82				312	
133	ECG, 3-channel (with Sp02, NIBP, temp, resp)	EQ011		82				312	
134	IV infusion pump	EQ032		82				312	
135	stretcher	EF018						312	
136									
137	*47505*								
138	*74305*								
139	*47500*								
140	*74320*								
141	*47510*								
142	*75980*								
143	*47511*								
144	*75982*								
145	*47525*								
146	*75984*								
147	*74363*								
148	*47556*								
149	*47555*								
150	*47553*								
151	*47630*								
152	*74327*								

	A	B	C	J	K	L	M	N	O
1	**REVISED/APPROVED AT 04/2015 MEETING**			**OUTPATIENT**		**INPATIENT**		**INPATIENT**	
2	***Please note: If a supply has a purchase price of $100 or more please bold the item name and CMS code.**			**47531**		**47532**		**47533**	
3				**cholangio - exist**		**cholangio - new**		**place ext - new**	
4	**Meeting Date: October** 2015 **Tab:** 6 Biliary Procedures Bundling **Specialty:** SIR, ACR	**CMS Code**	**Staff Type**	*Injection procedure for cholangiography, percutaneous, complete diagnostic procedure including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation;*		*Injection procedure for cholangiography, percutaneous, complete diagnostic procedure including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation;*		*Placement of biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and*	
5	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**
6	**GLOBAL PERIOD**			**000**	**000**	**000**	**000**	**000**	**000**
7	**TOTAL CLINICAL LABOR TIME**			**106**	**19**	**241**	**14**	**286**	**14**
8	**TOTAL PRE-SERV CLINICAL LABOR TIME**			**7**	**19**	**7**	**14**	**7**	**14**
9		*L037D*	*RN/LPN/MTA*	*3*	*19*	*3*	*14*	*3*	*14*
10		*L041B*	*RadTech*	*4*		*4*		*4*	
11	**TOTAL SERVICE PERIOD CLINICAL LABOR TIME**			**96**	**0**	**231**	**0**	**276**	**0**
12		*L037D*	*RN/LPN/MTA*	*53*		*30*		*34*	
13		*L041B*	*RadTech*	*41*		*94*		*120*	
14		*L051A*	*RN*	*2*		*107*		*122*	
15	**TOTAL POST-SERV CLINICAL LABOR TIME**	L037D	RN/LPN/MTA	**3**	**0**	**3**	**0**	**3**	**0**
16	**PRE-SERVICE**								
17	**Start: Following visit when decision for surgery or procedure made**								
18	Complete pre-service diagnostic & referral forms	L037D	RN/LPN/MTA	3	3	3	3	3	3
19	Coordinate pre-surgery services	L037D	RN/LPN/MTA		5		5		5
20	Schedule space and equipment in facility	L037D	RN/LPN/MTA		3		3		3
21	Provide pre-service education/obtain consent	L037D	RN/LPN/MTA		5				
22	Follow-up phone calls & prescriptions	L037D	RN/LPN/MTA		3		3		3
23	Availability of prior images confirmed	L041B	RadTech	2		2		2	
24	Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist	L041B	RadTech	2		2		2	
25	Other Clinical Activity - *specify:*								
26	**End: When patient enters office/facility for surgery/procedure**								
27	**SERVICE PERIOD**								
28	**Start: When patient enters office/facility for surgery/procedure:**								
29	Greet patient, provide gowning, ensure appropriate medical records are available	L037D	RN/LPN/MTA	3		3		3	
30	Obtain vital signs	L037D	RN/LPN/MTA	5		5		5	
31	Provide pre-service education/obtain consent	L037D	RN/LPN/MTA	5		5		5	
32	Prepare room, equipment, supplies	L041B	RT	2		2		2	
33	Setup scope (non facility setting only)								
34	Prepare and position patient/ monitor patient/ set up IV	L041B	RT	2		2		2	
35	Sedate/apply anesthesia	L051A	RN	2		2		2	
36	Other Clinical Activity - specify:								
37	Intra-service								
38	Assist Physician in Performing Procedure (CS)	L051A	RN			45		60	
39	Assist Physician in Performing Procedure	L037D	RN/LPN/MTA	15					
40	Assist Physician in Performing Procedure	L041B	RT	15		45		60	
41	Acquire images (75%)	L041B	RT	11		34		45	
42	Circulator (25%)	L037D	RN/LPN/MTA	4		11		15	
43									
44	Post-Service								
45	Monitor pt. following moderate sedation	L051A	RN			15		15	
46	Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation)	L051A	RN			45		45	
47	Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation)	L037D	RN/LPN/MTA	15					
48	Clean room/equipment by physician staff	L041B	RT	6		6		6	
49	Clean Scope								
50	Clean Surgical Instrument Package								
51	Complete diagnostic forms, lab & X-ray requisitions	L037D	RN/LPN/MTA	3		3		3	

	A	B	C	J	K	L	M	N	O
1	**REVISED/APPROVED AT 04/2015 MEETING**			**OUTPATIENT**		**INPATIENT**		**INPATIENT**	
2	***Please note: If a supply has a purchase price of $100 or more please bold the item name and CMS code.**			**47531**		**47532**		**47533**	
3				**cholangio - exist**		**cholangio - new**		**place ext - new**	
4	**Meeting Date: October** 2015 **Tab:** 6 Biliary Procedures Bundling **Specialty:** SIR, ACR	**CMS Code**	**Staff Type**	*Injection procedure for cholangiography, percutaneous, complete diagnostic procedure including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation;*		*Injection procedure for cholangiography, percutaneous, complete diagnostic procedure including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation;*		*Placement of biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and*	
5	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**
6	**GLOBAL PERIOD**			**000**	**000**	**000**	**000**	**000**	**000**
52	Review/read X-ray, lab, and pathology reports								
53	Check dressings & wound/ home care instructions /coordinate office visits /prescriptions	L037D	RN/LPN/MTA	3		3		3	
54	Technologist QC's images in PACS, checking for all images, reformats, and dose page	L041B	RT	2		2		2	
55	Review examination with interpreting MD	L041B	RT	2		2		2	
56	Exam documents scanned into PACS. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue	L041B	RT	1		1		1	
57	Other Clinical Activity - *specify:*								
61	**End: Patient leaves office**								

	A	B	C	J	K	L	M	N	O
1	**REVISED/APPROVED AT 04/2015 MEETING**			**OUTPATIENT**		**INPATIENT**		**INPATIENT**	
2	***Please note: If a supply has a purchase price of $100 or more please bold the item name and CMS code.**			**47531**		**47532**		**47533**	
3				**cholangio - exist**		**cholangio - new**		**place ext - new**	
4	**Meeting Date: October** 2015 **Tab:** 6 Biliary Procedures Bundling **Specialty:** SIR, ACR	**CMS Code**	**Staff Type**	*Injection procedure for cholangiography, percutaneous, complete diagnostic procedure including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation;*		*Injection procedure for cholangiography, percutaneous, complete diagnostic procedure including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation;*		*Placement of biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and*	
5	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**
6	**GLOBAL PERIOD**			**000**	**000**	**000**	**000**	**000**	**000**
62	**POST-SERVICE Period**								
63	**Start: Patient leaves office/facility**								
64	Conduct phone calls/call in prescriptions	L037D	RN/LPN/MTA	3		3		3	
65	***Office visits: List Number and Level of Office Visits***			**# visits**	**# visits**	**# visits**	**# visits**	**# visits**	**# visits**
71	**Total Office Visit Time**			**0**	**0**	**0**	**0**	**0**	**0**
72	Other Clinical Activity - *specify:*								
73	**End: with last office visit before end of global period**								
74	**MEDICAL SUPPLIES***	**CODE**	**UNIT**						
75	pack, minimum multi-specialty visit	SA048	pack	**1**		**1**		**1**	
76	pack, conscious sedation	SA044	pack			**1**		**1**	
77	**Nephroureteral Catheter**	**NEW**	**item**						
78	**catheter, balloon, PTA**	**SD152**	**item**						
79	**Viabil covered biliary stent**	**NEW**	**item**						
80	**internal/external biliary catheter**	**NEW**	**item**						
81	**stone basket**	**NEW**							
82	Radial Jaw	NEW	item						
83	kit, iv starter	SA019	kit			1		1	
84	kit, suture removal	SA031	kit						
85	pack, cleaning and disinfecting, endoscope	SA042	pack						
86	tray, shave prep	SA067	tray			1		1	
87	kit, AccuStick II Introducer System with RO Marker	SA071	kit			1		1	
88	cap, surgical	SB001	item	4		4		4	
89	cover-condom, transducer or ultrasound probe	SB005	item			1		1	
90	drape, sterile, femoral	SB009	item	1		1		1	
91	drape-towel, sterile 18inx26in	SB019	item	2		2		2	
92	gloves, non-sterile	SB022	pair	3		3		3	
93	gloves, sterile	SB024	pair	2		2		2	
94	gown, surgical, sterile	SB028	item	2		2		2	
95	mask, surgical	SB033	item	2		2		2	
96	mask, surgical, with face shield	SB034	item	2		2		2	
97	shoe covers, surgical	SB039	pair	4		4		4	
98	underpad 2ftx3ft (Chux)	SB044	item	1		1		1	
99	closed flush system, angiography	SC010	item	1		1		1	
100	needle, Chiba	SC035	item						
101	3 way stop cock (for irrigation)	SC049	item	1		1		1	
102	syringe 10-12ml	SC051	item	2		2		2	
103	syringe 60ml (for irrigation)	SC056	item	2		2		2	
104	syringe w-needle, OSHA compliant (SafetyGlide)	SC058	item	2		2		2	
105	dilator, vessel, angiographic	SD043	item					2	
106	guidewire, hydrophilic	SD089	item					1	
107	guidewire, STIFF	SD090	item					1	
108	vascular sheath	SD136	item						
109	percutaneous catheter fastener (Percu-Stay)	SD146	item					1	
110	catheter, (Glide)	SD147	item					1	
111	catheter, balloon inflation device	SD149	item						
112	drainage catheter, all purpose	SD161	item					1	
113	pouch, nephrostomy-biliary drainage	SD163	item					1	
114	guidewire bowl w-lid, sterile	SD171	item	1		1		1	
115	blade, surgical (Bard-Parker)	SF007	item			1		1	
116	applicator, sponge-tipped	SG009	item	4		4		4	
117	dressing, 12-7mm (Gelfoam)	SG033	item						
118	gauze, sterile 4in x 4in	SG055	item	6		6		6	
119	tape, surgical paper 1in (Micropore)	SG079	item	12		12		12	
120	lidocaine 1%-2% inj (Xylocaine)	SH047	ml	10		10		10	
121	sodium chloride 0.9% flush syringe	SH065	item	2		2		2	

	A	B	C	J	K	L	M	N	O
1	**REVISED/APPROVED AT 04/2015 MEETING**			**OUTPATIENT**		**INPATIENT**		**INPATIENT**	
2	***Please note: If a supply has a purchase price of $100 or more please bold the item name and CMS code.**			**47531**		**47532**		**47533**	
3				**cholangio - exist**		**cholangio - new**		**place ext - new**	
4	**Meeting Date: October** 2015 **Tab:** 6 Biliary Procedures Bundling **Specialty:** SIR, ACR	**CMS Code**	**Staff Type**	*Injection procedure for cholangiography, percutaneous, complete diagnostic procedure including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation;*		*Injection procedure for cholangiography, percutaneous, complete diagnostic procedure including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation;*		*Placement of biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and*	
5	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**
6	**GLOBAL PERIOD**			**000**	**000**	**000**	**000**	**000**	**000**
122	sodium chloride 0.9% irrigation (500-1000ml uou)	SH069	item	1		1		1	
123	povidone soln (Betadine)	SJ041	ml	60		60		60	
124	cup, biopsy-specimen sterile 4oz	SL036	item					1	
125	disinfectant, surface (Envirocide, Sanizide)	SM013	oz			1		1	
126	sanitizing cloth-wipe (surface, instruments, equipment)	SM022	item	3		3		3	
127	**EQUIPMENT**	**CODE**							
128	angiographic room	EL011		27		57		72	
129	portable ultrasound	EQ250				81		96	
130	light, exam	EQ168		51		81		96	
131	PACS Workstation Proxy	ED050		51		81		96	
132	table, instrument, mobile	EF027		87		297		312	
133	ECG, 3-channel (with Sp02, NIBP, temp, resp)	EQ011		87		297		312	
134	IV infusion pump	EQ032		87		297		312	
135	stretcher	EF018		87		297		312	
136				***Outpatient***	***Inpatient***	***Outpatient***	***Inpatient***	***Outpatient***	***Inpatient***
137	*47505*			*53%*	*44%*				
138	*74305*			*52%*	*45%*				
139	*47500*					*20%*	*79%*	*20%*	*79%*
140	*74320*					*22%*	*77%*	*22%*	*77%*
141	*47510*							*19%*	*80%*
142	*75980*							*20%*	*79%*
143	*47511*								
144	*75982*								
145	*47525*								
146	*75984*								
147	*74363*								
148	*47556*								
149	*47555*								
150	*47553*								
151	*47630*								
152	*74327*								

	A	B	C	P	Q	R	S	T	U
1	**REVISED/APPROVED AT 04/2015 MEETING**			**INPATIENT**		**OUTPATIENT**		**OUTPATIENT**	
2	***Please note: If a supply has a purchase price of $100 or more please bold the item name and CMS code.**			**47534**		**47535**		**47536**	
3				**place int/ext - new**		**ext => int/ext**		**exchange**	
4	**Meeting Date: October** 2015 **Tab:** 6 Biliary Procedures Bundling **Specialty:** SIR, ACR	**CMS Code**	**Staff Type**	*Placement of biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and*		*Conversion of external biliary drainage catheter to internal-external biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, fluoroscopy) and all associated*		*Exchange of biliary drainage catheter (eg. external, internal-external , or conversion of internal-external to external only), percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, fluoroscopy)*	
5	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**
6	**GLOBAL PERIOD**			**000**	**000**	**000**	**000**	**000**	**000**
7	**TOTAL CLINICAL LABOR TIME**			**310**	**14**	**241**	**19**	**136**	**19**
8	**TOTAL PRE-SERV CLINICAL LABOR TIME**			**7**	**14**	**7**	**19**	**7**	**19**
9		*L037D*	*RN/LPN/MTA*	*3*	*14*	*3*	*19*	*3*	*19*
10		*L041B*	*RadTech*	*4*		*4*		*4*	
11	**TOTAL SERVICE PERIOD CLINICAL LABOR TIME**			**300**	**0**	**231**	**0**	**126**	**0**
12		*L037D*	*RN/LPN/MTA*	*36*		*30*		*24*	
13		*L041B*	*RadTech*	*134*		*94*		*50*	
14		*L051A*	*RN*	*130*		*107*		*52*	
15	**TOTAL POST-SERV CLINICAL LABOR TIME**	L037D	RN/LPN/MTA	**3**	**0**	**3**	**0**	**3**	**0**
16	**PRE-SERVICE**								
17	**Start: Following visit when decision for surgery or procedure made**								
18	Complete pre-service diagnostic & referral forms	L037D	RN/LPN/MTA	3	3	3	3	3	3
19	Coordinate pre-surgery services	L037D	RN/LPN/MTA		5		5		5
20	Schedule space and equipment in facility	L037D	RN/LPN/MTA		3		3		3
21	Provide pre-service education/obtain consent	L037D	RN/LPN/MTA				5		5
22	Follow-up phone calls & prescriptions	L037D	RN/LPN/MTA		3		3		3
23	Availability of prior images confirmed	L041B	RadTech	2		2		2	
24	Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist	L041B	RadTech	2		2		2	
25	Other Clinical Activity - *specify:*								
26	**End: When patient enters office/facility for surgery/procedure**								
27	**SERVICE PERIOD**								
28	**Start: When patient enters office/facility for surgery/procedure:**								
29	Greet patient, provide gowning, ensure appropriate medical records are available	L037D	RN/LPN/MTA	3		3		3	
30	Obtain vital signs	L037D	RN/LPN/MTA	5		5		5	
31	Provide pre-service education/obtain consent	L037D	RN/LPN/MTA	5		5		5	
32	Prepare room, equipment, supplies	L041B	RT	2		2		2	
33	Setup scope (non facility setting only)								
34	Prepare and position patient/ monitor patient/ set up IV	L041B	RT	2		2		2	
35	Sedate/apply anesthesia	L051A	RN	2		2		2	
36	Other Clinical Activity - specify:								
37	Intra-service								
38	Assist Physician in Performing Procedure (CS)	L051A	RN	68		45		20	
39	Assist Physician in Performing Procedure	L037D	RN/LPN/MTA						
40	Assist Physician in Performing Procedure	L041B	RT	68		45		20	
41	Acquire images (75%)	L041B	RT	51		34		15	
42	Circulator (25%)	L037D	RN/LPN/MTA	17		11		5	
43									
44	Post-Service								
45	Monitor pt. following moderate sedation	L051A	RN	15		15		15	
46	Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation)	L051A	RN	45		45		15	
47	Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation)	L037D	RN/LPN/MTA						
48	Clean room/equipment by physician staff	L041B	RT	6		6		6	
49	Clean Scope								
50	Clean Surgical Instrument Package								
51	Complete diagnostic forms, lab & X-ray requisitions	L037D	RN/LPN/MTA	3		3		3	

	A	B	C	P	Q	R	S	T	U
1	**REVISED/APPROVED AT 04/2015 MEETING**			**INPATIENT**		**OUTPATIENT**		**OUTPATIENT**	
2	***Please note: If a supply has a purchase price of $100 or more please bold the item name and CMS code.**			**47534**		**47535**		**47536**	
3				**place int/ext - new**		**ext => int/ext**		**exchange**	
4	**Meeting Date: October** 2015 **Tab:** 6 Biliary Procedures Bundling **Specialty:** SIR, ACR	**CMS Code**	**Staff Type**	*Placement of biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and*		*Conversion of external biliary drainage catheter to internal-external biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, fluoroscopy) and all associated*		*Exchange of biliary drainage catheter (eg. external, internal-external , or conversion of internal-external to external only), percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, fluoroscopy)*	
5	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**
6	**GLOBAL PERIOD**			**000**	**000**	**000**	**000**	**000**	**000**
52	Review/read X-ray, lab, and pathology reports								
53	Check dressings & wound/ home care instructions /coordinate office visits /prescriptions	L037D	RN/LPN/MTA	3		3		3	
54	Technologist QC's images in PACS, checking for all images, reformats, and dose page	L041B	RT	2		2		2	
55	Review examination with interpreting MD	L041B	RT	2		2		2	
56	Exam documents scanned into PACS. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue	L041B	RT	1		1		1	
57	Other Clinical Activity - *specify:*								
61	**End: Patient leaves office**								

	A	B	C	P	Q	R	S	T	U
1	**REVISED/APPROVED AT 04/2015 MEETING**			**INPATIENT**		**OUTPATIENT**		**OUTPATIENT**	
2	***Please note: If a supply has a purchase price of $100 or more please bold the item name and CMS code.**			**47534**		**47535**		**47536**	
3				**place int/ext - new**		**ext => int/ext**		**exchange**	
4	**Meeting Date: October** 2015 **Tab:** 6 Biliary Procedures Bundling **Specialty:** SIR, ACR	**CMS Code**	**Staff Type**	*Placement of biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and*		*Conversion of external biliary drainage catheter to internal-external biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, fluoroscopy) and all associated*		*Exchange of biliary drainage catheter (eg. external, internal-external , or conversion of internal-external to external only), percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, fluoroscopy)*	
5	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**
6	**GLOBAL PERIOD**			**000**	**000**	**000**	**000**	**000**	**000**
62	**POST-SERVICE Period**								
63	**Start: Patient leaves office/facility**								
64	Conduct phone calls/call in prescriptions	L037D	RN/LPN/MTA	3		3		3	
65	***Office visits: List Number and Level of Office Visits***			**# visits**	**# visits**	**# visits**	**# visits**	**# visits**	**# visits**
71	**Total Office Visit Time**			**0**	**0**	**0**	**0**	**0**	**0**
72	Other Clinical Activity - *specify:*								
73	**End: with last office visit before end of global period**								
74	**MEDICAL SUPPLIES***	**CODE**	**UNIT**						
75	pack, minimum multi-specialty visit	SA048	pack	**1**		**1**		**1**	
76	pack, conscious sedation	SA044	pack	**1**		**1**		**1**	
77	**Nephroureteral Catheter**	**NEW**	**item**						
78	**catheter, balloon, PTA**	**SD152**	**item**						
79	**Viabil covered biliary stent**	**NEW**	**item**						
80	**internal/external biliary catheter**	**NEW**	**item**	**1**		**1**		**1**	
81	**stone basket**	**NEW**							
82	Radial Jaw	NEW	item						
83	kit, iv starter	SA019	kit	1		1		1	
84	kit, suture removal	SA031	kit			1		1	
85	pack, cleaning and disinfecting, endoscope	SA042	pack						
86	tray, shave prep	SA067	tray	1		1		1	
87	kit, AccuStick II Introducer System with RO Marker	SA071	kit	1					
88	cap, surgical	SB001	item	4		4		4	
89	cover-condom, transducer or ultrasound probe	SB005	item	1					
90	drape, sterile, femoral	SB009	item	1		1		1	
91	drape-towel, sterile 18inx26in	SB019	item	2		2		2	
92	gloves, non-sterile	SB022	pair	3		3		3	
93	gloves, sterile	SB024	pair	2		2		2	
94	gown, surgical, sterile	SB028	item	2		2		2	
95	mask, surgical	SB033	item	2		2		2	
96	mask, surgical, with face shield	SB034	item	2		2		2	
97	shoe covers, surgical	SB039	pair	4		4		4	
98	underpad 2ftx3ft (Chux)	SB044	item	1		1		1	
99	closed flush system, angiography	SC010	item	1		1		1	
100	needle, Chiba	SC035	item						
101	3 way stop cock (for irrigation)	SC049	item	1		1		1	
102	syringe 10-12ml	SC051	item	2		2		2	
103	syringe 60ml (for irrigation)	SC056	item	2		2		2	
104	syringe w-needle, OSHA compliant (SafetyGlide)	SC058	item	2		2		2	
105	dilator, vessel, angiographic	SD043	item	2					
106	guidewire, hydrophilic	SD089	item	1		1		1	
107	guidewire, STIFF	SD090	item	1		1		1	
108	vascular sheath	SD136	item						
109	percutaneous catheter fastener (Percu-Stay)	SD146	item	1		1		1	
110	catheter, (Glide)	SD147	item	1		1			
111	catheter, balloon inflation device	SD149	item						
112	drainage catheter, all purpose	SD161	item						
113	pouch, nephrostomy-biliary drainage	SD163	item	1		1		1	
114	guidewire bowl w-lid, sterile	SD171	item	1		1		1	
115	blade, surgical (Bard-Parker)	SF007	item	1					
116	applicator, sponge-tipped	SG009	item	4		4		4	
117	dressing, 12-7mm (Gelfoam)	SG033	item						
118	gauze, sterile 4in x 4in	SG055	item	6		6		6	
119	tape, surgical paper 1in (Micropore)	SG079	item	12		12		12	
120	lidocaine 1%-2% inj (Xylocaine)	SH047	ml	10		10		10	
121	sodium chloride 0.9% flush syringe	SH065	item	2		2		2	

	A	B	C	P	Q	R	S	T	U
1	**REVISED/APPROVED AT 04/2015 MEETING**			**INPATIENT**		**OUTPATIENT**		**OUTPATIENT**	
2	***Please note: If a supply has a purchase price of $100 or more please bold the item name and CMS code.**			**47534**		**47535**		**47536**	
3				**place int/ext - new**		**ext => int/ext**		**exchange**	
4	**Meeting Date: October** 2015 **Tab:** 6 Biliary Procedures Bundling **Specialty:** SIR, ACR	**CMS Code**	**Staff Type**	*Placement of biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and*		*Conversion of external biliary drainage catheter to internal-external biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, fluoroscopy) and all associated*		*Exchange of biliary drainage catheter (eg. external, internal-external , or conversion of internal-external to external only), percutaneous, including diagnostic cholangiography when performed, imaging guidance (eg, fluoroscopy)*	
5	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**
6	**GLOBAL PERIOD**			**000**	**000**	**000**	**000**	**000**	**000**
122	sodium chloride 0.9% irrigation (500-1000ml uou)	SH069	item	1		1		1	
123	povidone soln (Betadine)	SJ041	ml	60		60		60	
124	cup, biopsy-specimen sterile 4oz	SL036	item	1					
125	disinfectant, surface (Envirocide, Sanizide)	SM013	oz	1					
126	sanitizing cloth-wipe (surface, instruments, equipment)	SM022	item	3		3		3	
127	**EQUIPMENT**	**CODE**							
128	angiographic room	EL011		80		57		32	
129	portable ultrasound	EQ250		104					
130	light, exam	EQ168		104		81		56	
131	PACS Workstation Proxy	ED050		104		81		56	
132	table, instrument, mobile	EF027		320		297		152	
133	ECG, 3-channel (with Sp02, NIBP, temp, resp)	EQ011		320		297		152	
134	IV infusion pump	EQ032		320		297		152	
135	stretcher	EF018		320		297		152	
136				***Outpatient***	***Inpatient***	***Outpatient***	***Inpatient***	***Outpatient***	***Inpatient***
137	*47505*					*53%*	*44%*	*53%*	*44%*
138	*74305*					*52%*	*45%*	*52%*	*45%*
139	*47500*			*20%*	*79%*				
140	*74320*			*22%*	*77%*				
141	*47510*								
142	*75980*								
143	*47511*			*21%*	*78%*	*21%*	*78%*		
144	*75982*			*21%*	*78%*	*21%*	*78%*		
145	*47525*							*63%*	*34%*
146	*75984*							*67%*	*30%*
147	*74363*								
148	*47556*								
149	*47555*								
150	*47553*								
151	*47630*								
152	*74327*								

	A	B	C	V	W	X	Y	Z	AA
1	**REVISED/APPROVED AT 04/2015 MEETING**			**OUTPATIENT**		**INPATIENT**		**OUTPATIENT**	
2	***Please note: If a supply has a purchase price of $100 or more please bold the item name and CMS code.**			**47537**		**47541**		**47538**	
3				**removal**		**rendevous**		**stent - exist**	
4	**Meeting Date: October** 2015 **Tab:** 6 Biliary Procedures Bundling **Specialty:** SIR, ACR	**CMS Code**	**Staff Type**	*Removal of biliary drainage catheter, percutaneous, requiring fluoroscopic guidance (eg, with concurrent indwelling biliary stents), including diagnostic cholangiography when performed, imaging guidance (eg, fluoroscopy)*		*Placement of access through the biliary tree and into small bowel to assist with an endoscopic biliary procedure (eg, rendezvous procedure), percutaneous, including diagnostic cholangiography when performed, imaging*		*Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (eg, fluoroscopy and/or ultrasound), balloon dilation, catheter exchange or removal when performed, and all associated*	
5	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**
6	**GLOBAL PERIOD**			**000**	**000**	**000**	**000**	**000**	**000**
7	**TOTAL CLINICAL LABOR TIME**			**106**	**19**	**286**	**14**	**265**	**19**
8	**TOTAL PRE-SERV CLINICAL LABOR TIME**			**7**	**19**	**7**	**14**	**7**	**19**
9		*L037D*	*RN/LPN/MTA*	*3*	*19*	*3*	*14*	*3*	*19*
10		*L041B*	*RadTech*	*4*		*4*		*4*	
11	**TOTAL SERVICE PERIOD CLINICAL LABOR TIME**			**96**	**0**	**276**	**0**	**255**	**0**
12		*L037D*	*RN/LPN/MTA*	*53*		*34*		*32*	
13		*L041B*	*RadTech*	*41*		*120*		*108*	
14		*L051A*	*RN*	*2*		*122*		*115*	
15	**TOTAL POST-SERV CLINICAL LABOR TIME**	L037D	RN/LPN/MTA	**3**	**0**	**3**	**0**	**3**	**0**
16	**PRE-SERVICE**								
17	**Start: Following visit when decision for surgery or procedure made**								
18	Complete pre-service diagnostic & referral forms	L037D	RN/LPN/MTA	3	3	3	3	3	3
19	Coordinate pre-surgery services	L037D	RN/LPN/MTA		5		5		5
20	Schedule space and equipment in facility	L037D	RN/LPN/MTA		3		3		3
21	Provide pre-service education/obtain consent	L037D	RN/LPN/MTA		5				5
22	Follow-up phone calls & prescriptions	L037D	RN/LPN/MTA		3		3		3
23	Availability of prior images confirmed	L041B	RadTech	2		2		2	
24	Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist	L041B	RadTech	2		2		2	
25	Other Clinical Activity - *specify:*								
26	**End: When patient enters office/facility for surgery/procedure**								
27	**SERVICE PERIOD**								
28	**Start: When patient enters office/facility for surgery/procedure:**								
29	Greet patient, provide gowning, ensure appropriate medical records are available	L037D	RN/LPN/MTA	3		3		3	
30	Obtain vital signs	L037D	RN/LPN/MTA	5		5		5	
31	Provide pre-service education/obtain consent	L037D	RN/LPN/MTA	5		5		5	
32	Prepare room, equipment, supplies	L041B	RT	2		2		2	
33	Setup scope (non facility setting only)								
34	Prepare and position patient/ monitor patient/ set up IV	L041B	RT	2		2		2	
35	Sedate/apply anesthesia	L051A	RN	2		2		2	
36	Other Clinical Activity - specify:								
37	Intra-service								
38	Assist Physician in Performing Procedure (CS)	L051A	RN			60		53	
39	Assist Physician in Performing Procedure	L037D	RN/LPN/MTA	15					
40	Assist Physician in Performing Procedure	L041B	RT	15		60		53	
41	Acquire images (75%)	L041B	RT	11		45		40	
42	Circulator (25%)	L037D	RN/LPN/MTA	4		15		13	
43									
44	Post-Service								
45	Monitor pt. following moderate sedation	L051A	RN			15		15	
46	Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation)	L051A	RN			45		45	
47	Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation)	L037D	RN/LPN/MTA	15					
48	Clean room/equipment by physician staff	L041B	RT	6		6		6	
49	Clean Scope								
50	Clean Surgical Instrument Package								
51	Complete diagnostic forms, lab & X-ray requisitions	L037D	RN/LPN/MTA	3		3		3	

	A	B	C	V	W	X	Y	Z	AA
1	**REVISED/APPROVED AT 04/2015 MEETING**			**OUTPATIENT**		**INPATIENT**		**OUTPATIENT**	
2	***Please note: If a supply has a purchase price of $100 or more please bold the item name and CMS code.**			**47537**		**47541**		**47538**	
3				**removal**		**rendevous**		**stent - exist**	
4	**Meeting Date: October** 2015 **Tab:** 6 Biliary Procedures Bundling **Specialty:** SIR, ACR	**CMS Code**	**Staff Type**	*Removal of biliary drainage catheter, percutaneous, requiring fluoroscopic guidance (eg, with concurrent indwelling biliary stents), including diagnostic cholangiography when performed, imaging guidance (eg, fluoroscopy)*		*Placement of access through the biliary tree and into small bowel to assist with an endoscopic biliary procedure (eg, rendezvous procedure), percutaneous, including diagnostic cholangiography when performed, imaging*		*Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (eg, fluoroscopy and/or ultrasound), balloon dilation, catheter exchange or removal when performed, and all associated*	
5	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**
6	**GLOBAL PERIOD**			**000**	**000**	**000**	**000**	**000**	**000**
52	Review/read X-ray, lab, and pathology reports								
53	Check dressings & wound/ home care instructions /coordinate office visits /prescriptions	L037D	RN/LPN/MTA	3		3		3	
54	Technologist QC's images in PACS, checking for all images, reformats, and dose page	L041B	RT	2		2		2	
55	Review examination with interpreting MD	L041B	RT	2		2		2	
56	Exam documents scanned into PACS. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue	L041B	RT	1		1		1	
57	Other Clinical Activity - *specify:*								
61	**End: Patient leaves office**								

	A	B	C	V	W	X	Y	Z	AA
1	**REVISED/APPROVED AT 04/2015 MEETING**			**OUTPATIENT**		**INPATIENT**		**OUTPATIENT**	
2	***Please note: If a supply has a purchase price of $100 or more please bold the item name and CMS code.**			**47537**		**47541**		**47538**	
3				**removal**		**rendevous**		**stent - exist**	
4	**Meeting Date: October** 2015 **Tab:** 6 Biliary Procedures Bundling **Specialty:** SIR, ACR	**CMS Code**	**Staff Type**	*Removal of biliary drainage catheter, percutaneous, requiring fluoroscopic guidance (eg, with concurrent indwelling biliary stents), including diagnostic cholangiography when performed, imaging guidance (eg, fluoroscopy)*		*Placement of access through the biliary tree and into small bowel to assist with an endoscopic biliary procedure (eg, rendezvous procedure), percutaneous, including diagnostic cholangiography when performed, imaging*		*Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (eg, fluoroscopy and/or ultrasound), balloon dilation, catheter exchange or removal when performed, and all associated*	
5	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**
6	**GLOBAL PERIOD**			**000**	**000**	**000**	**000**	**000**	**000**
62	**POST-SERVICE Period**								
63	**Start: Patient leaves office/facility**								
64	Conduct phone calls/call in prescriptions	L037D	RN/LPN/MTA	3		3		3	
65	***Office visits: List Number and Level of Office Visits***			**# visits**	**# visits**	**# visits**	**# visits**	**# visits**	**# visits**
71	**Total Office Visit Time**			**0**	**0**	**0**	**0**	**0**	**0**
72	Other Clinical Activity - *specify:*								
73	**End: with last office visit before end of global period**								
74	**MEDICAL SUPPLIES***	**CODE**	**UNIT**						
75	pack, minimum multi-specialty visit	SA048	pack	**1**		**1**		**1**	
76	pack, conscious sedation	SA044	pack			**1**		**1**	
77	**Nephroureteral Catheter**	**NEW**	**item**						
78	**catheter, balloon, PTA**	**SD152**	**item**					**2**	
79	**Viabil covered biliary stent**	**NEW**	**item**					**1**	
80	**internal/external biliary catheter**	**NEW**	**item**					**1**	
81	**stone basket**	**NEW**							
82	Radial Jaw	NEW	item						
83	kit, iv starter	SA019	kit			1		1	
84	kit, suture removal	SA031	kit	1				1	
85	pack, cleaning and disinfecting, endoscope	SA042	pack						
86	tray, shave prep	SA067	tray			1		1	
87	kit, AccuStick II Introducer System with RO Marker	SA071	kit			1			
88	cap, surgical	SB001	item	4		4		4	
89	cover-condom, transducer or ultrasound probe	SB005	item			1			
90	drape, sterile, femoral	SB009	item	1		1		1	
91	drape-towel, sterile 18inx26in	SB019	item	2		2		2	
92	gloves, non-sterile	SB022	pair	3		3		3	
93	gloves, sterile	SB024	pair	2		2		2	
94	gown, surgical, sterile	SB028	item	2		2		2	
95	mask, surgical	SB033	item	2		2		2	
96	mask, surgical, with face shield	SB034	item	2		2		2	
97	shoe covers, surgical	SB039	pair	4		4		4	
98	underpad 2ftx3ft (Chux)	SB044	item	1		1		1	
99	closed flush system, angiography	SC010	item	1		1		1	
100	needle, Chiba	SC035	item						
101	3 way stop cock (for irrigation)	SC049	item	1		1		1	
102	syringe 10-12ml	SC051	item	2		2		2	
103	syringe 60ml (for irrigation)	SC056	item	2		2		2	
104	syringe w-needle, OSHA compliant (SafetyGlide)	SC058	item	2		2		2	
105	dilator, vessel, angiographic	SD043	item			2			
106	guidewire, hydrophilic	SD089	item			1		1	
107	guidewire, STIFF	SD090	item	1		1		1	
108	vascular sheath	SD136	item					1	
109	percutaneous catheter fastener (Percu-Stay)	SD146	item					1	
110	catheter, (Glide)	SD147	item			1		1	
111	catheter, balloon inflation device	SD149	item					1	
112	drainage catheter, all purpose	SD161	item						
113	pouch, nephrostomy-biliary drainage	SD163	item					1	
114	guidewire bowl w-lid, sterile	SD171	item	1		1		1	
115	blade, surgical (Bard-Parker)	SF007	item			1			
116	applicator, sponge-tipped	SG009	item	4		4		4	
117	dressing, 12-7mm (Gelfoam)	SG033	item						
118	gauze, sterile 4in x 4in	SG055	item	6		6		6	
119	tape, surgical paper 1in (Micropore)	SG079	item	12		12		12	
120	lidocaine 1%-2% inj (Xylocaine)	SH047	ml	10		10		10	
121	sodium chloride 0.9% flush syringe	SH065	item	2		2		2	

	A	B	C	V	W	X	Y	Z	AA
1	**REVISED/APPROVED AT 04/2015 MEETING**			**OUTPATIENT**		**INPATIENT**		**OUTPATIENT**	
2	***Please note: If a supply has a purchase price of $100 or more please bold the item name and CMS code.**			**47537**		**47541**		**47538**	
3				**removal**		**rendevous**		**stent - exist**	
4	**Meeting Date: October** 2015 **Tab:** 6 Biliary Procedures Bundling **Specialty:** SIR, ACR	**CMS Code**	**Staff Type**	*Removal of biliary drainage catheter, percutaneous, requiring fluoroscopic guidance (eg, with concurrent indwelling biliary stents), including diagnostic cholangiography when performed, imaging guidance (eg, fluoroscopy)*		*Placement of access through the biliary tree and into small bowel to assist with an endoscopic biliary procedure (eg, rendezvous procedure), percutaneous, including diagnostic cholangiography when performed, imaging*		*Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (eg, fluoroscopy and/or ultrasound), balloon dilation, catheter exchange or removal when performed, and all associated*	
5	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**
6	**GLOBAL PERIOD**			**000**	**000**	**000**	**000**	**000**	**000**
122	sodium chloride 0.9% irrigation (500-1000ml uou)	SH069	item	1		1		1	
123	povidone soln (Betadine)	SJ041	ml	60		60		60	
124	cup, biopsy-specimen sterile 4oz	SL036	item						
125	disinfectant, surface (Envirocide, Sanizide)	SM013	oz			1			
126	sanitizing cloth-wipe (surface, instruments, equipment)	SM022	item	3		3		3	
127	**EQUIPMENT**	**CODE**							
128	angiographic room	EL011		27		72		65	
129	portable ultrasound	EQ250				96			
130	light, exam	EQ168		51		96		89	
131	PACS Workstation Proxy	ED050		51		96		89	
132	table, instrument, mobile	EF027		87		312		305	
133	ECG, 3-channel (with Sp02, NIBP, temp, resp)	EQ011		87		312		305	
134	IV infusion pump	EQ032		87		312		305	
135	stretcher	EF018		87		312		305	
136				***Outpatient***	***Inpatient***	***Outpatient***	***Inpatient***	***Outpatient***	***Inpatient***
137	*47505*			*53%*	*44%*			*53%*	*44%*
138	*74305*			*52%*	*45%*			*52%*	*45%*
139	*47500*					*20%*	*79%*		
140	*74320*					*22%*	*77%*		
141	*47510*								
142	*75980*								
143	*47511*								
144	*75982*								
145	*47525*							*63%*	*34%*
146	*75984*							*67%*	*30%*
147	*74363*							*42%*	*58%*
148	*47556*							*34%*	*65%*
149	*47555*								
150	*47553*								
151	*47630*								
152	*74327*								

	A	B	C	AB	AC	AD	AE	AF	AG
1	**REVISED/APPROVED AT 04/2015 MEETING**			**INPATIENT**		**INPATIENT**			
2	***Please note: If a supply has a purchase price of $100 or more please bold the item name and CMS code.**			**47539**		**47540**		**47542**	
3				**stent-new w/o cath**		**stent-new w/cath**		**dilation**	
4	**Meeting Date: October** 2015 **Tab:** 6 Biliary Procedures Bundling **Specialty:** SIR, ACR	**CMS Code**	**Staff Type**	*Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (eg, fluoroscopy and/or ultrasound), balloon dilation, catheter exchange or removal when performed, and all associated*		*Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (eg, fluoroscopy and/or ultrasound), balloon dilation, catheter exchange or removal when performed, and all associated*		*Balloon dilation of biliary duct(s) or of ampulla (sphincteroplasty), percutaneous, including imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation, each duct*	
5	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**
6	**GLOBAL PERIOD**			**000**	**000**	**000**	**000**	**ZZZ**	**ZZZ**
7	**TOTAL CLINICAL LABOR TIME**			**331**	**14**	**361**	**14**	**90**	**0**
8	**TOTAL PRE-SERV CLINICAL LABOR TIME**			**7**	**14**	**7**	**14**	**0**	**0**
9		*L037D*	*RN/LPN/MTA*	*3*	*14*	*3*	*14*	*0*	*0*
10		*L041B*	*RadTech*	*4*		*4*		*0*	
11	**TOTAL SERVICE PERIOD CLINICAL LABOR TIME**			**321**	**0**	**351**	**0**	**90**	**0**
12		*L037D*	*RN/LPN/MTA*	*38*		*40*		*7*	
13		*L041B*	*RadTech*	*146*		*164*		*53*	
14		*L051A*	*RN*	*137*		*147*		*30*	
15	**TOTAL POST-SERV CLINICAL LABOR TIME**	L037D	RN/LPN/MTA	**3**	**0**	**3**	**0**	**0**	**0**
16	**PRE-SERVICE**								
17	**Start: Following visit when decision for surgery or procedure made**								
18	Complete pre-service diagnostic & referral forms	L037D	RN/LPN/MTA	3	3	3	3		
19	Coordinate pre-surgery services	L037D	RN/LPN/MTA		5		5		
20	Schedule space and equipment in facility	L037D	RN/LPN/MTA		3		3		
21	Provide pre-service education/obtain consent	L037D	RN/LPN/MTA						
22	Follow-up phone calls & prescriptions	L037D	RN/LPN/MTA		3		3		
23	Availability of prior images confirmed	L041B	RadTech	2		2			
24	Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist	L041B	RadTech	2		2			
25	Other Clinical Activity - *specify:*								
26	**End: When patient enters office/facility for surgery/procedure**								
27	**SERVICE PERIOD**								
28	**Start: When patient enters office/facility for surgery/procedure:**								
29	Greet patient, provide gowning, ensure appropriate medical records are available	L037D	RN/LPN/MTA	3		3			
30	Obtain vital signs	L037D	RN/LPN/MTA	5		5			
31	Provide pre-service education/obtain consent	L037D	RN/LPN/MTA	5		5			
32	Prepare room, equipment, supplies	L041B	RT	2		2			
33	Setup scope (non facility setting only)								
34	Prepare and position patient/ monitor patient/ set up IV	L041B	RT	2		2			
35	Sedate/apply anesthesia	L051A	RN	2		2			
36	Other Clinical Activity - specify:								
37	Intra-service								
38	Assist Physician in Performing Procedure (CS)	L051A	RN	75		85		30	
39	Assist Physician in Performing Procedure	L037D	RN/LPN/MTA						
40	Assist Physician in Performing Procedure	L041B	RT	75		85		30	
41	Acquire images (75%)	L041B	RT	56		64		23	
42	Circulator (25%)	L037D	RN/LPN/MTA	19		21		7	
43									
44	Post-Service								
45	Monitor pt. following moderate sedation	L051A	RN	15		15			
46	Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation)	L051A	RN	45		45			
47	Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation)	L037D	RN/LPN/MTA						
48	Clean room/equipment by physician staff	L041B	RT	6		6			
49	Clean Scope								
50	Clean Surgical Instrument Package								
51	Complete diagnostic forms, lab & X-ray requisitions	L037D	RN/LPN/MTA	3		3			

	A	B	C	AB	AC	AD	AE	AF	AG
1	**REVISED/APPROVED AT 04/2015 MEETING**			**INPATIENT**		**INPATIENT**			
2	***Please note: If a supply has a purchase price of $100 or more please bold the item name and CMS code.**			**47539**		**47540**		**47542**	
3				**stent-new w/o cath**		**stent-new w/cath**		**dilation**	
4	**Meeting Date: October** 2015 **Tab:** 6 Biliary Procedures Bundling **Specialty:** SIR, ACR	**CMS Code**	**Staff Type**	*Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (eg, fluoroscopy and/or ultrasound), balloon dilation, catheter exchange or removal when performed, and all associated*		*Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (eg, fluoroscopy and/or ultrasound), balloon dilation, catheter exchange or removal when performed, and all associated*		*Balloon dilation of biliary duct(s) or of ampulla (sphincteroplasty), percutaneous, including imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation, each duct*	
5	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**
6	**GLOBAL PERIOD**			**000**	**000**	**000**	**000**	**ZZZ**	**ZZZ**
52	Review/read X-ray, lab, and pathology reports								
53	Check dressings & wound/ home care instructions /coordinate office visits /prescriptions	L037D	RN/LPN/MTA	3		3			
54	Technologist QC's images in PACS, checking for all images, reformats, and dose page	L041B	RT	2		2			
55	Review examination with interpreting MD	L041B	RT	2		2			
56	Exam documents scanned into PACS. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue	L041B	RT	1		1			
57	Other Clinical Activity - *specify:*								
61	**End: Patient leaves office**								

	A	B	C	AB	AC	AD	AE	AF	AG
1	**REVISED/APPROVED AT 04/2015 MEETING**			**INPATIENT**		**INPATIENT**			
2	***Please note: If a supply has a purchase price of $100 or more please bold the item name and CMS code.**			**47539**		**47540**		**47542**	
3				**stent-new w/o cath**		**stent-new w/cath**		**dilation**	
4	**Meeting Date: October** 2015 **Tab:** 6 Biliary Procedures Bundling **Specialty:** SIR, ACR	**CMS Code**	**Staff Type**	*Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (eg, fluoroscopy and/or ultrasound), balloon dilation, catheter exchange or removal when performed, and all associated*		*Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (eg, fluoroscopy and/or ultrasound), balloon dilation, catheter exchange or removal when performed, and all associated*		*Balloon dilation of biliary duct(s) or of ampulla (sphincteroplasty), percutaneous, including imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation, each duct*	
5	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**
6	**GLOBAL PERIOD**			**000**	**000**	**000**	**000**	**ZZZ**	**ZZZ**
62	**POST-SERVICE Period**								
63	**Start: Patient leaves office/facility**								
64	Conduct phone calls/call in prescriptions	L037D	RN/LPN/MTA	3		3			
65	***Office visits: List Number and Level of Office Visits***			**# visits**	**# visits**	**# visits**	**# visits**	**# visits**	**# visits**
71	**Total Office Visit Time**			**0**	**0**	**0**	**0**	**0**	**0**
72	Other Clinical Activity - *specify:*								
73	**End: with last office visit before end of global period**								
74	**MEDICAL SUPPLIES***	**CODE**	**UNIT**						
75	pack, minimum multi-specialty visit	SA048	pack	**1**		**1**			
76	pack, conscious sedation	SA044	pack	**1**		**1**			
77	**Nephroureteral Catheter**	**NEW**	**item**						
78	**catheter, balloon, PTA**	**SD152**	**item**	**2**		**2**		**1**	
79	**Viabil covered biliary stent**	**NEW**	**item**	**1**		**1**			
80	**internal/external biliary catheter**	**NEW**	**item**	**1**		**1**			
81	**stone basket**	**NEW**							
82	Radial Jaw	NEW	item						
83	kit, iv starter	SA019	kit	1		1			
84	kit, suture removal	SA031	kit						
85	pack, cleaning and disinfecting, endoscope	SA042	pack						
86	tray, shave prep	SA067	tray	1		1			
87	kit, AccuStick II Introducer System with RO Marker	SA071	kit	1		1			
88	cap, surgical	SB001	item	4		4			
89	cover-condom, transducer or ultrasound probe	SB005	item	1		1			
90	drape, sterile, femoral	SB009	item	1		1			
91	drape-towel, sterile 18inx26in	SB019	item	2		2			
92	gloves, non-sterile	SB022	pair	3		3			
93	gloves, sterile	SB024	pair	2		2			
94	gown, surgical, sterile	SB028	item	2		2			
95	mask, surgical	SB033	item	2		2			
96	mask, surgical, with face shield	SB034	item	2		2			
97	shoe covers, surgical	SB039	pair	4		4			
98	underpad 2ftx3ft (Chux)	SB044	item	1		1			
99	closed flush system, angiography	SC010	item	1		1			
100	needle, Chiba	SC035	item						
101	3 way stop cock (for irrigation)	SC049	item	1		1			
102	syringe 10-12ml	SC051	item	2		2			
103	syringe 60ml (for irrigation)	SC056	item	2		2			
104	syringe w-needle, OSHA compliant (SafetyGlide)	SC058	item	2		2			
105	dilator, vessel, angiographic	SD043	item	2		2			
106	guidewire, hydrophilic	SD089	item	1		1			
107	guidewire, STIFF	SD090	item	1		1			
108	vascular sheath	SD136	item	1		1		1	
109	percutaneous catheter fastener (Percu-Stay)	SD146	item			1			
110	catheter, (Glide)	SD147	item	1		1			
111	catheter, balloon inflation device	SD149	item	1		1		1	
112	drainage catheter, all purpose	SD161	item						
113	pouch, nephrostomy-biliary drainage	SD163	item			1			
114	guidewire bowl w-lid, sterile	SD171	item	1		1			
115	blade, surgical (Bard-Parker)	SF007	item	1		1			
116	applicator, sponge-tipped	SG009	item	4		4			
117	dressing, 12-7mm (Gelfoam)	SG033	item	1					
118	gauze, sterile 4in x 4in	SG055	item	6		6			
119	tape, surgical paper 1in (Micropore)	SG079	item	12		12			
120	lidocaine 1%-2% inj (Xylocaine)	SH047	ml	10		10			
121	sodium chloride 0.9% flush syringe	SH065	item	2		2			

	A	B	C	AB	AC	AD	AE	AF	AG
1	**REVISED/APPROVED AT 04/2015 MEETING**			**INPATIENT**		**INPATIENT**			
2	***Please note: If a supply has a purchase price of $100 or more please bold the item name and CMS code.**			**47539**		**47540**		**47542**	
3				**stent-new w/o cath**		**stent-new w/cath**		**dilation**	
4	**Meeting Date: October** 2015 **Tab:** 6 Biliary Procedures Bundling **Specialty:** SIR, ACR	**CMS Code**	**Staff Type**	*Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (eg, fluoroscopy and/or ultrasound), balloon dilation, catheter exchange or removal when performed, and all associated*		*Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (eg, fluoroscopy and/or ultrasound), balloon dilation, catheter exchange or removal when performed, and all associated*		*Balloon dilation of biliary duct(s) or of ampulla (sphincteroplasty), percutaneous, including imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation, each duct*	
5	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**
6	**GLOBAL PERIOD**			**000**	**000**	**000**	**000**	**ZZZ**	**ZZZ**
122	sodium chloride 0.9% irrigation (500-1000ml uou)	SH069	item	1		1			
123	povidone soln (Betadine)	SJ041	ml	60		60			
124	cup, biopsy-specimen sterile 4oz	SL036	item					1	
125	disinfectant, surface (Envirocide, Sanizide)	SM013	oz	1		1			
126	sanitizing cloth-wipe (surface, instruments, equipment)	SM022	item	3		3			
127	**EQUIPMENT**	**CODE**							
128	angiographic room	EL011		87		97		30	
129	portable ultrasound	EQ250		111		121			
130	light, exam	EQ168		111		121		30	
131	PACS Workstation Proxy	ED050		111		121		30	
132	table, instrument, mobile	EF027		327		337		30	
133	ECG, 3-channel (with Sp02, NIBP, temp, resp)	EQ011		327		337		30	
134	IV infusion pump	EQ032		327		337		30	
135	stretcher	EF018		327		337		30	
136				***Outpatient***	***Inpatient***	***Outpatient***	***Inpatient***	***Outpatient***	***Inpatient***
137	*47505*								
138	*74305*								
139	*47500*			*20%*	*79%*	*20%*	*79%*		
140	*74320*			*22%*	*77%*	*22%*	*77%*		
141	*47510*					*19%*	*80%*		
142	*75980*					*20%*	*79%*		
143	*47511*								
144	*75982*								
145	*47525*								
146	*75984*								
147	*74363*			*42%*	*58%*	*42%*	*58%*	*42%*	*58%*
148	*47556*			*34%*	*65%*	*34%*	*65%*		
149	*47555*							*51%*	*47%*
150	*47553*								
151	*47630*								
152	*74327*								

	A	B	C	AH	AI	AJ	AK
1	**REVISED/APPROVED AT 04/2015 MEETING**						
2	***Please note: If a supply has a purchase price of $100 or more please bold the item name and CMS code.**			**47543**		**47544**	
3				**biopsy**		**stone removal**	
4	**Meeting Date: October** 2015 **Tab:** 6 Biliary Procedures Bundling **Specialty:** SIR, ACR	**CMS Code**	**Staff Type**	*Endoluminal biopsy(ies) of biliary tree, percutaneous, any method(s) (eg, brush, forceps and/or needle), including imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation, single or*		*Removal of calculi/debris from biliary duct(s) and/or gallbladder, percutaneous, including destruction of calculi by any method (eg, mechanical, electrohydraulic, lithotripsy) when performed, imaging guidance (eg, fluoroscopy)*	
5	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**
6	**GLOBAL PERIOD**			**ZZZ**	**ZZZ**	**ZZZ**	**ZZZ**
7	**TOTAL CLINICAL LABOR TIME**			**90**	**0**	**135**	**0**
8	**TOTAL PRE-SERV CLINICAL LABOR TIME**			**0**	**0**	**0**	**0**
9		*L037D*	*RN/LPN/MTA*	*0*	*0*	*0*	*0*
10		*L041B*	*RadTech*	*0*		*0*	
11	**TOTAL SERVICE PERIOD CLINICAL LABOR TIME**			**90**	**0**	**135**	**0**
12		*L037D*	*RN/LPN/MTA*	*7*		*11*	
13		*L041B*	*RadTech*	*53*		*79*	
14		*L051A*	*RN*	*30*		*45*	
15	**TOTAL POST-SERV CLINICAL LABOR TIME**	L037D	RN/LPN/MTA	**0**	**0**	**0**	**0**
16	**PRE-SERVICE**						
17	**Start: Following visit when decision for surgery or procedure made**						
18	Complete pre-service diagnostic & referral forms	L037D	RN/LPN/MTA				
19	Coordinate pre-surgery services	L037D	RN/LPN/MTA				
20	Schedule space and equipment in facility	L037D	RN/LPN/MTA				
21	Provide pre-service education/obtain consent	L037D	RN/LPN/MTA				
22	Follow-up phone calls & prescriptions	L037D	RN/LPN/MTA				
23	Availability of prior images confirmed	L041B	RadTech				
24	Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist	L041B	RadTech				
25	Other Clinical Activity - *specify:*						
26	**End: When patient enters office/facility for surgery/procedure**						
27	**SERVICE PERIOD**						
28	**Start: When patient enters office/facility for surgery/procedure:**						
29	Greet patient, provide gowning, ensure appropriate medical records are available	L037D	RN/LPN/MTA				
30	Obtain vital signs	L037D	RN/LPN/MTA				
31	Provide pre-service education/obtain consent	L037D	RN/LPN/MTA				
32	Prepare room, equipment, supplies	L041B	RT				
33	Setup scope (non facility setting only)						
34	Prepare and position patient/ monitor patient/ set up IV	L041B	RT				
35	Sedate/apply anesthesia	L051A	RN				
36	Other Clinical Activity - specify:						
37	Intra-service						
38	Assist Physician in Performing Procedure (CS)	L051A	RN	30		45	
39	Assist Physician in Performing Procedure	L037D	RN/LPN/MTA				
40	Assist Physician in Performing Procedure	L041B	RT	30		45	
41	Acquire images (75%)	L041B	RT	23		34	
42	Circulator (25%)	L037D	RN/LPN/MTA	7		11	
43							
44	Post-Service						
45	Monitor pt. following moderate sedation	L051A	RN				
46	Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation)	L051A	RN				
47	Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation)	L037D	RN/LPN/MTA				
48	Clean room/equipment by physician staff	L041B	RT				
49	Clean Scope						
50	Clean Surgical Instrument Package						
51	Complete diagnostic forms, lab & X-ray requisitions	L037D	RN/LPN/MTA				

	A	B	C	AH	AI	AJ	AK
1	**REVISED/APPROVED AT 04/2015 MEETING**						
2	***Please note: If a supply has a purchase price of $100 or more please bold the item name and CMS code.**			**47543**		**47544**	
3				**biopsy**		**stone removal**	
4	**Meeting Date: October** 2015 **Tab:** 6 Biliary Procedures Bundling **Specialty:** SIR, ACR	**CMS Code**	**Staff Type**	*Endoluminal biopsy(ies) of biliary tree, percutaneous, any method(s) (eg, brush, forceps and/or needle), including imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation, single or*		*Removal of calculi/debris from biliary duct(s) and/or gallbladder, percutaneous, including destruction of calculi by any method (eg, mechanical, electrohydraulic, lithotripsy) when performed, imaging guidance (eg, fluoroscopy)*	
5	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**
6	**GLOBAL PERIOD**			**ZZZ**	**ZZZ**	**ZZZ**	**ZZZ**
52	Review/read X-ray, lab, and pathology reports						
53	Check dressings & wound/ home care instructions /coordinate office visits /prescriptions	L037D	RN/LPN/MTA				
54	Technologist QC's images in PACS, checking for all images, reformats, and dose page	L041B	RT				
55	Review examination with interpreting MD	L041B	RT				
56	Exam documents scanned into PACS. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue	L041B	RT				
57	Other Clinical Activity - *specify:*						
61	**End: Patient leaves office**						

	A	B	C	AH	AI	AJ	AK
1	**REVISED/APPROVED AT 04/2015 MEETING**						
2	***Please note: If a supply has a purchase price of $100 or more please bold the item name and CMS code.**			**47543**		**47544**	
3				**biopsy**		**stone removal**	
4	**Meeting Date: October** 2015 **Tab:** 6 Biliary Procedures Bundling **Specialty:** SIR, ACR	**CMS Code**	**Staff Type**	*Endoluminal biopsy(ies) of biliary tree, percutaneous, any method(s) (eg, brush, forceps and/or needle), including imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation, single or*		*Removal of calculi/debris from biliary duct(s) and/or gallbladder, percutaneous, including destruction of calculi by any method (eg, mechanical, electrohydraulic, lithotripsy) when performed, imaging guidance (eg, fluoroscopy)*	
5	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**
6	**GLOBAL PERIOD**			**ZZZ**	**ZZZ**	**ZZZ**	**ZZZ**
62	**POST-SERVICE Period**						
63	**Start: Patient leaves office/facility**						
64	Conduct phone calls/call in prescriptions	L037D	RN/LPN/MTA				
65	***Office visits: List Number and Level of Office Visits***			**# visits**	**# visits**	**# visits**	**# visits**
71	**Total Office Visit Time**			**0**	**0**	**0**	**0**
72	Other Clinical Activity - *specify:*						
73	**End: with last office visit before end of global period**						
74	**MEDICAL SUPPLIES***	**CODE**	**UNIT**				
75	pack, minimum multi-specialty visit	SA048	pack				
76	pack, conscious sedation	SA044	pack				
77	**Nephroureteral Catheter**	**NEW**	**item**				
78	**catheter, balloon, PTA**	**SD152**	**item**			**1**	
79	**Viabil covered biliary stent**	**NEW**	**item**				
80	**internal/external biliary catheter**	**NEW**	**item**				
81	**stone basket**	**NEW**		**1**			
82	Radial Jaw	NEW	item	1			
83	kit, iv starter	SA019	kit				
84	kit, suture removal	SA031	kit				
85	pack, cleaning and disinfecting, endoscope	SA042	pack				
86	tray, shave prep	SA067	tray				
87	kit, AccuStick II Introducer System with RO Marker	SA071	kit				
88	cap, surgical	SB001	item				
89	cover-condom, transducer or ultrasound probe	SB005	item				
90	drape, sterile, femoral	SB009	item				
91	drape-towel, sterile 18inx26in	SB019	item				
92	gloves, non-sterile	SB022	pair				
93	gloves, sterile	SB024	pair				
94	gown, surgical, sterile	SB028	item				
95	mask, surgical	SB033	item				
96	mask, surgical, with face shield	SB034	item				
97	shoe covers, surgical	SB039	pair				
98	underpad 2ftx3ft (Chux)	SB044	item				
99	closed flush system, angiography	SC010	item				
100	needle, Chiba	SC035	item				
101	3 way stop cock (for irrigation)	SC049	item				
102	syringe 10-12ml	SC051	item				
103	syringe 60ml (for irrigation)	SC056	item				
104	syringe w-needle, OSHA compliant (SafetyGlide)	SC058	item				
105	dilator, vessel, angiographic	SD043	item				
106	guidewire, hydrophilic	SD089	item				
107	guidewire, STIFF	SD090	item				
108	vascular sheath	SD136	item	1		1	
109	percutaneous catheter fastener (Percu-Stay)	SD146	item				
110	catheter, (Glide)	SD147	item				
111	catheter, balloon inflation device	SD149	item			1	
112	drainage catheter, all purpose	SD161	item				
113	pouch, nephrostomy-biliary drainage	SD163	item				
114	guidewire bowl w-lid, sterile	SD171	item				
115	blade, surgical (Bard-Parker)	SF007	item				
116	applicator, sponge-tipped	SG009	item				
117	dressing, 12-7mm (Gelfoam)	SG033	item				
118	gauze, sterile 4in x 4in	SG055	item				
119	tape, surgical paper 1in (Micropore)	SG079	item				
120	lidocaine 1%-2% inj (Xylocaine)	SH047	ml				
121	sodium chloride 0.9% flush syringe	SH065	item				

	A	B	C	AH	AI	AJ	AK
1	**REVISED/APPROVED AT 04/2015 MEETING**						
2	***Please note: If a supply has a purchase price of $100 or more please bold the item name and CMS code.**			**47543**		**47544**	
3				**biopsy**		**stone removal**	
4	**Meeting Date: October** 2015 **Tab:** 6 Biliary Procedures Bundling **Specialty:** SIR, ACR	**CMS Code**	**Staff Type**	*Endoluminal biopsy(ies) of biliary tree, percutaneous, any method(s) (eg, brush, forceps and/or needle), including imaging guidance (eg, fluoroscopy) and all associated radiological supervision and interpretation, single or*		*Removal of calculi/debris from biliary duct(s) and/or gallbladder, percutaneous, including destruction of calculi by any method (eg, mechanical, electrohydraulic, lithotripsy) when performed, imaging guidance (eg, fluoroscopy)*	
5	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**
6	**GLOBAL PERIOD**			**ZZZ**	**ZZZ**	**ZZZ**	**ZZZ**
122	sodium chloride 0.9% irrigation (500-1000ml uou)	SH069	item				
123	povidone soln (Betadine)	SJ041	ml				
124	cup, biopsy-specimen sterile 4oz	SL036	item				
125	disinfectant, surface (Envirocide, Sanizide)	SM013	oz				
126	sanitizing cloth-wipe (surface, instruments, equipment)	SM022	item				
127	**EQUIPMENT**	**CODE**					
128	angiographic room	EL011		30		45	
129	portable ultrasound	EQ250					
130	light, exam	EQ168		30		45	
131	PACS Workstation Proxy	ED050		30		45	
132	table, instrument, mobile	EF027		30		45	
133	ECG, 3-channel (with Sp02, NIBP, temp, resp)	EQ011		30		45	
134	IV infusion pump	EQ032		30		45	
135	stretcher	EF018		30		45	
136				***Outpatient***	***Inpatient***	***Outpatient***	***Inpatient***
137	*47505*						
138	*74305*						
139	*47500*						
140	*74320*						
141	*47510*						
142	*75980*						
143	*47511*						
144	*75982*						
145	*47525*						
146	*75984*						
147	*74363*						
148	*47556*						
149	*47555*						
150	*47553*			*27%*	*72%*		
151	*47630*					*46%*	*53%*
152	*74327*					*48%*	*51%*

AMA/Specialty Society RVS Update Committee Summary of Recommendations

October 2015

Reflectance Confocal Microscopy

In February 2015, the CPT Editorial panel established six new Category I codes to describe reflectance confocal microscopy (RCM) for imaging of skin.

At the April 2015 RUC meeting, following the RUC's review and acceptance of physician work and direct practice expense, new information was brought to the attention of the RUC which called into question how much physician work and clinical labor are typically part of these six services. The identified source, the vendor's SEC 10-K Annual Report for the period ending 12/31/2013, included information which alluded to the physician work and clinical labor of a similar procedure possibly taking different time than the estimates originally presented to the RUC. Furthermore, it was also called into question if there were other devices used to perform this service that the RUC was unaware of at the April 2015 RUC meeting and that may necessitate a revised coding structure. The presenters who would have been able to offer an informed opinion on this document were no longer at the meeting when the issue was raised. Therefore, at the time, the RUC requested that the specialty re-survey this family of services and resubmit physician work and direct practice expense recommendations for the October 2015 RUC meeting.

The American Academy of Dermatology Association (AADA) appealed the RUC's recommendation to contractor-price these services and re-survey for October 2015. AADA requested that the RUC reconsider its previous recommendation to resurvey these services for October 2015, but to present the valid survey data from April 2015.

The RUC organized an Ad Hoc Appeals Committee to review the appeal and make a recommendation. The Appeals Committee noted the concerns about using these codes to report RCM using a handheld device and agreed with the specialty society to submit a parenthetical request to the CPT Editorial Panel to prevent this use as well as develop an education CPT Assistant article. The Appeals Committee noted that the RUC's primary concern in April was regarding defining the physician work versus clinical staff work for image acquisition and physician time to perform image review and interpretation. The Committee noted that another targeted survey, most likely to the same individuals, would not produce significantly different results. Therefore, it is appropriate that the specialty society present the survey data from April 2015.

On June 11 2015, the Ad Hoc Appeals Committee recommended for the RUC to reconsider its April 2015 recommendation for Reflectance Confocal Microscopy (RCM) codes 96931-96936 and that the RUC consider the AADA request to return to the October 2015 RUC meeting, present the April 2015 survey data with additional information in response to the SEC 10-K report and the RUC to make work and practice expense recommendations. The Ad Hoc Appeals Committee also supported the specialty society's submission to the CPT Editorial Panel to create parentheticals and a CPT Assistant article to foster correct reporting of these services.

At the October 2015 CPT Editorial Panel meeting, the Panel approved the following CPT Introductory Guideline to prevent the use of 96931-96936 with the screening handheld device:

> Codes 96931-96936 describe the acquisition and/or diagnostic interpretation of the device generated stitched image mosaics related to a single lesion. Do not report 96931-96936 for a reflectance confocal microscopy examination that does not produce mosaic images. For services rendered using reflectance confocal microscopy not generating mosaic images, use 96999.

96931 ***Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; image acquisition and interpretation and report, first lesion***

The RUC reviewed the survey results from 38 dermatologists and dermatopathologists and agreed with the following physician time components: pre-service time of 3 minutes, intra-service time of 25 minutes, and post-service time of 0 minutes.

The specialty society noted when a dermatologist identifies a lesion of concern, in lieu of biopsying the lesion, the dermatologist may order a reflectance confocal microscopy study. The image acquisition entails a nurse or technologist acquiring a series of 0.5mm by 0.5mm images then the machine's software stitches those images together to form a mosaic image so a lesion of up to 8mm in diameter can be reviewed. Several layers of the skin are imaged in this fashion and reviewed by the dermatopathologist or pathologist, including: the stratum corneum, the stratum granulosum, the stratum spinosum, the epidermal interface and the superficial dermis. Reading these images requires a great deal of skill to interpret.

To determine an appropriate work value for 96931, the RUC reviewed the survey respondents' estimated physician work value and agreed the respondents overestimated the physician work with the 25th percentile work RVU of 0.90. The specialty society noted and the RUC agreed that the physician work for 96931 and 96933 are identical and therefore should be valued the same. Therefore, the RUC also reviewed the 25th percentile work RVU of 0.80 from survey code 96933 and agreed that this value appropriately accounts for the physician work involved for both 96931 and 96933. To justify a work RVU of 0.80, the RUC reviewed top key reference code 88305 *Level IV - Surgical pathology, gross and microscopic examination* (work RVU=0.75, intra-service time of 25 minutes) and noted both services have identical intra-service time, whereas the survey code has more total time (28 minutes vs 25 minutes), justifying a somewhat higher work value for 96931. To further support a work RVU of 0.80, the RUC reviewed CPT code 43752 *Naso- or oro-gastric tube placement, requiring physician's skill and fluoroscopic guidance (includes fluoroscopy, image documentation and report)* (work RVU= 0.81, intra-service time of 20 minutes and total time of 30 minutes) and noted that both codes have similar intensities, while the survey code has more intra-service time and the reference code has more total time. The RUC agreed that both services should be valued similarly. **The RUC recommends a work RVU of 0.80 for CPT code 96931.**

96933 ***Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; interpretation and report, first lesion***

The RUC reviewed the survey results from 38 dermatologists and dermatopathologists and agreed with the following physician time components: pre-service time of 3 minutes, intra-service time of 25 minutes, and post-service time of 0 minutes.

The specialty society noted when a dermatologist identifies a lesion of concern, in lieu of biopsying the lesion, the dermatologist may order a reflectance confocal microscopy study. The image acquisition entails a nurse or technologist acquiring a series of 0.5mm by 0.5mm images then the machine's software stitches those images together to form a mosaic image so a lesion of up to 8mm in diameter can be reviewed. Several layers of the skin are imaged in this fashion and reviewed by the dermatopathologist or pathologist, including: the stratum corneum, the stratum granulosum, the stratum spinosum, the epidermal interface and the superficial dermis. Reading these images requires a great deal of skill to interpret.

To determine an appropriate work value for 96933, the RUC reviewed the survey respondents' 25th percentile work value of 0.80 and agreed this value appropriately accounts for the physician work involved. The specialty society noted and the RUC agreed that the physician work for 96931 and 96933 are identical and therefore should be valued the same. To justify a work RVU of 0.80, the RUC reviewed top key reference code 88305 *Level IV - Surgical pathology, gross and microscopic examination* (work RVU=0.75, intra-service time of 25 minutes) and noted both services have identical intra-service time, whereas the survey code has more total time (28 minutes vs 25 minutes), justifying a somewhat higher work value for 96931. To further support a work RVU of 0.80, the RUC reviewed CPT code 43752 *Naso- or oro-gastric tube placement, requiring physician's skill and fluoroscopic guidance (includes fluoroscopy, image documentation and report)* (work RVU= 0.81, intra-service time of 20 minutes and total time of 30 minutes) and noted that both codes have similar intensities, while the survey code has more intra-service time and the reference code has more total time. The RUC agreed that both services should be valued similarly. **The RUC recommends a work RVU of 0.80 for CPT code 96933.**

96934 ***Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; image acquisition and interpretation and report, each additional lesion (List separately in addition to primary procedure)***

The RUC reviewed the survey results from 36 dermatologists and dermatopathologists and agreed with the following physician time components: pre-service time of 0 minutes, intra-service time of 25 minutes, and post-service time of 0 minutes.

The specialty society noted when a dermatologist identifies a lesion of concern, in lieu of biopsying the lesion, the dermatologist may order a reflectance confocal microscopy study. The image acquisition entails a nurse or technologist acquiring a series of 0.5mm by 0.5mm images then the machine's software stitches those images together to form a mosaic image so a lesion of up to 8mm in diameter can be reviewed. Several layers of the skin are imaged in this fashion and reviewed by the dermatopathologist or pathologist, including: the stratum corneum, the stratum granulosum, the stratum spinosum, the epidermal interface and the superficial dermis. Reading these images requires a great deal of skill to interpret.

To determine an appropriate work value for 96934, the RUC reviewed the survey respondents' estimated physician work value and agreed the respondents somewhat overestimated the physician work with the 25th percentile work RVU of 0.79. The specialty society noted and the RUC

agreed that the physician work for 96934 and 96936 are identical and therefore should be valued the same. Therefore, the RUC also reviewed the 25th percentile work RVU of 0.76 from survey code 96933 and agreed that this value appropriately accounts for the physician work involved for both 96934 and 96936. To justify a work RVU of 0.76, the RUC reviewed top key reference code 88305 *Level IV - Surgical pathology, gross and microscopic examination* (work RVU=0.75, intra-service time of 25 minutes) and noted both services have identical intra-service time and total time, justifying a similar work value for both services. To further support a work RVU of 0.76, the RUC reviewed CPT code 43752 *Naso- or oro-gastric tube placement, requiring physician's skill and fluoroscopic guidance (includes fluoroscopy, image documentation and report)* (work RVU= 0.81, intra-service time of 20 minutes and total time of 30 minutes) and noted that both codes have similar intensities, while the survey code has more intra-service time and the reference code has more total time. The RUC agreed that both services should be valued similarly. **The RUC recommends a work RVU of 0.76 for CPT code 96934.**

96936 ***Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; interpretation and report only, each additional lesion (List separately in addition to primary procedure)***

The RUC reviewed the survey results from 37 dermatologists and dermatopathologists and agreed with the following physician time components: pre-service time of 0 minutes, intra-service time of 25 minutes, and post-service time of 0 minutes.

The specialty society noted when a dermatologist identifies a lesion of concern, in lieu of biopsying the lesion, the dermatologist may order a reflectance confocal microscopy study. The image acquisition entails a nurse or technologist acquiring a series of 0.5mm by 0.5mm images then the machine's software stitches those images together to form a mosaic image so a lesion of up to 8mm in diameter can be reviewed. Several layers of the skin are imaged in this fashion and reviewed by the dermatopathologist or pathologist, including: the stratum corneum, the stratum granulosum, the stratum spinosum, the epidermal interface and the superficial dermis. Reading these images requires a great deal of skill to interpret.

To determine an appropriate work value for 96936, the RUC reviewed the survey respondents' 25th percentile work value of 0.76 and agreed this value appropriately accounts for the physician work involved. The specialty society noted and the RUC agreed that the physician work for 96934 and 96936 are identical and therefore should be valued the same. To justify a work RVU of 0.76, the RUC reviewed top key reference code 88305 *Level IV - Surgical pathology, gross and microscopic examination* (work RVU=0.75, intra-service time of 25 minutes) and noted both services have identical intra-service time and total time, justifying a similar work value for both services. To further support a work RVU of 0.76, the RUC reviewed CPT code 43752 *Naso- or oro-gastric tube placement, requiring physician's skill and fluoroscopic guidance (includes fluoroscopy, image documentation and report)* (work RVU= 0.81, intra-service time of 20 minutes and total time of 30 minutes) and noted that both codes have similar intensities, while the survey code has more intra-service time and the reference code has more total time. The RUC agreed that both services should be valued similarly. **The RUC recommends a work RVU of 0.76 for CPT code 96936.**

Practice Expense
The practice expense for this issue was reviewed and approved at the previous RUC meeting. At that time the PE Subcommittee discussed at length the 2 minutes of time to *review imaging with interpreting physician.* The PE Subcommittee agreed to leave the time in because for the typical patient the physician doing the imaging and the physician interpreting the imaging are not the same person and the clinical staff needs time to review and verify that the interpreting physician has all the information needed. In addition, the PE Subcommittee allowed one modification at the October 2015 RUC meeting because CMS was concerned about the invoice to price the imaging tray. The invoice shows one price for the tray; however the specialty had itemized the contents of the imaging tray on the PE spreadsheet. The specialty revised the spreadsheet to remove the items of the tray and instead include one line item for *Imaging Tray*. **The RUC reviewed and approved the direct practice expense inputs with modifications at the April 2015 RUC meeting.**

New Technology
The service will be placed on the New Technology list and be re-reviewed by the RUC in three years to ensure correct valuation and utilization assumptions.

CPT Code (●New)	Tracking Number	CPT Descriptor	Global Period	Work RVU Recommendation
Category I **Medicine** **Special Dermatological Procedures** <u>Codes 96931-96936 describe the acquisition and/or diagnostic interpretation of the device generated stitched image mosaics related to a single lesion. Do not report 96931-96936 for a reflectance confocal microscopy examination that does not produce mosaic images. For services rendered using reflectance confocal microscopy not generating mosaic images, use 96999.</u>				
●96931	BB1	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; image acquisition and interpretation and report, first lesion	XXX	0.80

●96932	BB2	image acquisition only, first lesion	XXX	N/A (PE Only)
●96933	BB3	interpretation and report only, first lesion	XXX	0.80
✚●96934	BB4	image acquisition and interpretation and report, each additional lesion (List separately in addition to primary procedure) (Use 96934 in conjunction with 96931)	ZZZ	0.76
✚●96935	BB5	image acquisition only, each additional lesion (List separately in addition to primary procedure) (Use 96935 in conjunction with 96932)	ZZZ	N/A (PE Only)
✚●96936	BB6	interpretation and report only, each additional lesion (List separately in addition to primary procedure) (Use 96936 in conjunction with 96933)	ZZZ	0.76

Peter Smith, MD
Chair, RVU Update Committee
American Medical Association
330 North Wabash Ave., Suite 39300
Chicago IL 60611-5885

June 1, 2015

Dear Dr. Smith,

The American Academy of Dermatology (AAD) is a strong supporter of the RUC process for code valuation. We believe that it offers the best means of establishing relativity. As such, we were very disappointed at the procedural irregularities that transpired at the April meeting around valuation of the Reflectance Confocal Microscopy (RCM) codes.

As you know, during the April 2015 RUC meeting the AAD presented recommendations for practice expense inputs and work RVUs for the new CPT codes for RCM. Prior to the meeting, the Research Subcommittee approved a targeted survey and approved the vignettes that were used. The codes were surveyed using the RUC's electronic survey instrument. Presentation and discussion of both physician work and practice expense values proceeded in the typical manner once the definition of the 6 different codes was clarified. Work RVUs and PE were approved, and the primary presenters, who perform the procedure, left the meeting on Friday evening.

After approval of the RVUs and PE inputs, a RUC member discovered an SEC form 10-K (attached) which contained information describing a different use of RCM technology, using a hand-held device rather than the equipment that was described in the AAD presentation. The AAD had no prior knowledge of this document's existence. The existence of the hand-held device was known, but that is not the equipment for which the codes were intended and was not what was surveyed. Use of SEC documents as source of information by the RUC is unprecedented.

On Saturday morning, with 15 minutes notice to the presenting society and without providing a copy of the 10-K to the AAD, the tab was reopened, and a decision was made to negate the approved values and substitute carrier pricing. The AAD was asked to resurvey for the next meeting.

American Academy of Dermatology Association
Excellence in Dermatology™

1445 New York Ave., NW,
Suite 800
Washington, DC 20005-2134

Main: 202.842.3555
Fax: 202.842.4355
Website: www.aad.org

The AAD had the opportunity to review the 10-K after the meeting. We sought clarification from the manufacturer, Caliber ID. Caliber ID manufactures two types of equipment that use the confocal technology for in-vivo cellular level imaging of skin. The VivaScope 1500 is the equipment being used for the codes that were surveyed. The VivaScope 3000 is the handheld unit that was described in the annual report. The hand held device is available at 8 locations in the US. It is used for research purposes in places such as the Mayo Clinic and Memorial Sloan-Kettering. The hand-held VivaScope 3000 is not available separately from the VivaScope 1500. It is an add-on piece of equipment that would increase the cost. The invoices that were provided were for units that do not include the VivaScope 3000.

The following are the issues that were raised at the RUC meeting and the AAD's responses to those issues:

Issue 1: The 10-K describes a fast real-time use of a hand-held device to perform RCM.
Response: The 10-K describes what the company hopes for the future of RCM technology, using a handheld device called the VivaScope 3000. The VivaScope 3000 does not currently have the resolution or the ability to acquire the montage of images that are needed to provide patient care. The codes that were surveyed are based on use of the VivaScope 1500. The survey was sent only to persons who had been trained to use the VivaScope 1500.

Issue 2: The chair of the RUC suggested that there had been confusion on the part of the survey respondents regarding the survey vignette and the number of lesions.
Response: There is no evidence to support the idea that there was any confusion. The vignettes were approved by the Research Subcommittee and are very typical of general dermatology patients and practice. The codes clearly state that they are for either the first lesion, singular, or for a single subsequent lesion. The survey results were remarkably consistent, indicating a distinct lack of confusion. If persons completed the survey had been basing responses on use of a handheld device, the work intensity and time would have been lower.

Issue 3: The 10-K contains information that is used by patients to understand the RCM procedure.
Response: Companies use SEC reports as an opportunity to make claims to potential investors about their latest developments. Only the corporate financial statements in a 10-K report are required to be accurate, while forward looking technical information may be speculative. Such reports are not used by patients. We hope they are not being used for clinical decision making, and they should not be used by the RUC as a reliable source of information for challenging RUC survey results.

Issue 4: The 10-K suggests that image acquisition and physician work times are less than surveyed times.
Response: This is not the first time that outside information has suggested times and techniques different than those described by presenters of various specialties at the RUC. It is, however, the first time that documents were used to reopen an already approved tab, projecting a small portion of the document on the presentation screen where the specialty advisor and the reviewers see it for the first time. This was done after the presenters who are familiar with the procedure had left the meeting because the RUC had already approved RVU and PE recommendations and closed the tab. Moreover, this is the first time such documents were allowed to take precedence over accepted survey data, the standard of the RUC process. We are disappointed that this family of codes was treated differently.

Issue 5: RUC requests that the AAD resurvey the RCM code family.
Response: The codes as surveyed represent current clinical use. Given that the survey was done using a non-random survey of persons who were trained to use the VivaScope 1500, conducting an additional survey would require sending the survey to the same persons who previously received the survey and asking them to do it again. The likely outcomes of the resurvey would be either refusal to complete it again or a change of the answers that were previously provided, the implication of the resurvey being that the answers provided the first time were incorrect or inadequate. Biased results would be unavoidable.

Issue 6: Concerns were expressed about the potential for using the codes to report use of the handheld device for RCM.
Response: The persons who responded to the survey, identified by the manufacturer, were not responding based on use of a handheld device. Availability of the handheld device is currently very limited. However, the AAD recognizes that the use of the handheld device may increase, and certain resource inputs that are appropriate for the main device may not be for the add-on handheld device. We are therefore planning to ask the CPT Editorial Panel for parenthetical edit to the code descriptors to prevent use of the codes for use of handheld RCM devices. The society is also prepared to educate its members on the appropriate use of the codes by developing coding guidelines and a CPT Assistant article.

We therefore request that the RUC reconsider the request to resurvey. The AAD would be willing to return to the table to address additional questions that RUC members may have about the procedure or the survey. Reviewers would also have the opportunity to see the 10-K and to understand that the procedure described in that 10-K document is performed differently and with different equipment than RCM as described in the codes that were presented and as done by those completing the survey.

We look forward to continuing to work with the RUC to improve and refine the process used to establish relative values.

Sincerely,

Mark Kaufmann, MD, FAAD
AAD RUC Advisor

Attachment

AMA/Specialty Society RVS Update Committee (RUC)
Ad Hoc Appeals Committee Report
Reflectance Confocal Microscopy (RCM)
June 11, 2015

Members Present: Doctors Margie Andreae (Chair), James Blankenship, Thomas Cooper, Len Lichtenfeld, James Waldorf, MD, George Williams, MD

AADA Presenters: Doctors Mark Kaufman, Brent Moody, Jane Grant-Kels, Howard Rogers, Harold Rabinovitz
Commenting Specialty: Doctor Jonathan Myles (CAP)

In February 2015, the CPT Editorial panel established six new Category I codes to describe reflectance confocal microscopy (RCM) for imaging of skin. At the April 2015 RUC meeting, following the RUC's review and acceptance of physician work and direct practice expense recommendations, new information was brought to the attention of the RUC which called into question how much physician work and clinical labor are typically part of these six services. The identified source, the vendor's SEC 10-K Annual Report for the period ending 12/31/2013, included information which alluded to the physician work and clinical labor of a similar procedure possibly taking different time than the estimates originally presented to the RUC. Furthermore, it was also called into question if there were other devices used to perform this service that the RUC was unaware of at the April 2015 RUC meeting and that may necessitate a revised coding structure. The presenters who would have been able to offer an informed opinion on this document were no longer at the meeting when the issue was raised. Therefore, the RUC requested that the specialty re-survey this family of services and resubmit physician work and direct practice expense recommendations for the October 2015 RUC meeting.

On June 1, 2015, the American Academy of Dermatology Association (AADA) appealed the RUC's decision to contractor-price these services and re-survey for October. AADA indicated:

1) AADA did not have enough time to analyze the SEC 10-K form prior to the RUC's discussion, nor did they have AADA Advisors present to respond to the RUC's questions.
2) The SEC 10-K report does not describe the services that were surveyed. The SEC 10-K report describes what the company hopes for the future of RCM technology, using a handheld device called the VivaScope 3000. The codes that were surveyed are based on use of the VivaScope 1500. The survey was sent only to persons who had been trained to use the VivaScope 1500.
3) The 10-K report should not take precedent over accepted survey data, the standard RUC process.
4) These codes were not surveyed for and should not be used to report the use of the handheld device for RCM. Availability of the handheld device is currently very limited (currently used in approximately 8 research centers and not likely to be reported that this time). However, the AADA recognizes that the use of the handheld device may increase, and certain resource inputs that are appropriate for the main device may not be for the add-on handheld device. AADA is therefore planning to submit parenthetical edits to the CPT Editorial Panel to the code descriptors to prevent use of the codes for use of handheld RCM devices. The society is also prepared to educate its members on the appropriate use of the codes by developing coding guidelines and a CPT Assistant article.

AADA requests that the RUC reconsider its previous recommendation to resurvey these services for October 2015, but to present the valid survey data from April 2015.

The Committee noted the concerns about using these codes to report RCM using a handheld device and agreed with the specialty society to submit a parenthetical request to the CPT Editorial Panel to prevent this use as well as develop an education CPT Assistant article.

The Committee noted that the RUC's primary concern in April was regarding defining the physician work versus clinical staff work for image acquisition and physician time to perform image review and interpretation. The Committee noted that another targeted survey, most likely to the same individuals, would not produce significantly different results. Therefore, it is appropriate that the specialty society present the survey data from April 2015.

The Ad Hoc Appeals Committee recommends the RUC reconsider its April 2015 recommendation for Reflectance Confocal Microscopy (RCM) codes 969XX1-969XX6 and that the RUC consider the AADA request to return to the October 2015 RUC meeting, present the April 2015 survey data with additional information in response to the SEC 10-K report and the RUC to make work and practice expense recommendations. The Ad Hoc Appeals Committee also supports the specialty society's submission to the CPT Editorial Panel to create parentheticals and a CPT Assistant article to foster correct reporting of these services.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

(MARK ONE)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2013

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
FOR THE TRANSITION PERIOD FROM TO .

COMMISSION FILE NUMBER 001-35379

LUCID, INC.

(Exact name of registrant as specified in its charter)

New York **(State or other jurisdiction of incorporation or organization)**	**16-1406957** **(I.R.S. Employer Identification No.)**
50 Methodist Hill Drive, Suite 1000 **Rochester, NY** **(Address of principal executive offices)**	**14623** **(Zip Code)**

Registrant's telephone number, including area code (585) 239-9800

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, $0.01 Par Value
Warrants
(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act (Check one):

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer (Do not check if a smaller reporting company) ☐ Smaller reporting company ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the voting stock held by non-affiliates of the registrant as of June 30, 2013 (the last business day of the registrant's most recently completed second fiscal quarter) was approximately $7.7 million. For the sole purpose of making this calculation, the term "non-affiliate" has been interpreted to exclude directors, officers and holders of 10% or more of the Company's common stock.

As of February 28, 2014, 8,507,374 shares of Registrant's common stock were outstanding.

Documents incorporated by reference: Portions of the definitive Proxy Statement for the Registrant's 2014 Annual Meeting of Shareholders that the Registrant intends to file with the Securities and Exchange Commission within 120 days of the end of the Registrant's fiscal year ended December 31, 2013 are incorporated by reference into Part III of this Annual Report on Form 10-K.

LUCID, INC.

Annual Report on Form 10-K
For the Year Ended December 31, 2013

Table of Contents

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K and the information incorporated herein by reference contain forward-looking statements that involve a number of risks and uncertainties including information with respect to our plans and strategy for our business and related financing, thereof, contain forward-looking statements that involve risks, uncertainties and assumptions. All statements that express expectations, estimates, forecasts or projections are forward-looking statements. Words such as "expects," "anticipates," "intends," "plans," "believes," "seeks," "estimates," "projects," "forecasts," "may," "should," and variations of such words and similar expressions are intended to identify such forward-looking statements. These statements include but are not limited to statements under the captions "Business," "Risk Factors," and "Management's Discussion and Analysis of Financial Condition and Results of Operations" as well as other sections in this Annual Report on Form 10-K. You should be aware that the occurrence of any of the events discussed under the heading "Item 1A. Risk Factors" and elsewhere in this report could substantially harm our business, results of operations and financial condition and that if any of these events occurs, the trading price of our securities could decline and you could lose all or a part of the value of your shares of our securities. The cautionary statements made in this report are intended to be applicable to all related forward-looking statements wherever they may appear in this Annual Report on Form 10-K. We urge you not to place undue reliance on these forward-looking statements, which speak only as of the date of this Annual Report on Form 10-K. Except as required by law, we assume no obligation to update our forward-looking statements, even if new information becomes available in the future.

Unless the context otherwise indicates, references in this report to the terms "Lucid," "the Company," "we," "our," and "us" refer to Lucid, Inc. operating as Caliber Imaging & Diagnostics, or Caliber I.D., and its subsidiary if pertaining to the period before January 29, 2013.

PART I

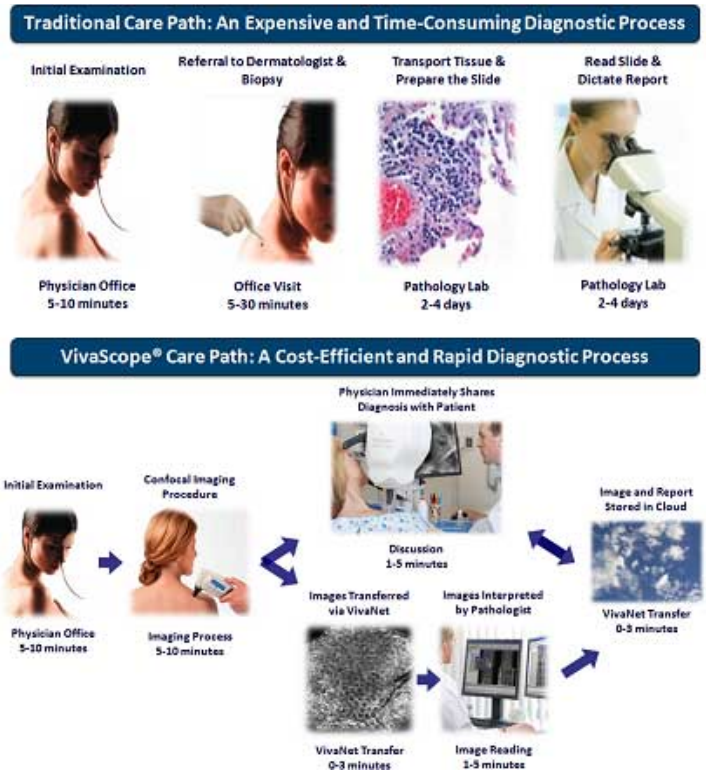
Item 1. Business

Overview

We are a medical device company that develops, manufactures, markets and sells point-of-care cellular imaging systems. Our patented and FDA-cleared VivaScope® technology provides physicians with real-time images of the epidermis and superficial dermis of the skin, as well as other epithelial tissues at a cellular level that can be interpreted by the physician at the bedside and/or transferred securely to a pathologist on VivaNet®, our HIPAA-compliant private telepathology network for remote diagnosis. With sensitivity and specificity that can rival the current "gold standard", clinical histopathology (illustrated below right), but without all of the associated costs of a traditional biopsy, our platform imaging technology has the potential to significantly improve patient outcomes while simultaneously reducing costs.

Our core products are FDA 510(k) cleared for clinical use and have regulatory approvals in most major markets. Our technology is already in use by physicians and researchers at major academic hospitals, and by pharmaceutical and cosmetic companies across the globe. Our devices allow these researchers to quickly and efficiently study the efficacy of new products, test ingredients, validate claims and determine safety. The technology is protected by 78 issued or pending patents worldwide.

To date, our proprietary platform imaging technology has been the subject of more than 350 independently sponsored studies or publications spanning numerous clinical and research fields. Extensive research has been conducted in dermatologic disorders including melanoma and nonmelanoma skin cancers, dermatoses, inflammatory and pigmentation disorders. Additionally, the technology has been used to noninvasively study burns, wound healing, neuropathy and oral tissues. Ex-vivo research has been conducted in head and neck, breast biopsy and surgical specimens. Our in-vivo products are ideal for applications in which a traditional biopsy is counterproductive, such as validating the diagnosis of benign lesions (thus, reducing unnecessary biopsies), monitoring noninvasive therapies and determining product efficacy. In the future, the technology may be used to perform real-time pathology in the operating room on tissues removed from the body and to identify tissues in the body during surgery.



We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, and we are eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation, from which we are currently exempt as a smaller reporting company, and stockholder approval of any golden parachute payments not previously approved in connection with a transaction resulting in a change of control. We expect to take advantage of these exemptions. Some investors may find our common stock less attractive as a result of our utilization of these exemptions, which may result in a less active trading market for our common stock and a more volatile stock price.

In addition, Section 107 of the JOBS Act also provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

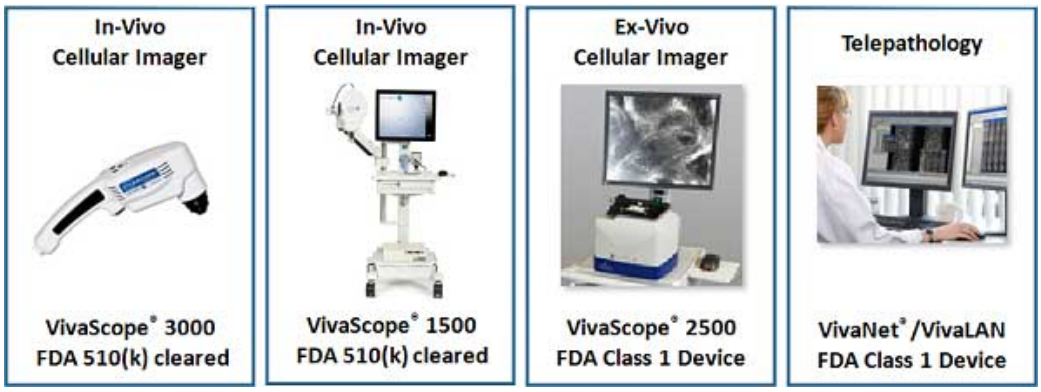
We could remain an "emerging growth company" until 2016, or until the earliest of (i) the last day of the first fiscal year in which our annual gross revenues exceed $1 billion, (ii) the date that we become a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, which would occur if the market value of our common stock that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter, or (iii) the date on which we have issued more than $1 billion in non-convertible debt during the preceding three year period. Please see Part II, Item 1A. Risk Factors.

We were organized as a New York corporation on November 27, 1991 under the name Lucid Technologies, Inc. We subsequently amended our Certificate of Incorporation to change our name to Lucid, Inc**.** We are operating as Caliber Imaging & Diagnostics, or Caliber I.D. Our principal executive offices are located at 50 Methodist Hill Drive, Suite 1000, Rochester, New York 14623. Our telephone number is (585) 239-9800. Our web site is www.caliberid.com.

Product Portfolio

Our product portfolio consists of a variety of in-vivo and ex-vivo imaging systems, as well as a telepathology system, covering a wide variety of applications.

Our VivaScope in-vivo devices, the VivaScope® 3000 (handheld device) and the VivaScope® 1500, use confocal cellular imaging to create a layer-by-layer scan of living tissue, with a >0.2mm imaging depth. This provides physicians with a microscopic view of living cells in the skin, with 3-5 micron cellular resolution comparable to histology. Our in-vivo imagers are FDA 510(k) cleared with an intended use to "acquire, store, retrieve, display and transfer in-vivo images of tissue, including blood collagen and pigment, in exposed unstained epithelium and the supporting stroma for review by physicians to assist in forming a clinical judgment."



Our VivaScope ex-vivo device, the VivaScope® 2500, uses confocal imaging to produce electro-optically enlarged images of unstained and unsectioned excised surgical tissue without the laborious tissue preparation procedures required to prepare the microscope slides used in traditional pathologic examination of tissue. As a Class I medical device, the VivaScope 2500 is exempt from 510(k) clearance.

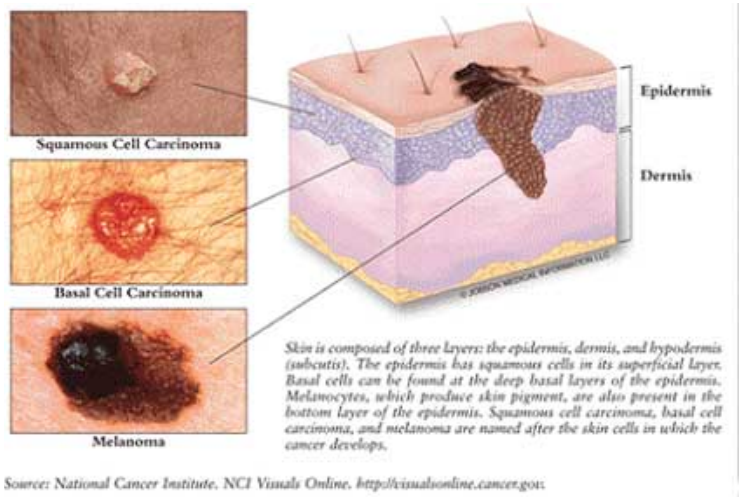
Our VivaNet telepathology server transfers images from the point of capture at a physician's office or operating room to another physician, pathologist or other diagnostic reader for near real-time diagnosis and reporting. This HIPAA-compliant, cloud-based system stores images and diagnostic reports as a part of a patient's permanent, electronic, medical record, increasing efficiency and potentially reducing costs for medical institutions as compared to current histology record retention processes. Our VivaLAN product is a telepathology system which retains all patient data within the customer's facility. As Class I medical devices, our VivaNet and VivaLAN systems are exempt from 510(k) clearance.

Primary Market Opportunities

Skin Cancer Screening and Diagnosis

We believe there is significant market opportunity for our products in skin cancer screening and diagnosis, where our non-invasive, platform imaging technology can provide immediate and significant benefits for patients, physicians, and payers.

Skin cancer is the most prevalent cancer in the United States, with 3.5 million new cases annually and a lifetime incidence rate of 20% (one in five Americans), more than the combined incidence of breast, prostate, lung and colon cancers. Conventionally, skin cancers are diagnosed initially by visual inspection, with any suspect areas subsequently biopsied, an invasive and painful procedure in which a tissue sample is surgically removed – which can lead to complications such as infection or scarring – and then examined in a laboratory over the next few days.



Empirical data show that visual inspection is a poor diagnostic screening tool. Of the approximately 14.5 million biopsies performed annually in the United States at an estimated cost of $4.9 billion, only 3.5 million reveal skin cancer; the remaining 11 million biopsies are unnecessary. Visual inspection may miss skin cancers that appear benign. Of the three most common skin cancers, basal cell carcinoma (BCC), squamous cell carcinoma (SCC) and melanoma, melanoma is by far the most lethal. However, to detect the approximately 75,000 new cases of melanoma diagnosed in the United States annually, physicians perform an estimated 2.2 million biopsies –as many as 29 biopsies for each confirmed case of melanoma. Clearly, there is a significant unmet need for more accurate, cost-efficient, and rapid diagnosis of skin cancers and benign lesions.

With diagnostic sensitivity and specificity that can rival the current "gold standard", clinical histopathology, physicians using our non-invasive, point-of-care imaging technology can quickly and accurately differentiate between malignant and non-malignant tissues. In addition, physicians can quickly get a second opinion by instantly transmitting patient images through our secure VivaNet telepathology network to a trained pathologist. Thus, while our proprietary platform imaging technology does not entirely replace the need for surgical biopsies, widespread adoption of our technology would significantly reduce the number of biopsies performed and, as a result, costs. By eliminating or reducing the number of unnecessary biopsies performed, we estimate that our technology could result in cost avoidance of more than $1 billion annually.

Our technology also offers significant secondary benefits to patients, physicians and payers. Patients benefit by receiving an immediate and painless diagnosis at the point-of-care, rather than having to wait for days or even weeks for results to come back from the pathology lab. When lesions are benign, confocal imaging can reduce the time, expense and side effects of an unnecessary biopsy. When lesions are malignant, treatment may begin immediately depending on the diagnosis, or can be planned, reducing the time to a treatment or cure. We believe that physicians who are early adopters will have a significant competitive advantage over late adopters: patients informed of the advantages of VivaScope technology over traditional biopsy are likely to migrate to dermatology or primary care practices offering this service, attracting new patients and increasing overall practice revenues. Finally, in addition to significantly reduced costs, payers will benefit by earlier and more widespread detection of skin cancers, allowing them to be treated more proactively.

Microscopy, Medical and Therapeutic Research

Other market opportunities are the microscopy, medical, and therapeutic research and development markets where our platform of products has allowed researchers and developers at academic centers, pharmaceutical and cosmetic companies to quickly and efficiently capture and store tissue images. These are attractive markets to target because our technology allows researchers and product developers to (1) repeatedly and nondestructively examine the same tissue, demonstrating tissue changes over time; and (2) quickly evaluate the safety and efficacy of new products without the time and expense of traditional biopsies, significantly shortening development cycles, and at a lower price point and smaller form factor compared to our competitors.

There are applications and opportunities for the VivaScope platform in a number of different research and development markets spanning the globe including:

- ***Microscopy*** – Advanced imaging for research and industrial uses such as for biological, life and physical sciences applications.
- ***Personal Care Products*** – Studying the development, efficacy and safety of products such as cosmetics, sunscreens and topical creams for anti-aging, pigmentation, moisturization, etc.
- ***Academic Centers*** – Supporting the pre-clinical and clinical activities of medical academic centers; often funded by government grants.
- ***Pharmaceutical / Ingredient Manufacturers*** – Evaluating individual ingredients or drugs for safety and efficacy in pre-clinical or clinical trials or prior to using ingredients in other products.
- ***Contract Research Organizations*** – Conducting studies on behalf of cosmeceutical or pharmaceutical corporations to test the safety and efficacy of products.
- ***Small Animal Research*** – Imaging of genetically engineered animal models for the study of the progression or treatment of disease.

Our Sales and Marketing Strategies

Our technology clearly offers meaningful advantages over the standard-of-care. Ultimately, we believe that third-party payers will cover our technology, but, in the interim, our sales and marketing strategies focus on markets where our technology offers significant benefits that are not reimbursement-sensitive. As we have indicated, the markets that we are initially targeting are skin cancer screening via managed care organizations, concierge medicine groups and physicians, and medical and therapeutic research and development.

In addition, we intend to raise our visibility through trade publications, appearances at trade shows, social media campaigns, direct-to-consumer advertising, targeted public relations, investor relations, strategic placement of loaner systems with potential high-revenue customers, and other general marketing efforts.

Skin Cancer Screening and Diagnosis

Strategies here will be focused on managed care organizations, concierge medicine groups and physicians. Dermatology is one of the largest areas of expense for managed care organizations (e.g. integrated healthcare networks, HMOs, and ACOs) and rapid adoption of our technology can significantly reduce short-, intermediate- and long-term costs for these organizations through (1) fewer referrals to dermatologists; (2) the reduction in unnecessary biopsies; and (3) earlier detection of potentially deadly skin cancers.

We believe that larger managed care organizations and integrated health networks, with a market in excess of a $465 billion, are attractive markets to target because they are highly concentrated: in the U.S., only 25 companies account for approximately two thirds of industry revenues. This concentration can help us generate significant sales with a relatively small managed care-focused sales force.

Examples of the managed care organizations and integrated health networks that we intend to target are as follows:

- UnitedHealth Group Inc.
- WellPoint, Inc.
- Kaiser Foundation Health Plan and Hospitals
- Humana Inc.
- Aetna Inc.
- Cigna Health Group
- Coventry Health Care, Inc
- Health Net, Inc.
- HealthSpring, Inc.

By comparison, concierge medicine groups are less focused on cost avoidance and more focused on providing best-in-class care for their patients, who pay an annual fee of $1,500-$1,800 per year, on average, and are willing to bear significant additional out-of-pocket expenses for best-in-class care, such as a non-invasive optical biopsy using our VivaScope technology.

We believe that both managed care organizations and concierge medicine groups will adopt an imaging center solution to service their network of patients and subscribers, and we intend to work closely with individual managed care organizations and concierge medicine groups to either integrate these imaging centers into existing facilities or launch new facilities owned either by the managed care organizations, concierge medicine groups, or possibly Caliber I.D.

Finally, we will continue to actively market our VivaScope technology to physicians outside of the U.S., where we already have traction and where reimbursement is less of a barrier to entry. To date, we have shipped 180 VivaScope systems to physicians, the majority of whom are outside of the United States.

Microscopy, Medical and Therapeutic Research

Other market opportunities that are readily addressable are the microscopy, medical, and therapeutic research and development markets (i.e. companies developing pharmaceuticals, biotherapeutics, cosmetics, cosmeceuticals, as well as companies engaged in human and animal cellular imaging pathology). With more than 300 VivaScope systems shipped, our platform of products are proven to be suited for this market, allowing researchers and product developers to quickly and efficiently capture and store tissue images.

Examples of the skin care product research and development companies to whom we have shipped a VivaScope system (*) and/or that we intend to target are as follows:

- Allergan, Inc.
- Arch Chemicals, Inc.
- Ashland Inc.
- Avon Products Inc.*
- BASF SE
- Bayer AG
- Beiersdorf AG*
- Clariant International AG
- Colgate-Palmolive Co.*
- E.I. du Pont de Nemours and Co.
- Eastman Chemical Company
- Genentech, Inc.*
- Genzyme
- GlaxoSmithKline PLC*
- Janson Beckett Cosmeceuticals
- Johnson & Johnson*
- Kao Corporation*
- Kimberly Clark Corporation*
- L'Oréal SA*
- McNeil PPC, Inc.
- Medicis Pharmaceutical Corporation
- Merck & Co Inc.
- Neutrogena*
- Ortho Dermatologics
- Pfizer Incorporated*
- Proctor & Gamble Company*
- Revlon, Inc.*
- Roche Holding Limited
- Royal DSM NV
- Sanofi-Aventis
- Schick Manufacturing, Inc.*
- SkinMedica Incorporated*
- The Body Shop International
- The Estée Lauder Companies Inc.*
- Unilever Group*

We believe our unique platform of products and prestigious customer base present an attractive revenue opportunity for us in the United States and we have begun building a sales and support force focused on the microscopy, medical and therapeutic research and development markets. Annual expenditures in the US research market are approximately $140 billion. We have recently hired three sales representatives with extensive experience in these markets to cover the East Coast, Midwest and West Coast territories. In 2014 in the United States, we intend to market and sell into our existing customer base as well as well as participate in numerous trade shows and direct marketing campaigns to help grow our customer base.

Secondary Market Opportunities

In the future, our platform imaging technology could provide significant benefits in a variety of in-vivo and ex-vivo clinical applications by allowing physicians to quickly assess the efficacy and outcomes of therapeutic treatment. They could also identify, differentiate and diagnose various tissue types in surgery for rapid assessment of tissue pathology.

Therapeutic Monitoring

Therapeutic monitoring is a market where our technology provides numerous benefits over existing technologies, allowing physicians to quickly and efficiently monitor treatment results noninvasively, at the cellular level. The future of skin cancer treatment lies with minimally or noninvasive therapies that successfully eradicate skin cancer with little-to-no scarring. At present, the only way to determine if a treatment is successful is to visually monitor the patient for obvious signs of reoccurrence, or perform a traditional biopsy, which is invasive, painful, time consuming and often leaves a scar.

We believe that the therapeutic monitoring market is an attractive market to target because our technology allows physicians to (1) repeatedly and nondestructively examine tissue to determine whether it is responding to therapy; and (2) quickly and efficiently examine the tissue that has been treated to determine whether a minimally invasive therapy was successful. We are already in partnership discussions with several original equipment manufacturers (OEMs) to integrate our VivaScope 3000 in-vivo handheld imaging device into their existing systems.

Examples of the applications within this market are as follows:

- Superficial Radiation Therapy
- Laser Ablation Therapy
- Photo Dynamic Therapy
- Brachytherapy
- Topical Biotherapeutics

We will need to integrate our VivaScope software with the OEM product, potentially obtain regulatory approvals for the new integrated product, and develop training programs for users of the new device. Since sales of an OEM product will typically consist of components of a VivaScope System, we expect the sales price to be less than a standard system.

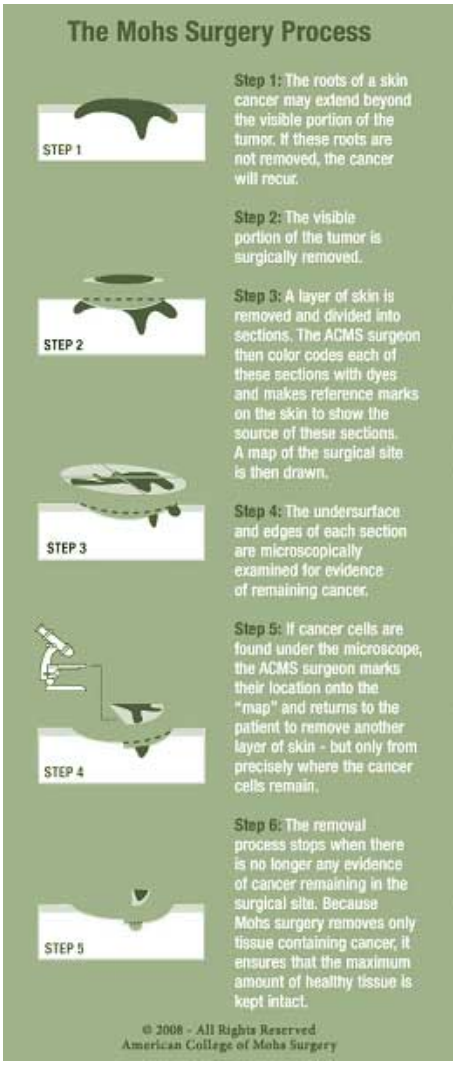
Enable Real-Time Pathology

Our technology may allow surgeons to receive diagnostic information in minutes, on fresh tissue in the operating room, allowing surgeons to determine in real-time whether their efforts have been successful. Adoption of our technology could drastically reduce procedural time and the re-operative rate per patients, significantly reducing costs and improving patient outcomes. We believe that our platforms could eventually be used to further improve accuracy by allowing surgeons to proactively image tissue to differentiate and identify exactly which tissue should be removed.

Mohs surgery. The Mohs procedure entails removing one thin layer of tissue at a time, testing each layer until cancerous tissue is no longer detected which, although time-consuming, is beneficial because it spares the greatest amount of healthy tissue while completely removing the skin cancer. With cure rates for BCC and SCC at 98% or higher, significantly better than the rates for standard excision or any other accepted method, Mohs is clearly the most effective technique for removing BCCs and SCCs on the face, head and neck. Of the 3.5 million new BCC and SCC cases diagnosed per year in the United States, one in four (25%) patients with BCC or SCC will have a Mohs procedure to eliminate the cancer, resulting in a significant potential market opportunity.

The current approach for Mohs surgery involves removing a thin layer of tissue, which is then prepared by frozen section histology at an in-house lab for subsequent examination by the surgeon (or, in most of Europe, a pathologist). Preparation of each excision takes 20-45 minutes, during which time the patient waits with an open wound, often on their face under local anesthesia. While most Mohs procedures require only a few excisions, more invasive cases can require as many as 20 excisions; thus, on average, a Mohs procedure requires a minimum of two hours and, for invasive cases, can tie up an operating suite for much longer. While waiting for the slides to be prepared, Mohs surgeons typically operate on other patients, rotating back and forth between patients as pathology results become available. While effective, this is a time-consuming process that requires each patient to stay in the operating suite for a prolonged period of time.

By comparison, our VivaScope 2500 ex-vivo device allows surgeons to receive the same information in as little as four minutes – a five-fold decrease in the minimum time to receive pathology results – which then reduces the total operating suite time to an hour or less per procedure. As a result, individual patients spend much less time in the operating suite and, by eliminating unnecessary transfers between patients, surgeons are able to perform substantially more procedures within a given period of time. Ultimately we believe that our VivaScope 3000 in-vivo device could be used to further improve accuracy and decrease downtime by allowing surgeons to image the tissue directly to determine whether enough tissue has been excised. The VivaScope 3000 is already being used in Australia to identify surgical margins in difficult Mohs surgery cases and, in one study, changed the treatment plan in approximately 73% of patients either by more precisely targeting the tumor margins to reduce the number of excisions, or by demonstrating that a noninvasive topically-applied therapy was a more appropriate treatment plan.



Based on our market research, we believe that conventional Mohs histopathology is reasonably well entrenched in the U.S. and, as a result, will require a considerable investment of resources to displace. However, in Europe, the Mohs procedure is newer, and with our inherent advantages over conventional pathology, we believe we can seize a meaningful share of this market in the near-term. We believe that widespread use of our technology in Mohs surgery in Europe would create tailwinds toward adoption of our technology in the U.S.

Importantly; this market also allows us to gather data that supports the use of our technology in various other surgical applications and real-time pathology, opening up other market opportunities in the future.

Thyroid. Another area where adoption of our technology could significantly improve patient outcomes while simultaneously reducing costs is in thyroid cancer surgeries, where our technology has demonstrated feasibility in two independently sponsored studies.

Thyroid cancer affects approximately 500,000 people in the U.S., with over 200,000 thyroid surgeries annually. During thyroid surgery, the surgeon removes cancerous tissue from the thyroid while being careful to avoid damaging the adjacent parathyroid glands. Visually differentiating the parathyroid glands is extremely challenging, and, as a result, the parathyroid glands are damaged in approximately one-third of surgeries causing temporary (or occasionally permanent) hypocalcemia.

At present, surgeons use pathological frozen section analysis of head and neck specimens to determine whether any of the tissue removed contained any of the four parathyroid glands and, if so, they must then re-implant that tissue, which is only moderately successful. Similar to Mohs surgery, preparation of each slide takes 20-45 minutes, which significantly prolongs the amount of time that a patient spends in the operating suite under general anesthesia.

By comparison, our VivaScope 2500 ex-vivo device allows surgeons to receive the same information in as little as four minutes, significantly reducing procedure times and costs. Ultimately, we believe that our VivaScope 3000 in-vivo device could be used to further improve accuracy and decrease downtime by allowing surgeons to proactively image the tissue through a surgical incision to differentiate between various tissue types and identify exactly which tissue needs to be removed.

Breast. Breast cancer is one of the most prevalent and deadly cancers affecting women, accounting for approximately 23% of all cancers (excluding non-melanoma skin cancers) and causing approximately 459,000 deaths worldwide (14% of cancer deaths). In the United States, the lifetime incidence rate is 12% (one in eight), with approximately 235,000 new cases annually, of which approximately 65,000 are non-invasive (in situ) breast cancers.

Conventionally, treatment of in situ breast cancer involves surgical excision of the tumor through a lumpectomy or similar surgery. However, surgeons cannot differentiate between cancerous and healthy tissue, and must use pathology to determine whether enough tissue has been removed. Due to its inherent nature, breast tissue histology cannot be expedited and tissue processing takes more than 24 hours to complete, so it is currently impossible to determine whether enough tissue was removed during the surgery itself and thus, the patient is sent home waiting to find out if another surgery is needed. As a result, a second surgery is required in as many as 20-40% of cases to remove cancerous tissue that was missed during the first surgery.

Distribution Partners

Outside of the U.S., we have established exclusive distribution relationships pursuant to which the distributor sells our products within its specified territory. Our largest distributor is Mavig GmbH ("Mavig") with territories including Europe and the Mediterranean region. ConBio (China) Co., Ltd. is our distributor in the People's Republic of China, including Hong Kong.

Research and Development

Our technical R&D plan includes routine hardware and software product improvements that are generally driven by customer feedback. These items include activities such as the development of more clinically and environmentally acceptable disposables, enhanced VivaScope application software (VivaScan®) with features honed for use by private practice dermatologists and VivaNet® telepathology workstation features that will enhance the efficiency of pathologists in analyzing images and reporting their interpretations.

For the years ended December 31, 2013 and 2012, we incurred research and development expenses of $1.5 million and $3.8 million, respectively. During 2012 we redesigned many optical and electrical components within our in-vivo confocal imagers to improve quality, manufacturability and functionality. This project began in the first quarter and was substantially completed by September 2012. Our redesigned products generate images which have a significantly improved level of optical quality and our devices now have greater reliability and repeatability. We have also improved the user interface with a touch-screen monitor and have incorporated an ergonomic redesign of the handheld device.

We have plans to further improve our existing products, both to further increase functionality as well as to streamline production and decrease costs. In addition, customers using our devices continue to suggest modifications to facilitate additional applications, many of which are easily accommodated.

To build support for the utility and economic value of our products, we conduct, sponsor or support clinical and other studies. Ongoing and planned U.S. and European studies include:

- An ongoing U.S. based multi-center trial funded by the National Cancer Institute evaluating >400 pigmented lesions suspicious for malignancy based on clinical exam.
- Two planned payer-based pilot studies to evaluate the economics of confocal imaging to set reimbursement rates within a primary care and dermatology clinical setting for the treatment of skin cancer.
- An ongoing European-based study evaluating confocal images over a telepathology network with clinical sites in Italy and Spain.
- A planned U.S. based study to differentiate parathyroid gland from lymph node and other tissues, intraoperatively.

Scientific Advisory Board

We utilize our scientific advisory board ("SAB") to: assist us with medical education programs; advise us in the design of future products; help us design Company initiated clinical studies; and assist us in evaluation of external investigator proposed studies.

Martin C. Mihm Jr. MD, Chair. Dr. Mihm is clinical professor of dermatology and pathology at Harvard Medical School and director and co-director of the melanoma programs at the Brigham and Women's Hospital and the Dana Farber Cancer Institute as well as co-director of the European Organization for Research and Treatment of Cancer (EORTC) melanoma pathology program. Dr. Mihm holds five adjunct professorships at different medical schools in the United States.

Allan Halpern MD. Dr. Halpern is Chief of the Dermatology Service and co-leader of the Melanoma Disease Management Team at Memorial Sloan-Kettering Cancer Center (MSKCC). He pioneered the development and use of whole-body photography for the early detection of melanoma. He previously served as the director of the Pigmented Lesion Clinic at the University of Pennsylvania.

Giovanni Pellacani MD, PhD. Dr. Pellacani is currently the Chairman of the Department of Dermatology of the University of Modena and Reggio Emila. He is a member of the scientific board in the International Dermoscopy Society (IDS); European Association of Dermato Oncology (EADO); International Confocal Working Group (ICWG); Associazione Italiana di Diagnostica Non Invasiva in Dermatologia (AIDNID). He has published over 200 papers, 19 book chapters and over 150 abstracts in national and international congresses and conferences.

Salvador Gonzalez MD, PhD. Dr. Gonzalez is a faculty member of Memorial Sloan-Kettering Cancer Center in New York and a research advisor at the Hospital Ramón y Cajal, Madrid. He is world renowned as an expert in the fields of optical diagnosis and sun protection. His work was fundamental for the approval of Reflective Confocal Microscopy by the FDA (Food & Drugs Administration). He is the President of the International Confocal Working Group and of the Grupo Español de Microscopía Confocal (Spanish Group of Confocal Microscopy). In February 2012, he was awarded the category of Full Professor (Catedrático) by the Spanish Education Ministry.

Phyllis Gimotty PhD. Dr. Gimotty is Professor of Biostatistics and a member of the Abramson Cancer Center's Biostatistical Unit at the University of Pennsylvania. She serves as the Director of two biostatistics cores that support translational cancer research in melanoma and esophageal cancer. She also serves as the Principal Investigator of the Cancer Biostatistics Training Grant and is the Associate Director of Biostatistics Educational Programs in the Basic Sciences in the School of Medicine at the University of Pennsylvania.

Clinical Advisory Board

We plan to utilize our Clinical Advisory Board to advise us on all aspects of clinical applications in the U.S.-Market space. We anticipate adding additional members to the Clinical Advisory Board in 2014. Currently, the sole member of our clinical advisory board is:

Babar Rao MD, Chair. Dr. Rao is Assistant Clinical Professor of Dermatology and Program Director of the Dermatology Residency Program at Robert Wood Johnson Medical School in New Jersey. He is certified by the American Board of Dermatology and the American Board of Dermatopathology. He is a member of many professional organizations in Dermatology and has published numerous papers and book chapters.

Intellectual Property

General. Our policy is to protect our intellectual property by obtaining U.S. and foreign patents to protect the technology, inventions, and improvements important to the development of our business, U.S. and international trademarks to protect our company name, logo, brands and trade secrets, which we enforce through confidentiality agreements with our employees, members of our board of directors and scientific advisory board, and through non-disclosure agreements with certain others outside the Company. Our employees and consultants are required to execute patent assignment agreements.

Patents. We currently hold 58 patents, which consist of 45 U.S. patents, five Australian patents, three Japanese patents, three European patents, one Chinese patent and one Canadian patent. These patents are all owned by the Company, with the exception of two non-fundamental patents which are co-owned. We also have 20 additional U.S. and foreign patents pending. In addition to patents that cover our technology, the Company has patented solutions around clinical applications and the clinical care path, and therefore is not dependent upon any one particular patent. Our patent portfolio covers tissue stabilization and navigation during live clinical imaging, surgical pathology, and a HIPAA-compliant telepathology system for the remote transfer, viewing, diagnosis and storage of confocal images generated by all of our devices, allowing users access to confocal diagnostic specialists throughout the world. Generally, we file foreign counterparts of our most fundamental U.S. patents and we have been successful in obtaining issuance of these fundamental foreign patents in Europe, Australia, Japan, China and Canada while other foreign patent applications remain pending. We have granted limited licenses to our European intellectual property to our distribution partner in Europe. Given the continuous nature of our applications, many of our patents have expiration dates fifteen or more years into the future.

Trademarks and Domain Names. We have obtained U.S. trademark registrations for the following marks: "VivaScope", "Caliber I.D.", "Lucid", VivaBlock", "VivaStack", "VivaCam", "VivaNet", "VivaCell", "VivaScan", "VivaScopy" as well as our corporate logo. Certain foreign trademarks have been obtained corresponding to some of our U.S. trademarks and others are pending foreign trademark approval.

Manufacturing

Our in-house manufacturing process is largely an assembly-and-test process that operates under the standardized procedures of our quality system. Piece parts such as mechanically machined components, populated circuit boards, precision optical components and electro-mechanical optical scanning devices are purchased from suppliers to either our custom specifications or the standard specifications of the supplier. We also purchase computers, LCD displays and medical grade equipment carts which are integrated into our completed VivaScope Systems. The application software for our VivaScopes is written by our in-house software staff and runs under a Windows operating system.

Generally, we single-source our component purchases to suppliers with which we have had a long-term relationship. In the event these suppliers are unable to deliver parts we generally have back-up suppliers established. A few of our VivaScope components are from sole source suppliers, which means we are purchasing a unique component from them that is not available from other suppliers. As we design future generations of VivaScopes, it is our intention to eliminate these specialized sole sourced component designs whenever possible.

Competition

Currently our largest competitive threat in clinical markets is a surgical biopsy, which is the standard of care. Although we possess patented technology for our VivaScope products and our VivaNet telepathology system, we face competition, both nationally and internationally, from companies marketing technologies which offer an alternative to confocal microscopy and traditional biopsy. Many of these companies have established name recognition, reputation, and market presence, and may have greater financial, technical, sales, marketing and other resources than we have, enabling them to better withstand the impact of risks associated with a highly competitive industry.

Companies that have developed devices using confocal microscopy include those which have applications in ophthalmology, such as Nidek, and in gastroenterology, such as Mauna Kea Technologies, which has a confocal endomicroscopy device. Although we do not currently view these companies as competitors, these companies may compete with us in their respective application areas, which could possibly become broader and expand into our applications. Our confocal imaging devices compete with other noninvasive screening technologies which are sold by companies such as FotoFinder Systems, Inc., Mela Sciences, Inc., Michelson Diagnostics and Verisante. Though we do not believe that we compete with any specific large companies currently, major medical imaging companies such as General Electric Co., Siemens and Philips Healthcare, each of which manufacture and market precision medical diagnostic products, could decide to develop or acquire a product or products to compete with our VivaScope confocal imagers.

Regulation

FDA Regulation of Medical Devices. Our products are considered medical devices and are subject to regulation by the FDA. The Food, Drug, and Cosmetic Act, or "FD&C Act," and other federal and state statutes and regulations govern the research, design, development, preclinical and clinical testing, manufacturing, safety, approval or clearance, labeling, packaging, storage, record keeping, servicing, promotion, import and export, and distribution of medical devices.

The FDA cleared our 510(k) application for our VivaScope System (i.e., our VivaScope 1500 and VivaScope 3000) as a Class II device in September 2008. Our ex-vivo imager, the VivaScope 2500 is registered with the FDA as a Class I device, similar to conventional medical microscopes used by pathologists to view microscope slides of human tissue, and our VivaNet telepathology server is registered with the FDA as a Class I device. We believe these FDA clearances for our VivaScope products and telepathology are sufficient for us to pursue our business strategy for the foreseeable future. Future products or applications may require additional FDA clearances and may also involve clinical trials to demonstrate whether they are safe and effective for their indicated medical applications.

Devices like our VivaScopes that are approved or cleared and placed in commercial distribution are subject to numerous regulatory requirements, including: 1) establishment registration and device listing; 2) Quality System Regulation (QSR) which is an FDA requirement that manufacturers follow design, testing, control, documentation and other quality assurance procedures; 3) labeling regulations that impose labeling restrictions and prohibit the promotion of products for unapproved or "off-label" uses; 4) medical device reporting regulations that require reporting to the FDA if a device caused or contributed to a death or serious injury or malfunctioned so as to cause or contribute to a death or serious injury if the malfunction were to recur; and 5) corrections and removal reporting regulations that require manufacturers to report field corrections and product recalls or removals undertaken to reduce risk to health by the device or to correct an FD&C violation that presents a risk to health. Also, the FDA may require postmarket surveillance studies or establishment and maintenance of a system for tracking products through the distribution channel to the patient level.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may lead to any of the following sanctions: 1) warning letters; 2) fines and civil penalties resulting in unanticipated expenditures; 3) approval delays or refusal to approve our applications, including supplements; 4) withdrawal of FDA approval; 5) product recall or seizure; 6) interruption of production; 7) operating restrictions; 8) injunctions; and 9) criminal prosecution. To date, we have never received any such enforcement actions by the FDA.

Medical Device Regulation Outside of the U.S. Sales of our medical devices outside of the U.S. are subject to foreign government regulations that vary substantially from country to country. Some countries have little to no regulation whereas other countries have a premarket notice or premarket acceptance similar to the FDA for clinical applications. The time required to obtain approval in a foreign country may be either shorter or longer than that required for FDA approval, and the requirements for approval may differ. Generally, sales of our products outside of the U.S. for non-clinical use require little or no registration.

Our VivaScope 1500 and VivaScope 3000 are entitled to bear the CE mark for distribution as medical devices in the European Union, ("EU"). The EU has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear the CE conformity marking, indicating that the device conforms to the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout Europe.

Outside of the European Union, regulatory approval needs to be sought on a country-by-country basis in order for us to market our products for clinical applications. In this regard, we have obtained regulatory approval to market our VivaScope 1500 for clinical applications in Canada through its Health Canada Administration, in Australia through its Therapeutic Goods Administration, in Brazil through its Brazilian Health Surveillance Agency, and in China through its State Food and Drug Administration, although in China we are currently in a renewal process.

One aspect of CE compliance is that manufacturers are required to comply with international standards for quality management maintained by the International Organization for Standardization, ("ISO") and its 13485 series of standards for quality operations necessary for EU and SFDA registration. The method of assessing conformity to EU regulations varies depending on the class of the product. Generally conformance involves self-assessment by the manufacturer and third party assessment by a "Notified Body." This third party assessment may consist of an audit of the manufacturer's quality system and specific testing of the manufacturer's product. An assessment by a Notified Body of one country within the European Union is required in order for a manufacturer to commercially distribute the product throughout the European Union. In order to meet this requirement, our quality system, device designs and manufacturing facilities are assessed annually by GMED North America, a certified EU Notified Body.

Other U.S. Government Regulation. The advertising of our medical devices is, and will continue to be, subject to both FDA and Federal Trade Commission regulations. In addition, the sale and marketing of our medical devices are subject to complex federal and state laws and regulations generally intended to deter, detect, and respond to fraud and abuse in the healthcare system. These laws and regulations often restrict or prohibit pricing, discounting, commissions and other commercial practices that are typical outside of the healthcare market. In particular, anti-kickback and self-referral laws and regulations limit our promotional programs and financial arrangements related to the sale of our products and related services to physicians seeking reimbursement from Medicare, Medicaid, private insurers or patients. Sanctions for violating the above federal laws include criminal and civil penalties ranging from punitive sanctions, damage assessments, money penalties, imprisonment, denial of Medicare and Medicaid payments, or exclusion from the Medicare and Medicaid programs.

Many states have adopted laws or have pending legislative proposals similar to the federal fraud and abuse laws, some of which prohibit the payment or receipt of remuneration for the referral of patients and physician self-referrals regardless of whether the service was reimbursed by Medicare or Medicaid. Many states have also adopted laws or are considering legislation to increase patient protections, such as limiting the use and disclosure of patient-specific health information. These state laws typically impose criminal and civil penalties similar to the federal laws.

Private enforcement of healthcare fraud is also increasing, due in part to amendments to the Civil False Claims Act in 1986. These amendments encourage private persons to sue on behalf of the government. HIPAA, in addition to its privacy provisions, created a series of new healthcare-related crimes. Our products fall under the regulation of HIPAA when our HIPAA-compliant telepathology server is used for clinical applications.

Product Liability and Insurance

Our business exposes us to the risks of product liability claims that are inherent in the testing, manufacturing and marketing of medical devices, including those which may arise from design flaws or the misuse or malfunction of our products. We may be subject to product liability claims if any one of our products causes or appears to have caused an injury. Claims may be made by patients, healthcare providers or others using our medical devices. Although we carry product liability insurance that covers our VivaScope products, our anticipated current and anticipated product liability insurance may not be available to us in amounts and on acceptable terms, if at all, and if available, the coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at an acceptable cost or on acceptable terms with adequate coverage, or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may harm our business.

Employees

As of December 31, 2013, we had 28 full-time employees. Ten of our employees were engaged in product and software research and development, two in clinical and regulatory affairs, seven in production, six in marketing and sales and three in administration.

Item 1A. Risk Factors

You should consider carefully the following information about the risks described below, together with the other information contained in this Annual Report on Form 10-K and in our other public filings in evaluating our business. If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline.

Risks related to Our Financial Position and Capital Requirements

We have a history of losses, and we anticipate that we will incur continued losses for the foreseeable future.

We reported net losses of approximately $5.5 million and $9.8 million in 2013 and 2012, respectively. As of December 31, 2013, we had an accumulated deficit of approximately $52.0 million. We have devoted substantially all of our resources to research and development and sales of our products. Our success will depend upon, among other things, our ability to successfully market and sell our products and to generate revenues. Unanticipated problems, expenses and delays are frequently encountered in developing and commercializing new technology. These include, but are not limited to, competition, the need to gain clinical acceptance of our technology, the need for sales and marketing expertise, regulatory concerns, and setbacks in the continued development of new technology. We expect to continue to incur operating losses for the foreseeable future and require additional capital to fund ongoing operations. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity. If we are not able to fund our cash needs, we will not be able to continue as a going concern, and it is likely that all of our investors would lose their investment. If we are unable to obtain the necessary capital or financing to fund our cash needs it will adversely affect our ability to fund operations and continue as a going concern. Additional financing may not be available when needed or may not be available on terms acceptable to us. If adequate funds are not available, we may be required to delay, scale back or eliminate one or more of our business strategies, which may affect our overall business results of operations and financial condition,

Our limited cash resources and working capital deficit may result in our inability to continue operations unless we obtain additional financing.

As of December 31, 2013, we had cash and cash equivalents of $0.8 million and a working capital deficit of $5.1 million. In 2013, our cash used in operating activities totaled $4.8 million. As a result of our limited cash resources and working capital deficit, we are delinquent in paying a number of our creditors. Unless we obtain additional financing in the coming months, we will need to substantially curtail operations and may be unable to continue our business.

Our indebtedness and financing arrangements could negatively impact our business.

As of December 31, 2013, we had approximately $12.0 million of outstanding debt. We cannot be sure that our future working capital or cash flows, combined with any funds resulting from our current fund raising efforts, will be sufficient to meet our debt obligations and commitments. Any failure by us to repay such debt in accordance with its terms or to renegotiate and extend such terms would have a negative impact on our business and financial condition, and may result in legal claims by our creditors. In addition, the existence of our outstanding debt many hinder or prevent us from raising new equity or debt financing. Our ability to make scheduled payments on our debt as they become due will depend on our future performance and our ability to implement our business strategy successfully. Failure to pay our interest expense or make our principal payments would result in a default. A default, if not waived, could result in acceleration of our indebtedness, in which case the debt would become immediately due and payable. If this occurs, we may be forced to sell or liquidate assets, obtain additional equity capital or refinance or restructure all or a portion of our outstanding debt on terms that may be less favorable to us. In the event that we are unable to do so, we may be left without sufficient liquidity and we may not be able to repay our debt and the lenders may be able to foreclose on our assets or force us into bankruptcy proceedings or involuntary receivership.

We cannot assure you that we will be able to achieve or accomplish the projections of our future plans and prospects included in this report.

This report includes certain projections of our plans and prospects for the future. Our future actions and results may differ materially from these projections due to risks, uncertainties and other factors, many of which are beyond our control, including but not limited to:

- the level and timing of expenses for product development and sales, general and administrative expenses;
- our ability to successfully enter into or maintain partnering arrangements, and the terms of those relationships;
- commercial success with our existing product and success in identifying and sourcing new product opportunities;
- the development of new competitive technologies or products by others and competitive pricing pressures;
- the failure to obtain appropriate reimbursement for public and private third-party payers;
- the occurrence of unforeseen regulatory, including FDA, requirements or restrictions;
- changes in demand for our products;

- changes in product development costs;
- changes in the amount that we invest to develop, acquire or license new technologies and processes;
- business interruptions;
- departures of executives or other key management employees;
- foreign exchange fluctuations;
- changes in general economic, industry and market conditions, both domestically and in our foreign markets; and
- changes in governmental, accounting and tax rules and regulations, environmental, health and safety requirements, and other rules and regulations.

Based on the above factors and other risks and uncertainties, our future plans and prospects may differ materially from our projections.

The report of our independent registered public accounting firm expresses substantial doubt about our ability to continue as a going concern.

Our auditors have indicated in their reports on our financial statements for the fiscal years ended December 31, 2013 and 2012 that conditions exist that raise substantial doubt about our ability to continue as a going concern due to our recurring losses from operations, deficit in equity, and the need to raise additional capital to fund operations. A "going concern" opinion could impair our ability to finance our operations through the sale of debt or equity securities. Our ability to continue as a going concern will depend on our ability to obtain additional financing when necessary, which is not certain. If we are unable to achieve these goals, our business would be jeopardized and we may not be able to continue. If we ceased operations, it is likely that all of our investors would lose their investment.

Any additional capital raising will likely cause dilution to existing stockholders and, if capital raising is a secured raise, it may restrict our operations or adversely affect our ability to operate our business.

The sale of equity or issuance of debt to raise capital could result in dilution to our stockholders. The incurrence of indebtedness, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, expending capital, or declaring dividends, or which impose financial covenants on us that impede our ability to manage our operations.

Risks Related to the Development and Commercialization of Our Products

We have limited marketing experience, sales force or distribution capabilities. If we are unable to recruit key personnel to perform these functions, we may not be able to successfully commercialize our products.

Our ability to produce revenues ultimately depends on our ability to sell our products. We currently have limited experience in marketing or selling our products, and a limited marketing and sales staff and distribution capabilities. Developing a marketing and sales force is time-consuming and will involve the investment of significant amounts of financial and management resources, and could delay the launch of new products or expansion of existing product sales. In addition, we will compete with many companies that currently have extensive and well-funded marketing and sales operations. If we fail to establish successful marketing and sales capabilities or fail to enter into successful marketing arrangements with third parties, our ability to generate revenues will suffer.

Furthermore, even if we enter into marketing and distributing arrangements with third parties, we may have limited or no control over the sales, marketing and distribution activities of these third parties, and these third parties may not be successful or effective in selling and marketing our products. If we fail to create successful and effective marketing and distribution channels, our ability to generate revenue and achieve our anticipated growth could be adversely affected. If these distributors experience financial or other difficulties, sales of our products could be reduced, and our business, financial condition and results of operations could be harmed.

Our commercial success in clinical markets depends upon attaining significant market acceptance of our products by physicians, patients and healthcare payers.

The medical device industry is highly competitive and subject to rapid technological change. Our success in clinical markets depends, in part, upon physicians continuing to perform a significant number of diagnostic procedures and our ability to achieve and maintain a competitive position in the development of technologies and products in the skin cancer diagnosis field. If physicians, patients, or other healthcare providers opt to use our competitors' products, or healthcare payers do not accept our products, our commercial opportunity in clinical markets will be reduced and our potential revenues will suffer.

Biopsy of the lesion, followed by pathologic examination of the tissue specimen, is today's widely accepted standard of care with a long history of use. Two alternative diagnostic tools, clinical photography and dermoscopy, are currently gaining acceptance in the U.S. medical community. In addition, technological advances may result in improvements in these alternative diagnostic tools or new technologies may emerge that produce superior diagnostic results as compared to VivaScope and our telepathology server.

If we are unable to obtain adequate reimbursement from healthcare payers, or acceptable prices, for our products, our revenues and prospects for profitability in the clinical market will suffer.

Our future revenues and ability to become profitable will depend heavily upon the availability of adequate and timely reimbursement for the use of our products and services from governmental and other third-party payers. Reimbursement by a third-party payer may depend upon a number of factors, including the third-party payer's determination that use of a product is: (i) a covered benefit under its health plan, (ii) safe, effective and medically necessary, (iii) appropriate for the specific patient, (iv) cost effective, and (v) neither experimental nor investigational. Obtaining reimbursement approval for our products and services from each government or other third-party payer will be a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data to each payer. We may not be able to provide data sufficient to gain acceptance with respect to reimbursement. Even when a payer determines that a product is eligible for reimbursement, the payer may impose coverage limitations that preclude payment for some product uses that are approved by the FDA or similar authorities. Moreover, eligibility for coverage does not imply that any product will be reimbursed in all cases or at a rate that allows us to make a profit or even cover our costs. If we are not able to obtain coverage and profitable reimbursement promptly from government-funded and private third-party payers for our products, our ability to generate revenues and become profitable will be compromised.

The termination of our distribution relationships with any of our key distributors, or a decline in revenue from such distributors, could have a material adverse effect on our business, financial condition, and results of operations.

Our sales to date have been to a limited number of distributors and customers. For the year ended December 31, 2013, sales to two distributors were in the amounts of approximately $1.4 million and $0.5 million representing 42% and 15%, respectively, of our total revenues. Our distribution agreements with these key distributors may be terminated, or our distributors may fail to perform their obligations under such agreements. If either of these events occurs, our marketing and distribution efforts may be impaired and our revenues may be adversely impacted. We may experience greater or lesser customer concentration in the future. However, it is likely that our revenue and profitability will continue to be dependent on a very limited number of large customers and distributors. In certain countries our regulatory approval is in the name of the distributor. In the event the relationship with such distributor terminated, we would need to go through the process of reobtaining the regulatory approval in another name which would impact our ability to sell product until such approval was obtained. The loss of, material reduction in sales volume to, or significant adverse change in our relationship with any of our key distributors could have a material adverse effect on our revenue in any given period and may result in significant annual and quarterly revenue variations. Although we may be able to sell directly to customers if our relationships with any or all of our key distributors terminate, the development of our sales and distribution capabilities could involve significant expense and delay.

We operate in highly competitive markets, which may result in others discovering, developing or commercializing products before, or more successfully, than we do.

Currently our largest competitive threat in clinical markets is a surgical biopsy, which is the standard of care. Although we possess patented technology for our VivaScope products and our VivaNet telepathology system, we face competition, both nationally and internationally, from companies marketing technologies which offer an alternative to confocal microscopy and traditional biopsy. Many of these companies have established name recognition, reputation, and market presence, and may have greater financial, technical, sales, marketing and other resources than we have, enabling them to better withstand the impact of risks associated with a highly competitive industry.

Companies that have developed devices using confocal microscopy include those which have applications in ophthalmology, such as Nidek, and in gastroenterology, such as Mauna Kea Technologies, which has a confocal endomicroscopy device. Although we do not currently view these companies as competitors, these companies may compete with us in their respective application areas, which could possibly become broader and expand into our applications. Our confocal imaging devices compete with other noninvasive screening technologies which are sold by companies such as FotoFinder Systems, Inc., Mela Sciences, Inc., Michelson Diagnostics and Verisante. Though we do not believe that we compete with any specific large companies currently, major medical imaging companies such as General Electric Co., Siemens and Philips Healthcare, each of which manufacture and market precision medical diagnostic products, could decide to develop or acquire a product or products to compete with our VivaScope confocal imagers.

In the medical and therapeutic product research and development market companies with confocal microscopy products that we compete with include Nikon Corporation, Olympus Corporation, Carl Zeiss AG and Leica Microsystems Inc. These companies have established name recognition, reputation, and market presence, and greater financial, technical, sales, marketing and other resources than we have.

New product development in the medical device industry is both costly and labor intensive with very low success rates for successful commercialization; if we cannot successfully develop or obtain future products, our ability to grow may be impaired.

Our long-term success is dependent, in large part, on the design, development and commercialization of new products and services in the medical technology industry. The product development process is time-consuming, unpredictable and costly. There can be no assurance that we will be able to develop or acquire new products, successfully complete clinical trials, obtain the necessary regulatory clearances or approvals required from the FDA on a timely basis, or at all, manufacture our potential products in compliance with regulatory requirements or in commercial volumes, or that potential products will achieve market acceptance. In addition, changes in regulatory policy for product approval during the period of product development, and regulatory agency review of each submitted new application, may cause delays or rejections. It may be necessary for us to enter into licensing arrangements in order to market effectively any new products or new indications for existing products. There can be no assurance that we will be successful in entering into such licensing arrangements on terms favorable to us or at all. Failure to develop, obtain necessary regulatory clearances or approvals for, or successfully market potential new products could have a material adverse effect on our business, financial condition and results of operations.

If our products are approved for reimbursement, we anticipate experiencing significant pressures on pricing.

Our customers can include hospitals and physicians that typically bill various third-party payers, including governmental programs (e.g., Medicare and Medicaid), private insurance plans and managed care programs, for the healthcare diagnostic services provided to their patients. The ability of customers to obtain appropriate reimbursement for their products and services from private and governmental third-party payers is critical to the success of medical technology companies. The availability of reimbursement affects which products or services customers purchase and the prices they may be willing to pay. Reimbursement varies from country to country and can significantly impact the acceptance of new products and services. In the U.S. and in some foreign markets pricing and profitability of medical devices may be subject to government control. In the U.S. many private payers look to the Centers for Medicare & Medicaid Services, or CMS, which administer the Medicare program, in setting their reimbursement policies and amounts. If CMS or other agencies limit coverage or decrease or limit reimbursement payments for doctors and hospitals, this may affect coverage and reimbursement determinations by many private payers. Legislative or administrative reforms to reimbursement systems in a manner that significantly reduces reimbursement for procedures using our medical devices or denies coverage for those procedures, including price regulation, competitive pricing, coverage and payment policies, comparative effectiveness of diagnostic tools, technology assessments and managed-care arrangements, could have a material adverse effect on our business, financial condition or results of operations.

Even if reimbursement programs cover a device for certain uses, that does not mean that the level of reimbursement will be sufficient for commercial success. We expect to experience pricing pressures in connection with the commercialization of our products and our future products due to efforts by private and government-funded payers to reduce or limit the growth of healthcare costs, the increasing influence of health maintenance organizations, and additional legislative proposals to reduce or limit increase in public funding for healthcare services. Efforts to impose greater discounts and more stringent cost controls upon healthcare providers by private and public payers are expected to continue. Payers frequently review their coverage policies for existing and new diagnostic tools and can, sometimes without advance notice, deny or change their coverage policies. Significant limits on the scope of services covered or on reimbursement rates and fees on those services that are covered could have a material adverse effect on our ability to commercialize our products and therefore, on our liquidity and our business, financial condition, and results of operations.

We operate in a heavily regulated sector, and our ability to remain viable will depend on future legislative action and favorable government decisions at various points by various agencies.

Our products are regulated in the markets we operate as well as the associated manufacturing, labeling and record keeping procedures. Regulatory clearance or approval to market a diagnostic product may contain limitations on the indicated uses of the product. Marketing clearance or approval can also be withdrawn by regulators due to failure to comply with regulatory standards or the occurrence of unforeseen problems following initial clearance or approval. In addition, regulators have the authority to change or modify their regulations at any time, and also has the authority to change the medical classification of our products, thereby increasing the associated regulations to which we must adhere.

The regulations affecting healthcare change frequently, thereby increasing the uncertainty and risk associated with any healthcare related venture, including our business and our products. In addition, regulations and guidance are often revised or reinterpreted in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted or regulations, guidance, or interpretations changed, and what the impact of such changes, if any, may be.

Applicable laws and regulations are extremely complex and, in some cases, still evolving. Though we incur significant fees related to regulatory compliance, if our operations are found to be in violation of any of the laws and regulations that govern our activities, we may be subject to the applicable penalty associated with the violation, including civil and criminal penalties, damages, fines or curtailment of our operations. Any action against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's time and attention from the operation of our business.

If we fail to comply with ongoing regulatory requirements, or if we experience unanticipated problems, our products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data and promotional activities for such product, will be subject to continual review and periodic inspections by the FDA and other regulatory bodies. Regulatory approval of our products may be subject to limitations on the indicated uses for which the products may be marketed or contain requirements for costly post marketing testing and surveillance to monitor the safety or effectiveness of the products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturer or manufacturing processes, or failure to comply with regulatory requirements, may result in restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recall, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties.

Our business is subject to inspection by the FDA and international authorities, and we could face penalties if we are found to be non-compliant with the regulations of the FDA or international authorities.

The FDA and various other authorities will inspect our facilities from time to time to determine whether we are in compliance with regulations relating to medical device manufacturing, including regulations concerning design, manufacturing, testing, quality control, product labeling, distribution, promotion, and record keeping practices. Our facility was most recently inspected by the FDA in August 2009. A determination that we are in material violation of such regulations could lead to the imposition of civil penalties, including fines, product recalls, product seizures or, in extreme cases, criminal sanctions or a shutdown of our manufacturing facility. Even if regulatory approvals to market a product are obtained from the FDA, such approvals may contain limitations on the indicated uses of the product. The FDA could also limit or prevent the manufacture or distribution of our products and has the power to require the recall of products. FDA regulations depend heavily on administrative interpretation, and future interpretations made by the FDA or other regulatory bodies with possible retroactive effect may adversely affect us.

If the FDA or international authorities determine that our promotional materials or activities constitute promotion of our products for an unapproved use or other claim in violation of applicable law relating to the promotion of our products, it could demand that we cease the use of or modify our promotional materials or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider promotional or other materials to constitute promotion of telepathology or VivaScope for an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. Our competitors may also assert claims either directly or indirectly with the FDA concerning any alleged illegal or improper marketing promotional activity.

Healthcare policy changes, including legislation to reform the U.S. healthcare system, may have a material adverse effect on our business, financial condition, results of operations and cash flows.

Political, economic and regulatory influences are subjecting the healthcare industry to potential fundamental changes that could substantially affect our results of operations. In response to perceived increases in health care costs in recent years, there have been and continue to be proposals and enactments by the Obama administration, members of U.S. Congress, state governments, regulators and third-party payers to control these costs and, more generally, to reform the U.S. healthcare system. These changes are causing the marketplace to put increased emphasis on the delivery of more cost-effective treatments. Certain of these proposals and enactments or regulations promulgated to enforce them may limit the prices we are able to charge for our products or the amount of reimbursement that may be available if such products are approved for reimbursement. The adoption of some or all of these enactments and proposals could have a material adverse effect on us. We cannot predict the final form these might take or their effects on our business.

The Patient Protection and Affordable Care Act and Health Care and Education Affordability Reconciliation Act of 2010 were enacted into law in the U.S. in March 2010. As a U.S. headquartered company with sales in the U.S., this healthcare reform legislation will materially impact us. Certain provisions of the legislation will not be effective for a number of years, there are many programs and requirements for which the details have not yet been fully established or consequences not fully understood, and it is unclear what the full impact of the legislation will be. The legislation imposes on medical device manufacturers such as a 2.3 percent excise tax on U.S. sales of Class I, II and III medical devices beginning in 2013. Both downward pressure on reimbursement and the excise tax could have a material adverse effect on our business, financial condition and the results of operations. Other provisions of this legislation, including Medicare provisions aimed at improving quality and decreasing costs, comparative effectiveness research, an independent payment advisory board, and pilot programs to evaluate alternative payment methodologies, could meaningfully change the way healthcare is developed and delivered, and may adversely affect our business and results of operations. Further, we cannot predict what healthcare programs and regulations ultimately will be implemented at the federal or state level, or the effect of any future legislation or regulation in the U.S. or internationally. However, any changes that lower reimbursements for our products or reduce medical procedure volumes could adversely affect our business and results of operations.

We must comply with complex statutes prohibiting fraud and abuse, and both we and physicians utilizing our products could be subject to significant penalties for noncompliance.

There are extensive federal and state laws and regulations prohibiting fraud and abuse in the healthcare industry that can result in significant criminal and civil penalties. These federal laws include: the Anti-Kickback Law which prohibits certain business practices and relationships, including the payment or receipt of remuneration for the referral of patients or the purchase, order or recommendation of goods or services for which payment will be made by Medicare or other federal healthcare programs; the physician self-referral prohibition, commonly referred to as the Stark Law; the Anti-Inducement Law, which prohibits providers from offering anything to a Medicare or Medicaid beneficiary to induce that beneficiary to use items or services covered by either program; the Civil False Claims Act, which prohibits any person from knowingly presenting or causing to be presented false or fraudulent claims for payment by the federal government, including the Medicare and Medicaid programs; HIPAA, which creates federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program and which also imposes certain obligations on entities with respect to the privacy, security and transmission of individually identifiable health information; the federal False Statements Statute, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; and the Civil Monetary Penalties Law, which authorizes the Department of Health and Human Services, ("HHS"), to impose civil penalties administratively for fraudulent or abusive acts. We are also subject to state laws that are analogous to the above federal laws, such as state anti-kickback and false claims laws (some of which may apply to healthcare items or services reimbursed by any third-party payer, including commercial insurers), as well as certain state laws that require pharmaceutical and medical device companies to comply with industry voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government.

Sanctions for violating these laws include criminal and civil penalties that range from punitive sanctions, damage assessments, money penalties, imprisonment, denial of Medicare and Medicaid payments, or exclusion from the Medicare and Medicaid programs, or both. As federal and state budget pressures continue, federal and state administrative agencies may also continue to escalate investigation and enforcement efforts to root out waste and to control fraud and abuse in governmental healthcare programs. Private enforcement of healthcare fraud has also increased, due in large part to amendments to the Civil False Claims Act in 1986 that were designed to encourage private persons to sue on behalf of the government. Our ongoing efforts to comply with these laws may be costly, and a violation of any of these federal and state fraud and abuse laws and regulations could have a material adverse effect on our liquidity and financial condition. The risk of our being found in violation of these laws is increased by the fact that many of them have not been definitively interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of subjective interpretations. In addition, these laws and their interpretations are subject to change. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and damage our reputation. An investigation into the use of telepathology, telepathology workstations and VivaScope by physicians may dissuade physicians from either purchasing or using telepathology, telepathology workstations and VivaScope and could have a material adverse effect on our ability to commercialize our products.

The application of the privacy provisions of HIPAA is unclear, and we will become subject to other laws and regulations regarding the privacy and security of medical information.

HIPAA, among other things, protects the privacy and security of individually identifiable health information by limiting its use and disclosure. HIPAA directly regulates "covered entities" (insurers, clearinghouses, and most healthcare providers) and indirectly regulates "business associates" with respect to the privacy of patients' medical information. All entities that receive and process protected health information are required to adopt certain procedures to safeguard the security of that information. It is unclear whether we would be deemed to be a covered entity or a business associate under the HIPAA regulations. In either case, we will be required to physically safeguard the integrity and security of the patient information that we, or our physician customers, receive, store, create or transmit. If we fail to safeguard patient information, then we or our physician customers may be subject to civil monetary penalties, and this could adversely affect our ability to market our products. We also may be liable under state laws governing the privacy of health information. As and when we expand our commercialization efforts in the foreign markets that we have targeted, we will also become subject to a variety of international laws, regulations and policies designed to protect the privacy of health information. The costs associated with our ongoing compliance could be substantial, which could negatively impact our profitability.

Clinical trials associated with future applications of our technology may involve lengthy and expensive processes with uncertain outcomes, and results of earlier studies and trials may not be predictive of future trial results.

In the future, as we explore additional applications of our technology, clinical trials may be required for regulatory approval. We are not currently conducting any clinical trials related to any regulatory approval and we have no current plans to conduct any such clinical trials. However, should we decide to conduct such clinical trials, we cannot predict whether we will encounter problems with any future clinical trials, which would cause us or regulatory authorities to delay or suspend those clinical trials, or delay the analysis of data from those clinical trials. We estimate that clinical trials involving any of the various potential applications of VivaScope and telepathology which we may choose to pursue could continue for several years and that such trials may also take significantly longer to complete and may cost more money that we expect. Failure can occur at any stage of testing, and we may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent commercialization of the current, or a future, more advanced, version of our products, including but not limited to: delays in obtaining regulatory approvals to commence a clinical trial; slower than anticipated patient recruitment and enrollment; negative or inconclusive results from clinical trials; unforeseen safety issues; an inability to monitor patients adequately during or after treatment; and problems with investigator or patient compliance with the trial protocols.

A number of companies in the medical device industry, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after seeing promising results in earlier clinical trials. Despite the successful results reported in early clinical trials regarding our products, we do not know whether any clinical trials we or our clinical partners may conduct will produce favorable results. The failure of clinical trials to produce favorable results could have a material adverse effect on our business, financial condition and results of operations.

Alternative applications of our technology may not be successful, which will limit our ability to grow and generate revenue.

Although we believe the early exploratory and pilot studies for other clinical applications of our technology beyond the early detection and diagnosis of skin cancer are encouraging, there can be no assurance any of these research and development activities, engineering efforts, or clinical studies will be successful or that any FDA clearances will be achieved for any of these other clinical applications. If alternative applications of our technology are not successful, our ability to grow the Company and generate revenue will be adversely impacted.

We face the risk of product liability claims and may not be able to obtain or maintain adequate insurance to protect against these claims.

Our business exposes us to the risk of product liability claims that is inherent in the testing, manufacturing and marketing of medical devices, including those that may arise from the misuse or malfunction of, or design flaws in, our products. We may be subject to product liability claims if any of our products cause, or merely appears to have caused, an injury or if a patient alleges that any of our products failed to provide appropriate diagnostic information on a lesion where melanoma, another skin cancer, or another form of disease, was subsequently found to be present. Claims may be made by patients, healthcare providers or others involved with telepathology, telepathology workstations or VivaScope. Although we carry product liability insurance that covers our VivaScope products, our anticipated current and anticipated product liability insurance may not be available to us in amounts and on acceptable terms, if at all, and if available, the coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at an acceptable cost or on acceptable terms with adequate coverage, or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may harm our business. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could result in significant costs and significant harm to our business.

We may be subject to claims against us even if the apparent injury is due to the actions of others. For example, we rely on the expertise of physicians, nurses and other associated medical personnel to operate VivaScope. If these medical personnel are not properly trained or are negligent, we may be subjected to liability. These liabilities could prevent or interfere with our product commercialization efforts. Defending a suit, regardless of merit, could be costly, could divert management attention and might result in adverse publicity, which could result in the withdrawal of, or inability to recruit, clinical trial volunteers, or result in reduced acceptance of VivaScope in the market.

Insurance and surety companies have reassessed many aspects of their businesses and, as a result, may take actions that could negatively affect our business. These actions could include increasing insurance premiums, requiring higher self-insured retentions and deductibles, reducing limits, restricting coverage, imposing exclusions, and refusing to underwrite certain risks and classes of business. Any of these actions may adversely affect our ability to obtain appropriate insurance coverage at reasonable costs, which could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to the Operation of Our Business

We rely on intellectual property and proprietary rights and may not be able to protect these rights.

We rely heavily on proprietary technology that we protect primarily through patents, licensing arrangements, trade secrets, copyrights, trademarks, proprietary know-how and non-disclosure agreements. We have 58 issued patents and 20 pending patent applications worldwide. There can be no assurance that any pending or future patent applications will be granted or that any current or future patents, regardless of whether we are an owner or a licensee of the patent, will not be challenged, rendered unenforceable, invalidated, or circumvented or that the rights will provide a competitive advantage to us. There can also be no assurance that our trade secrets or non-disclosure agreements will provide meaningful protection of our proprietary information. Further, we cannot assure you that others will not independently develop similar technologies or duplicate any technology developed by us or that our technology will not infringe upon patents or other rights owned by others. In addition, in the future, we may be required to assert infringement claims against third parties, and there can be no assurance that one or more parties will not assert infringement claims against us. Any resulting litigation or proceeding could result in significant expense to us and divert the efforts of our management personnel as well as lead to unfavorable publicity that harms our reputation and causes the market price of our common stock to drop, whether or not such litigation or proceeding is determined in our favor. In addition, to the extent that any of our intellectual property and proprietary rights were ever deemed to violate the proprietary rights of others in any litigation or proceeding or as a result of any claim, we may be prevented from using them, which could cause a termination of our ability to sell our products. Litigation could also result in a judgment or monetary damages being levied against us.

We may be adversely affected by breaches of online security.

To the extent that our activities involve the storage and transmission of confidential information, security breaches could damage our reputation and expose us to a risk of loss, or to litigation and possible liability. A substantial portion of our revenue in future years will rely upon the transmission and storage of medical data through a virtual private network, or VPN, across the Internet. Our business may be materially adversely affected if our security measures do not prevent security breaches. In addition, such information may be subject to HIPAA privacy and security regulations, the potential violation of which may trigger concerns by healthcare providers, which may adversely impact our business, financial condition and results of operations.

All of our manufacturing operations are conducted at a single location. Any disruption at our facility could increase our expenses.

All of our manufacturing operations are conducted at a single location. We take precautions to safeguard our facility, including insurance, health and safety protocols, contracted off-site engineering services, and off-site storage of computer data. However, a natural disaster, such as a fire, flood or earthquake, could cause substantial delays in our operations, damage or destroy our manufacturing equipment or inventory, and cause us to incur additional expenses. The insurance we maintain against fires, floods, earthquakes and other natural disasters may not be adequate to cover our losses in any particular case.

Our manufacturing operations are dependent upon third-party suppliers, making us vulnerable to supply problems and price fluctuations, which could harm our business.

Our manufacturing efforts currently rely on various suppliers that supply components and subassemblies required for the final assembly and test of our devices. Some of these suppliers are sole-source suppliers. Contract manufacturers of some of our components, such as completed circuit boards, may also rely on sole-source suppliers to manufacture some of the components used in our products. Our manufacturers and suppliers may encounter problems during manufacturing due to a variety of reasons, including failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunction, long lead times and environmental factors, any of which could delay or impede their ability to meet our demand. Our reliance on these outside manufacturers and suppliers also subjects us to other risks that could harm our business, including: suppliers may make errors in manufacturing components that could negatively affect the effectiveness or safety of our products, or cause delays in shipment of our products; we may not be able to obtain adequate supply in a timely manner or on commercially reasonable terms; we may have difficulty locating and qualifying alternative suppliers for our sole-source suppliers; our suppliers manufacture products for a range of customers, and fluctuations in demand for the products these suppliers manufacture for others may affect their ability to deliver components to us in a timely manner; and our suppliers may encounter financial hardships unrelated to our demand for components, which could inhibit their ability to fulfill our orders and meet our requirements.

Any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders.

Our success will depend on our ability to attract and retain our personnel.

Our success is particularly dependent upon the continued service of our executive officers and other key employees. We have currently executed employment agreements with our CEO, CFO, CTO and VP of Operations. The agreements range in term from three to five years and each are renewable for additional one-year terms unless either we or the executive send written notice to the other party of its intention not to renew at least ninety (90) days prior to expiration of the then-current term. Each of these executives has agreed, pursuant to his or her respective employment agreement, not to compete with us, nor solicit our customers or employees, for a period of one (1) year following the termination of such executive's employment. All of our employees, including our executive officers, have executed our standard form of Employee Invention, Copyright, Proprietary Information and Conflicts of Interest Agreement. The loss of the services of any of our executive officers or other key employees could have a material adverse effect on our business and results of operations. Our future success will depend in part upon our ability to attract and retain highly qualified personnel. We may not be successful in hiring, retaining or developing sufficient qualified individuals.

Our employees may engage in misconduct or improper activities, including noncompliance with regulatory standards and prohibitions on insider trading.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with applicable manufacturing standards, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

We may be liable for contamination or other harm caused by materials that we handle, and changes in environmental regulations could cause us to incur additional expense.

Our manufacturing, research and development and clinical processes do not generally involve the handling of potentially harmful biological materials or hazardous materials, but they may occasionally do so. We are subject to federal, state and local laws and regulations governing the use, handling, storage and disposal of hazardous and biological materials. If violations of environmental, health and safety laws occur, we could be held liable for damages, penalties and costs of remedial actions. These expenses or this liability could have a significant negative impact on our business, financial condition and results of operations. We may violate environmental, health and safety laws in the future as a result of human error, equipment failure or other causes. Environmental laws could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We may be subject to potentially conflicting and changing regulatory agendas of political, business and environmental groups. Changes to or restrictions on permitting requirements or processes, hazardous or biological material storage or handling might require an unplanned capital investment or relocation. Failure to comply with new or existing laws or regulations could harm our business, financial condition and results of operations.

Failure to maintain an effective system of internal control over financial reporting may not allow us to be able to accurately report our financial condition, results of operations or prevent fraud.

We regularly review and update our internal control over financial reporting, disclosure controls and procedures, and corporate governance policies and procedures, and have concluded that our internal control over financial reporting was not fully effective. We maintain controls and procedures to mitigate risks, such as processing system failures and errors. Any system of controls and procedures, however well designed and operated, is based in part on certain assumptions and can provide only reasonable assurances that the objectives of the system are met. Events could occur which are not prevented or detected by our internal controls. Any failure or circumvention of our controls and procedures or failure to comply with regulations related to controls and procedures could cause a failure to meet our reporting obligations under applicable federal securities laws, which could have a material adverse effect on our business, results of operations and financial condition.

If our products contain defects or otherwise fail to perform as expected, we could be liable for damages and incur unanticipated warranty, recall and other related expenses, our reputation could be damaged, we could lose market share and, as a result, our financial condition or results of operations could suffer.

Our products are complex and may contain defects or experience failures due to any number of issues in design, materials, deployment and/or use. If any of our products contain a defect or do not operate properly, we may have to devote significant time and resources to find and correct the issue. Such efforts could divert the attention of our management team and other relevant personnel from other important tasks. A product recall or a significant number of product returns could be expensive; damage our reputation and relationships with our customers and distributors; result in the loss of business to competitors; and result in litigation against us. Because our products are relatively new and we do not yet have the benefit of long-term experience observing product performance in the field, our estimates of a product lifespan and incidence of claims may be inaccurate. Should actual product failure rates, claims levels, material usage, or other issues differ from the original estimates, we could end up incurring materially higher warranty or recall expenses than we anticipate.

We are an "emerging growth company," or "EGC", and any decision on our part to comply only with certain reduced disclosure requirements applicable to "emerging growth companies" could make our common stock less attractive to investors.

We are an "EGC" as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, and we are eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation, from which we are currently exempt as a smaller reporting company, and stockholder approval of any golden parachute payments not previously approved in connection with a transaction resulting in a change of control.

In addition, Section 107 of the JOBS Act also provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

We expect to take advantage these exemptions. If we do take advantage of any of these exemptions, investors may find our financial statements and other disclosures not comparable to companies that comply with public company effective dates, and will find our common stock less attractive as a result. The result may be a less active trading market for our common stock and the stock price may be more volatile.

Poor or uncertain global economic conditions have had and could continue to have an adverse effect on our operating results.

The global economic environment began to deteriorate significantly in 2008, with declining values in real estate, increased unemployment and volatility in the global financial markets resulting in reduced credit lending by banks, solvency concerns of major financial institutions and sovereign debt issues. Economic and market conditions have continued to be volatile and uncertain in many markets around the world. In Europe where the sale of our products constituted 41% of our total sales in fiscal 2013, sovereign debt issues, government austerity programs, and bank credit issues continue to affect the capital markets of numerous European countries. These circumstances have had, and are expected to continue to have, a negative impact on our business. If the global economy continues to be weak or deteriorate further, there will likely be a negative impact on our revenues, operating margins and earnings.

Risks Relating to Our Securities

Because our securities are quoted on the OTCQB marketplace, our liquidity and the price of our securities are limited and our investors may be subject to significant restrictions on the resale of our securities due to state "Blue Sky" laws.

Our common stock and warrants are traded on the OTCQB marketplace quotation system, which is a FINRA-sponsored entity and operated inter-dealer automated quotation system for equity securities not included in a national exchange. Quotation of our securities on the OTCQB marketplace limits the liquidity and price of our securities more than if our securities were quoted or listed on the NYSE Amex or the Nasdaq Capital Market, which are national securities exchanges. Lack of liquidity will limit the price at which you may be able to sell our securities or your ability to sell our securities at all.

Each state has its own securities laws, often called "blue sky" laws, which (i) limit sales of securities to a state's residents unless the securities are registered in that state or qualify for an exemption from registration, and (ii) govern the reporting requirements for broker-dealers doing business directly or indirectly in the state. Before a security is sold in a state, there must be a registration in place to cover the transaction, or the transaction must be exempt from registration. The applicable broker must be registered in that state. We do not know whether our securities will be registered or exempt from registration under the laws of any state. Since our securities are listed on the OTCQB marketplace, a determination regarding registration will be made by those broker-dealers, if any, who agree to serve as the market-makers for our securities. There may be significant state blue sky law restrictions on the ability of investors to sell, and on purchasers to buy, our securities. You should therefore consider the resale market for our securities to be limited, as you may be unable to resell your securities without the significant expense of state registration or qualification.

The exercise of our warrants may also be subject to "blue sky" laws. As a result, depending on the state of residence of a holder of the warrants, a holder may not be able to exercise its warrants unless we comply with any state securities law requirements necessary to permit such exercise or an exemption applies. Although we plan to use our reasonable efforts to assure that holders will be able to exercise their warrants under applicable state securities laws if no exemption exists, there is no assurance that we will be able to do so. As a result, the ability to exercise the warrants may be limited. The value of the warrants may be significantly reduced if holders are not able to exercise their warrants under applicable state securities laws.

Because our shares are subject to the penny stock rules, it may be more difficult to sell our shares.

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than $5.00 (other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system). The OTC Markets does not meet such requirements and for so long as the price of our common stock is less than $5.00, our securities will be deemed penny stocks. The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that prior to effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser's written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our securities, and therefore security holders may have difficulty selling their shares.

Our stock price may remain volatile and purchasers of our common stock could incur substantial losses.

As a result of the volatility which our stock has incurred since our initial public offering, a decline in the market price of our common stock could cause stockholders to lose some or all of their investment and may adversely impact our ability to attract and retain employees and raise capital. In addition, stockholders may initiate securities class action lawsuits if the market price of our stock drops significantly. Whether or not meritorious, litigation brought against us could result in substantial costs and could divert the time and attention of our management. Our insurance to cover claims of this sort may not be adequate.

The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock: the announcement of new products or product enhancements by us or our competitors; developments or disputes concerning patents or other intellectual property rights; changes in the structure of third-party reimbursement in the U.S.; the departure of key personnel; results of our research and development efforts and our clinical trials; regulatory developments in the U.S. and foreign countries; developments concerning our clinical collaborators, suppliers or marketing partners; changes in financial estimates or recommendations by securities analysts; lack of trading volume in the stock, failure of any new products, if approved, to achieve commercial success; product liability claims and litigation against us; the strength and variations in our financial results or those of companies that are perceived to be similar to us; general economic, industry and market conditions; and future sales of our common stock.

Concentration of ownership among our directors, executive officers, and principal stockholders may prevent new investors from influencing significant corporate decisions.

Based upon beneficial ownership as of December 31, 2013, our directors, executive officers, holders of more than 5% of our common stock, and their affiliates, in the aggregate, beneficially owned a significant percentage of our outstanding common stock. To the extent that our affiliates may purchase additional shares, that percentage will be even higher. As a result, these stockholders, subject to any fiduciary duties owed to our other stockholders under New York law, will be able to exercise a controlling influence over matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, and will have significant control over our management and policies. Some of these persons or entities may have interests that differ from those of the stockholders. For example, these stockholders may support proposals and actions with which you may disagree or which are not in your interests. The concentration of ownership could delay or prevent a change in control of our Company or otherwise discourage a potential acquirer from attempting to obtain control of our Company, which in turn could reduce the price of our common stock. In addition, these stockholders, some of whom have representatives sitting on our Board of Directors, could use their voting influence to maintain our existing management and directors in office, delay or prevent changes of control of our Company, or support or reject other management and board proposals that are subject to stockholder approval, such as amendments to our employee stock plans and approvals of significant financing transactions.

Our charter documents and New York law may inhibit a takeover that stockholders consider favorable and could also limit the market price of our stock.

Provisions of our certificate of incorporation and bylaws and applicable provisions of New York law may make it more difficult for or prevent a third party from acquiring control of us without the approval of our Board of Directors. These provisions:

- limit who may call a special meeting of stockholders; and,
- do not permit cumulative voting in the election of our directors, which would otherwise permit less than a majority of stockholders to elect directors;

In addition, Section 912 of the New York Business Corporation Law generally provides that a New York corporation may not engage in a business combination with an interested stockholder for a period of five years following the interested stockholder's becoming such. An interested stockholder is generally a stockholder owning at least 20% of a corporation's outstanding voting stock. These provisions may have the effect of entrenching our management team and may deprive stockholders of the opportunity to sell shares to potential buyers at a premium over prevailing prices. This potential inability to obtain a control premium could reduce the price of our common stock.

We do not intend to pay dividends on our common stock and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We have never declared or paid any cash dividend on our common stock and do not currently intend to do so for the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Therefore, the success of an investment in shares of our common stock will depend upon any future appreciation in their value. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which our stockholders have purchased their shares.

Future sales of our common stock may cause our stock price to decline.

If our existing stockholders sell, or indicate intent to sell, substantial amounts of our common stock in the public market the trading price of our common stock could decline significantly. Moreover, a relatively small number of our stockholders own large blocks of shares. We cannot predict the effect, if any, that public sales of these shares or the availability of these shares for sale will have on the market price of our common stock.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We lease approximately 9,000 square feet of office, laboratory, and assembly space in the same building as our principal executive offices located at 50 Methodist Hill Drive, Suite 1000, Rochester, NY 14623 under a lease which expires in March 2021. As a cost-reduction measure, we recently moved from our previous location at 95 Methodist Hill Drive, Suite 500. In addition, in January 2014, we entered into a lease agreement for office space in Andover, MA that expires in February 2017. We believe these facilities will be adequate to meet our current and reasonably foreseeable requirements, and that, if needed, we will be able to obtain additional space on commercially reasonable terms.

Item 3. Legal Proceedings

We are not currently subject to any material legal proceedings, nor, to our knowledge, is any material legal proceeding threatened against us. From time to time, we may be a party to certain legal proceedings, incidental to the normal course of our business. While the outcome of these legal proceedings cannot be predicted with certainty, we do not expect that these proceedings will have a material effect upon our financial condition or results of operations.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our units, each consisting of one share of common stock and one warrant, were traded on the OTC Bulletin Board and were maintained by the Financial Industry Regulatory Authority under the symbol "LCDCU" from December 28, 2011 to February 24, 2012. Upon a mandatory separation of our units on February 27, 2012, our units ceased trading on the OTC Bulletin Board and our common stock and warrants began trading on the OTC Bulletin Board, now OTCQB under the symbols "LCDX" and "LCDXW," respectively.

The following tables set forth the range of high and low per share sales prices for our common stock, as reported by the OTCQB marketplace from the date on which our common stock began trading through December 31, 2013. These over-the-counter market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and do not represent actual transactions:

	2013		2012	
Period	**High ($)**	**Low ($)**	**High ($)**	**Low ($)**
Quarter ended March 31	$ 1.50	$ 1.00	—	—
Quarter ended June 30	$ 1.30	$ 0.25	$ 2.00	$ 0.51
Quarter ended September 30	$ 1.30	$ 0.70	$ 2.25	$ 0.45
Quarter ended December 31	$ 1.05	$ 0.51	$ 2.00	$ 0.25

Holders

As of February 28, 2014, there were approximately 150 holders of record of our common stock. Because shares of our common stock are held by depositories, brokers and other nominees, the number of beneficial holders of our shares is larger than the number of stockholders of record.

Dividends

We have never paid any cash dividends on our common stock and we do not anticipate paying such cash dividends in the foreseeable future. We currently anticipate that we will retain all future earnings, if any, for use in the development of our business.

Securities Authorized for Issuance under Equity Compensation Plans

The following table sets forth information as of December 31, 2013 with respect to compensation plans (including individual compensation arrangements) under which equity securities are authorized for issuances:

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
Equity compensation plans approved by security holders [1]	1,740,500	$ 1.76	501,000
Equity compensation plans not approved by security holders [2]	1,770,500	1.03	259,721
Total	3,511,000	$ 1.39	760,721

(1) Includes the Lucid, Inc. Year 2000 Stock Option Plan, the Lucid, Inc. 2007 Long-Term Incentive Plan, and the Lucid, Inc. 2010 Long-Term Equity Incentive Plan. No further awards may be made under the Year 2000 Stock Option Plan or the 2007 Long-Term Incentive Plan.

(2) Includes the Lucid, Inc. 2012 Stock Option and Incentive Plan adopted by the Board of Directors in July 2012 and subject to stockholder approval at the next stockholder meeting.

See Note 13 of Item 8 of this Annual Report on Form 10-K for a summary of our equity compensation plans.

Recent Sales of Unregistered Securities

Set forth below is information regarding shares of common stock issued by us during the year ended December 31, 2013 that were not registered under the Securities Act. Also included is the consideration, if any, received by us for such shares and warrants and information relating to the section of the Securities Act, or rule of the SEC, under which exemption from registration was claimed.

a. Common Stock Warrants Issued in Lieu of Cash Payment for Services Rendered

In December 2013, we issued to our public relations firm stock warrants to purchase up to 42,500 shares of our common stock, at an exercise price of $1.00 per share, in connection with a letter agreement for services.

b. Common Stock Warrants

During 2013, we issued warrants to purchase 132,583 shares of common stock as a result of anti-dilution adjustments triggered by the issuances of shares of common stock and warrants.

No underwriters were involved in the foregoing issuances of securities. Unless otherwise stated, the sales of the above securities were deemed to be exempt from registration under the Securities Act in reliance upon Section 4(2) of the Securities Act or Regulation D promulgated thereunder of the Securities Acts as transactions by an issuer not involving any public offering.

All of the foregoing securities are deemed restricted securities for purposes of the Securities Act. The certificates representing the issued shares of capital stock and the warrants described herein included appropriate legends setting forth that the applicable securities have not been registered and the applicable restrictions on transfer.

Item 6. Selected Financial Data

We are not required to provide the information required by this Item because we are a smaller reporting company.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes appearing elswhere in this report. Some of the information contained in this discussion and analysis or set forth elsewhere in this report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties – see "Special Note Regarding Forward-Looking Statements." You should review "Item 1A. Risk Factors" for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

	Year Ended December 31,	
	2013	**2012**
Statement of Operations Data:		
Revenue	$ 3,341,253	$ 2,434,585
Operating expenses:		
Cost of revenue	2,687,397	2,401,729
General and administrative	2,305,264	4,025,245
Sales and marketing	1,670,041	1,809,434
Engineering, research and development	1,531,245	3,764,816
Total operating expenses	8,193,947	12,001,224
Loss from operations	(4,852,694)	(9,566,639)
Other expenses, net	(626,557)	(253,986)
Net loss	$ (5,479,251)	$ (9,820,625)
Basic and diluted net loss per common share	$ (0.65)	$ (1.23)
Weighted-average number of common shares outstanding	8,384,708	7,998,662

We are a medical device company that develops, manufactures, markets and sells point-of-care cellular imaging systems. Our patented and FDA-cleared VivaScope® technology provides physicians with real-time images of the epidermis and superficial dermis of the skin, as well as other epithelial tissues at a cellular level that can be interpreted by the physician at the bedside and/or transferred securely to a pathologist on VivaNet®, our HIPAA-compliant private telepathology network for remote diagnosis. With sensitivity and specificity that can rival the current "gold standard", clinical histopathology, but without all of the associated costs of a traditional biopsy, our platform imaging technology has the potential to significantly improve patient outcomes while simultaneously reducing costs.

Our core products are FDA 510(k) cleared for clinical use and have regulatory approvals in most major markets. Our technology is already in use by physicians and researchers at major academic hospitals, and by pharmaceutical and cosmetic companies across the globe. Our devices allow these researchers to quickly and efficiently study the efficacy of new products, test ingredients, validate claims and determine safety. The technology is protected by 78 issued or pending patents worldwide.

To date, our proprietary platform imaging technology has been the subject of more than 350 independently sponsored studies or publications spanning numerous clinical and research fields. Extensive research has been conducted in dermatologic disorders including melanoma and nonmelanoma skin cancers, dermatoses, inflammatory and pigmentation disorders. Additionally, the technology has been used to noninvasively study burns, wound healing, neuropathy and oral tissues. Ex-vivo research has been conducted in head and neck, breast biopsy and surgical specimens. Our in-vivo products are ideal for applications in which a traditional biopsy is counterproductive, such as validating the diagnosis of benign lesions (thus, reducing unnecessary biopsies), monitoring noninvasive therapies and determining product efficacy. In the future, the technology may be used to perform real-time pathology in the operating room on tissues removed from the body and to identify tissues in the body during surgery.

Product Portfolio

Our product portfolio consists of a variety of in-vivo and ex-vivo imaging systems, as well as a telepathology system, covering a wide variety of applications.

Our VivaScope in-vivo devices, the VivaScope® 3000 (handheld device) and the VivaScope® 1500, use confocal cellular imaging to create a layer-by-layer scan of living tissue, with a >0.2mm imaging depth. This provides physicians with a microscopic view of living cells in the skin, with 3-5 micron cellular resolution comparable to histology. Our in-vivo imagers are FDA 510(k) cleared with an intended use to "acquire, store, retrieve, display and transfer in-vivo images of tissue, including blood collagen and pigment, in exposed unstained epithelium and the supporting stroma for review by physicians to assist in forming a clinical judgment."

Our VivaScope ex-vivo device, the VivaScope 2500, uses confocal imaging to produce electro-optically enlarged images of unstained and unsectioned excised surgical tissue without the laborious tissue preparation procedures required to prepare the microscope slides used in traditional pathologic examination of tissue. As a Class I medical device, the VivaScope 2500 is exempt from 510(k) clearance.

We have devoted substantially all of our resources to the development of our technologies, which expenses have included research and development, conducting clinical investigations for our product candidates, protecting our intellectual property and the general and administrative support of these operations. While we have generated revenue through product sales, we have funded our operations largely through an initial public equity offering and multiple rounds of private debt and equity financings. We have never been profitable and we reported net losses of approximately $5.5 million and $9.8 million for the years ended December 31, 2013 and 2012, respectively. As of December 31, 2013, we had total stockholders' deficit of approximately $12.5 million. We expect to incur operating losses for the foreseeable future as we invest substantial resources to promote the commercialization, and attempt to achieve widespread adoption, of our products. We expect that research and development expenses and sales and marketing expenses will increase along with general and administrative costs, as we grow and operate as a public company. We will need to generate significant revenues to achieve profitability and we may never do so.

As of December 31, 2013, we had cash and cash equivalents of $0.8 million and a working capital deficit of $5.1 million. In 2013, our cash used in operating activities totaled $4.8 million. As a result of our limited cash resources and working capital deficit, we are delinquent in paying a number of our creditors. Unless we obtain additional financing in the coming months, we will need to substantially curtail operations and may be unable to continue our business.

Our revenues are derived from the sale of our products and services, primarily VivaScopes, as well as an immaterial amount of revenue from maintenance and support services. We recognize product revenue when evidence of an agreement exists, title has passed (generally upon shipment) or services have been rendered. Certain direct sales contracts require installation at the customer's location prior to acceptance. As such, revenue recognition on these contracts is typically delayed until all aspects of delivery, including installation, are complete. In addition, should the contract include training, revenue recognition is delayed until training is complete.

Results of Operations

Years Ended December 31, 2013 and 2012

We reported a net loss of $5.5 million or $(0.65) per share for the year ended December 31, 2013 as compared to a consolidated net loss of $9.8 million or $(1.23) per share for the year ended December 31, 2012. The decrease in net losses in 2013 resulted primarily from an increase in sales and an overall decrease in operating expenses.

The following presents a more detailed discussion of our operating results:

Product sales. For the years ended December 31, 2013 and 2012, we recorded sales of our products of $3.3 million and $2.4 million, respectively. The increase was primarily attributed to an increase in sales in North America of $0.4 million combined with an increase in distributor sales in Europe and Asia of $0.3 million and $0.1 million, respectively. Percentages of total sales by geographic region are as follows:

	Year Ended December 31,			
	2013		2012	
	Product Sales (in millions)	Percent	Product Sales (in millions)	Percent
North America	$ 0.9	27%	$ 0.5	23%
Europe	1.3	41%	1.0	39%
Asia	0.7	23%	0.6	25%
Latin America	0.3	7%	0.2	8%
Australia	0.1	2%	0.1	5%
Total	$ 3.3	100%	$ 2.4	100%

Sales of our products for the quarter ended December 31, 2013 increased $0.4 million from $0.7 million for the quarter ended September 30, 2013 to $1.1 million for the quarter ended December 31, 2013. The increase was primarily due to increased sales to distributors in China and Brazil.

During the year ended December 31, 2012, we began a significant enhancement program to increase the speed and functionality of our VivaScope confocal imagers. We believe the sales of our existing products were negatively impacted during 2012 primarily because we informed our key distributors at the end of 2011 about the 2012 enhancement program. The 2012 enhancement program was substantially completed by September 31, 2012.

Cost of revenue. For the year ended December 31, 2013 and 2012, we incurred cost of revenue of $2.7 million and $2.4 million, respectively. As a percentage of product sales, cost of revenue was 80% and 99% for the years ended December 31, 2013 and 2012, respectively. The decrease in cost of sales as a percentage of product sales reflects a decrease in warranty repairs as well as decreased charges to increase our warranty reserves.

General and administrative expenses. General and administrative expenses consist primarily of salaries and benefits, professional fees, occupancy costs for our office, insurance costs and general corporate expenses, including those costs associated with being a public company. General and administrative expenses decreased $1.7 million from $4.0 million for the year ended December 31, 2012 to $2.3 million for the year ended December 31, 2013. The decrease resulted from decreases in professional fees of $0.5 million, related primarily to legal and audit fees, as well as a decrease in severance expenses since our reduction in force during 2012. For the years ended December 31, 2013 and 2012, general and administrative expenses included non-cash stock-based compensation expenses of $0.2 million and $1.0 million, respectively.

Sales and marketing expenses. Sales and marketing expenses consist primarily of salaries and benefits and general marketing expenses. Sales and marketing expenses decreased $0.1 million from $1.8 million for the year ended December 31, 2012 to $1.7 million for the year ended December 31, 2013. For the years ended December 31, 2013 and 2012, sales and marketing expenses included non-cash stock-based compensation expenses of $32,000 and $0.1 million, respectively.

Engineering, research and development expenses. Engineering, research and development expenses consist primarily of salaries and benefits and material costs used in the development of new products and product improvements. Engineering, research and development expenses decreased $2.3 million from $3.8 million for the year ended December 31, 2012 to $1.5 million for the year ended December 31, 2013. This decrease primarily resulted from a decrease in severance costs of $0.6 million, a decrease in stock-based compensation charges of $0.6 million and a $0.6 million decrease in consulting fees. For the years ended December 31, 2013 and 2012, engineering, research and development expenses included non-cash stock-based compensation expenses of approximately $0.1 and $0.7 million, respectively.

Interest expense. Interest expense increased $0.4 million from $0.4 million for the year ended December 31, 2012 to $0.8 million for the year ended December 31, 2013. The increase in interest expense was a result of the placement of our 2013 Term Loan in May 2013 in the amount of $5.0 million.

Gain (loss) on extinguishment of debt. We recorded a gain on extinguishment of debt of $0.1 million for the year ended December 31, 2013 for the favorable settlement of a promissory note payable, as compared to a loss on extinguishment of debt of $0.4 million during the prior year resulting from the conversion of debt in 2012 related to our 2011 initial public offering.

Fair value adjustment of warrants. For the years ended December 31, 2013 and 2012, we recognized income of $0.1 million and $0.6 million, respectively, to record changes in the fair value of certain of our outstanding warrants not indexed to our own stock.

Liquidity and Capital Resources

As of December 31, 2013, we had $2.3 million in current assets and $7.4 million in current liabilities, resulting in a working capital deficit of $5.1 million. As of December 31, 2012, we had $2.5 million in current assets and $3.1 million in current liabilities, respectively, resulting in a working capital deficit of $0.6 million. Our working capital decrease was a result of our current liabilities increasing from $3.1 million in 2012 to $7.4 million in 2013 as a result of the classification of our 2013 Term Loan as a current liability at December 31, 2013. The lender has agreed to convert the amounts due under this note into equity pending the raise of $6.0 million in funds (See "Term Loans" below for additional information.) Our current assets consist of cash and cash equivalents, accounts receivable, inventories, prepaid expenses and other current assets. Our current liabilities consist of the current portion of our long-term debt, accounts payable, accrued expenses, and deferred revenue.

As of December 31, 2013, we had cash and cash equivalents of $0.8 million and a working capital deficit of $5.1 million. In 2013, our cash used in operating activities totaled $4.8 million. As a result of our limited cash resources and working capital deficit, we are delinquent in paying a number of our creditors. Unless we obtain additional financing in the coming months, we will need to substantially curtail operations and may be unable to continue our business.

We engaged R.F. Lafferty & Co., Inc. ("Lafferty") to provide general investment banking services to us in March 2014, replacing H.C. Wainwright & Co., LLC ("H.C. Wainwright") as our investment bankers. We have agreed to pay Lafferty a retainer for its services as well as to issue common stock, warrants to purchase common stock, a finder's fee and a transaction fee upon the closing of a financing. See Note 17 - Subsequent Events under Item 8 of this Annual Report on Form 10-K for further information.

We anticipate to continue to generate losses for at least the next year as we develop and expand our products and offerings and seek to commercialize our products and expand our corporate infrastructure. We will continue to require significant amounts of additional capital to fund our operations, and such capital may not be available when we need it on terms that we find favorable, if at all. We are seeking to raise these funds as described above, though we may seek additional debt financings, credit facilities, partnering or other corporate collaborations and licensing arrangements. If adequate funds are not available or are not available on acceptable terms, our ability to fund our operations, take advantage of opportunities, develop products and technologies, and otherwise respond to competitive pressures could be significantly delayed or limited, and we may need to downsize or halt our operations. Prevailing market conditions may not allow for such a fundraising or new investors may not be prepared to purchase our securities at prices that are greater than the current market price.

In October 2013, we entered into a letter agreement with the holder of the Loan and Security Agreement (the "2012 Term Loan") and 2013 Term Loan. With respect to the 2013 Term Loan, the parties agreed that upon closing of the offering described above in which we raise at least $6 million, all outstanding amounts of principal and interest under the 2013 Term Loan will convert into our common stock on the same terms as such shares sold to other investors in the offering. With respect to the 2012 Term Loan, the holder agreed to (i) extend the maturity date by three years to July 5, 2020, (ii) provide that interest will be payable only on maturity, and (iii) provide that the events of default will only be nonpayment at maturity or our insolvency. Upon conversion of the 2013 Term Loan as set forth above, we agreed to issue to the holder a fully-vested warrant to purchase 150,000 shares of our common stock at an exercise price equal to the higher of $1.00 per share or the price at which shares are sold in the offering.

There can be no assurance that we will be successful in our plans described above or in attracting alternative debt or equity financing. These conditions have raised substantial doubt about our ability to continue as a going concern.

Because of the numerous risks and uncertainties associated with research, development and commercialization of medical devices, we are unable to estimate the exact amounts of our working capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the cost of development and growth of our VivaScope business;
- the cost of commercialization activities of our products, and of our future product candidates, including marketing, sales and distribution costs;

- the number and characteristics of any future product candidates we pursue or acquire;
- the scope, progress, results and costs of researching and developing our future product candidates, and conducting clinical trials;
- the timing of, and the costs involved in, maintaining and obtaining regulatory approvals for our existing products and future product candidates;
- the cost of manufacturing our existing VivaScope products and maintaining our telepathology server, as well as such costs associated with any future product candidates we successfully commercialize;
- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties on, our future products, if any.

As of the date of this report we are delinquent in paying a number of creditors and our liquid assets (cash, cash equivalents and accounts receivable) are not sufficient to meet our obligations many of which are past due. These conditions have raised substantial doubt about the Company's ability to continue as a going concern.

Summary of Cash Flows

	For the Year Ended December 31,	
	2013	**2012**
Operating activities	$ (4,837,180)	$ (7,704,665)
Investing activities	(27,652)	(79,493)
Financing activities	4,724,894	3,814,464
Net decrease in cash and cash equivalents	(139,938)	(3,969,694)

Net cash used in operating activities. Cash used in operating activities was $4.8 million and $7.7 million for the years ended December 31, 2013 and 2012, respectively. The decrease in cash used in operating activities resulted primarily from the decrease in net loss of $4.3 million, offset by increased cash payments for expenses.

Net cash used in investing activities. Cash used in investing activities was approximately $28,000 and $0.1 million for the years ended December 31, 2013 and 2012, respectively, and represents the purchases of fixed assets during these periods.

Net cash provided by financing activities. Cash provided by financing activities was $4.7 million and $3.8 million for the years ended December 31, 2013 and 2012, respectively. The increase in 2013 resulted from the placement of the 2013 Term Loan for $5.0 million, as compared to the placement of the 2012 Term Loan for $7.0 million in 2012 which was partially used to repay existing debt of $3.4 million.

Term Loans. In July 2012, we borrowed $7.0 million from an affiliate pursuant to the 2012 Term Loan, which refinanced a previous loan in the amount of $3.0 million. The 2012 Term Loan bears interest at a rate of 7% per annum, payable quarterly commencing in July 2014 and is secured by all of our assets. The 2012 Term Loan contains customary affirmative and negative covenants, including covenants restricting the incurrence of debt, imposition of liens, the payment of dividends, and entering into affiliate transactions. The 2012 Term Loan also contains customary events of default, including among others, nonpayment of principal or interest, material inaccuracy of representations and failure to comply with covenants. If an event of default occurs and is continuing under the 2012 Term Loan, the entire outstanding balance may become immediately due and payable. In October 2013, we entered into a letter agreement with the holder of the 2012 Term Loan, pursuant to which the holder agreed to (i) extend the maturity date by three years to July 5, 2020, (ii) provide that interest will be payable only on maturity, and (iii) provide that the events of default will only be nonpayment at maturity or our insolvency.

In May 2013, we borrowed an additional $5.0 million from the same affiliate under the 2013 Term Loan. The 2013 Term Loan matures in November 2014 and may be prepaid at any time. The 2013 Term Loan bears interest at a rate of 7% per annum, payable upon maturity, and is secured by all of our assets. The 2013 Term Loan includes cross default provisions with the existing 2012 Term Loan. In October 2013, we entered into a letter agreement with the holder of the 2013 Term Loan, pursuant to which the parties agreed that upon the closing of an offering by us in which we raise at least $6 million, all outstanding amounts of principal and interest under the 2013 Term Loan will convert into our common stock on the same terms as such shares sold to other investors in the offering. Upon conversion of the 2013 Term Loan as set forth above, we agreed to issue to the holder a fully-vested warrant to purchase 150,000 shares of our common stock at an exercise price equal to the higher of $1.00 per share or the price at which shares are sold in the offering.

Promissory Notes. As of December 31, 2012, two non-interest bearing promissory notes owed to non-affiliated lenders were outstanding totaling $0.4 million. In May 2013, the outstanding balance of one of the promissory notes was settled in full, resulting in a gain on extinguishment of debt of approximately $81,000 for the year ended December 31, 2013. As of December 31, 2013 the remaining promissory note totaled approximately $24,000 and was classified as a current liability.

Trade Payables and Receivables. Generally, the terms for our trade payables are 30 days from the date of receipt. Certain vendors require partial or full prepayment, especially for parts unique to our orders. As of the date of this report, we are overdue in paying a number of vendors and such condition may adversely impact the Company's business and its ability to continue to operate as a business.

As of December 31, 2013, we had accounts receivable of approximately $0.5 million. We generally request 50% prepayment from all customers, with the balance due 30 days after shipment, although in certain circumstances we require the full balance prior to shipment. Amounts collected prior to the recognition of revenue are recognized as customer deposits and are included in "accrued expenses and other current liabilities" in the accompanying condensed balance sheets.

Warrants. At December 31, 2013, we had warrants to purchase up to 4,280,553 shares of our common stock outstanding at a weighted average exercise price of $3.17. In March 2014, warrants to purchase 1.4 million shares of our common stock at $1.00 per share were terminated when the Company ended its relationship with H.C. Wainwright.

Stock Options. At December 31, 2013, we had stock options outstanding to purchase 3,511,000 shares of our common stock at a weighted average exercise price of $1.39. In addition, 760,721 shares are available for issuance under our stock option plans upon the grant or issuance of awards.

Off-Balance Sheet Arrangements

We had no off-balance sheet arrangements as of December 31, 2013 and as of the date of this report.

Recently Issued Accounting Pronouncements

In the normal course of business, management evaluates all new accounting pronouncements issued by the Financial Accounting Standards Board, SEC, Emerging Issues Task Force, American Institute of Certified Public Accountants and other authoritative accounting bodies to determine the potential impact they may have on our financial statements. Based upon this review, we do not expect any of the recently issued accounting pronouncements to have a material impact on our financial statements.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition, liquidity and results of operations are based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and assumptions that affect amounts reported therein. The following lists our current accounting policies involving significant management judgment and provides a brief description of these policies:

Fair Value. Certain elements of our financial statements require us to make estimates regarding the fair market value of our common stock. In 2013 and 2012, the Company estimated fair market value of our common stock based largely on recent trading history and volume. Because the trading in our stock has been thin and sporadic, exclusive use of the most recent trading price could, at times yield an amount which was not the best indication of fair value.

Historically, we have used estimates of the fair value of our common stock at various dates for the purpose of:

- Determining the fair value of our common stock on the date of grant of a stock-based compensation award to our employees and non-employees as one of the inputs into determining the grant date fair value of the award.

- Determining the fair value of our common stock on the date of grant of a restricted stock award to determine the amount of compensation expense to be recorded over the requisite service period.

- Determining the fair value of our common stock at each reporting period as an input into our model to value warrants classified as liabilities and to value warrants issued in payment of services.

Management has estimated the fair value of our common stock during 2012 and 2013 as follows:

Date of Valuation	Estimate of Fair Value	Purpose
October 1, 2012	$ 2.00	Grants of stock-based awards
November 8, 2012	$ 2.00	Grants of stock-based awards
December 18, 2012	$ 1.40	Issuance of common stock in a private transaction
February 27, 2013	$ 1.41	Grants of stock-based awards
September 13, 2013	$ 0.75	Grants of stock-based awards
November 7, 2013	$ 1.00	Grants of stock-based awards

Stock-Based Compensation. We measure compensation cost for stock-based compensation at fair value and recognize compensation over the service period for awards expected to vest. The fair value of each restricted stock award is based on management's estimate of the fair value of our common stock on the date of grant and is recognized as compensation expense using straight-line amortization over the requisite service period. The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes pricing model and is recognized as compensation expense using straight-line amortization over the requisite service period.

Management has estimated the fair value of our stock option awards during 2012 and 2013 as follows:

Date of Valuation	Type of Stock-Based Award Granted	Weighted Average Estimate of Fair Value	Valuation Method
October 1, 2012	Stock option	$ 1.23	Black-Scholes pricing model
November 8, 2012	Stock option	$ 0.87	Black-Scholes pricing model
February 27, 2013	Stock option	$ 0.60	Black-Scholes pricing model
February 27, 2013	Stock option	$ 0.81	Black-Scholes pricing model
September 13, 2013	Stock option	$ 0.45	Black-Scholes pricing model
November 7, 2013	Stock option	$ 0.65	Black-Scholes pricing model

The determination of fair value using the Black-Scholes model requires a number of complex and subjective variables. Key assumptions in the Black-Scholes pricing model include the fair value of common stock, the expected term, expected volatility of the common stock, the risk-free interest rate, and estimated forfeitures. We determined the fair value of our common stock using a variety of factors, discussed above. The expected term is estimated by using the contractual term of the awards and the length of time for the recipient to exercise the awards. Management based expected volatilities on a volatility factor computed based on the historical equity volatilities of the common stock of public comparable firms. The risk-free interest rate was based on the implied yield available at the time the options were granted on U.S. Treasury zero coupon issues with a remaining term equal to the expected term of the option. Estimated forfeitures are based on management's current expectations. The expected dividend yield is 0% for all periods presented, based upon our historical practice of not paying cash dividends on its common stock.

Stock Warrants. We account for warrants that are indexed to our own stock or separately traded, such as our warrants registered in our initial public offering, as a component of equity and record those amounts at estimated fair value computed at the date of grant. Certain other warrants, which were issued prior to our initial public offering, contain complex provisions which require estimates of fair value to appropriately record our potential liabilities. These warrants are treated as a liability and were initially recorded at estimated fair value computed at the date of grant and are adjusted to fair value at each reporting period. The fair value of warrants is derived using the Black-Scholes pricing model. The Company believes that the Black-Scholes pricing model results in a value that is not materially different from the value determined using a binomial pricing model. We review each warrant with complex provisions for triggering events at each reporting period and reclassify warrants from liabilities to stockholders' equity as needed.

Income Taxes. We recognize income taxes under the asset and liability method. As such, deferred taxes are based on temporary differences, if any, between the financial statement and tax bases of assets and liabilities that will result in future taxable or deductible amounts. The deferred taxes are determined using the enacted tax rates that are expected to apply when the temporary differences reverse. Income tax expense is based on taxes payable for the period plus the change during the period in deferred income taxes. Valuation allowances are established when it is more likely than not that the deferred tax assets will not be realized and the deferred tax assets are reduced to the amount expected to be realized.

Tax positions are recognized only when it is more likely than not (likelihood of greater than 50%) that the position would be sustained upon examination based solely on the technical merits of the position. Tax positions that meet the more likely than not threshold are measured using a probability- weighted approach as the largest amount of tax benefit that is greater than 50% likely of being realized upon settlement. We recognize accrued interest and penalties, if any, related to income tax liabilities as a component of income tax expense.

Revenue Recognition. We recognize revenue when evidence of an arrangement exists, title has passed (generally upon shipment) or services have been rendered, the selling price is fixed or determinable and collectability is reasonable assured. When transactions include multiple deliverables, we apply the accounting guidance for multiple element arrangements to determine if those deliverables constitute separate units of accounting. Revenue on arrangements that include multiple elements is allocated to each element based on the relative fair value of each element. Each element's allocated revenue is recognized when the revenue recognition criteria for that element have been met. Multiple element arrangements have not been material through December 31, 2013. When allocating arrangement consideration, fair value is generally determined by objective evidence, which is based on the price charged when each element is sold separately. All costs related to product shipment are recognized at time of shipment and included in cost of revenue. We do not provide for rights of return to customers on product sales.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are not required to provide the information required by this Item because we are a smaller reporting company.

Item 8. Financial Statements and Supplementary Data

LUCID, INC.

FINANCIAL STATEMENT INDEX

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of
Lucid, Inc.
Rochester, New York

We have audited the accompanying balance sheets of Lucid, Inc. (the "Company") as of December 31, 2013 and 2012 and the related statements of operations, changes in stockholders' deficit and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Lucid, Inc. as of December 31, 2013 and 2012, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company's recurring losses from operations, deficit in equity, and projected need to raise additional capital to fund operations raise substantial doubt about its ability to continue as a going concern. Management's plans concerning these matters are also discussed in Note 2 to the financial statements. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Marcum LLP

Boston, Massachusetts

March 12, 2014

LUCID, INC.
BALANCE SHEETS
AS OF DECEMBER 31, 2013 AND 2012

	2013	2012
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 786,509	$ 926,447
Accounts receivable	499,667	559,336
Inventories - net	708,862	926,236
Prepaid expenses and other current assets	291,135	49,155
Total current assets	2,286,173	2,461,174
PROPERTY AND EQUIPMENT – Net	100,783	107,409
DEFERRED FINANCING COSTS – Net	4,906	6,128
OTHER ASSETS	15,893	15,991
TOTAL ASSETS	$ 2,407,755	$ 2,590,702
LIABILITIES AND STOCKHOLDERS' DEFICIT		
CURRENT LIABILITIES:		
Current portion of long-term debt	$ 23,500	$ 379,311
Current portion of notes payable – related party	5,000,000	—
Accounts payable	536,460	955,514
Accrued expenses and other current liabilities	1,720,867	1,515,334
Current portion of deferred revenue	130,119	244,081
Total current liabilities	7,410,946	3,094,240
WARRANT LIABILITY	1,717	61,808
NOTES PAYABLE – RELATED PARTY - Net	6,757,848	6,698,386
OTHER LONG-TERM LIABILITIES	730,515	443,623
TOTAL LIABILITIES	14,901,026	10,298,057
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' DEFICIT:		
Preferred Stock — par value $.05 per share; 10,000,000 authorized; none issued or outstanding	—	—
Common Stock — par value $.01 per share; 60,000,000 authorized; 8,507,374 issued and outstanding on December 31, 2013 and 2012	85,074	85,074
Additional paid-in capital	39,372,962	38,679,627
Accumulated deficit	(51,951,307)	(46,472,056)
TOTAL STOCKHOLDERS' DEFICIT	(12,493,271)	(7,707,355)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$ 2,407,755	$ 2,590,702

See accompanying notes to financial statements.

LUCID, INC.
STATEMENTS OF OPERATIONS
FOR THE YEARS ENDED DECEMBER 31, 2013 AND 2012

	2013	2012
REVENUES:	$ 3,341,253	$ 2,434,585
OPERATING EXPENSES:		
Cost of revenue	2,687,397	2,401,729
General and administrative	2,305,264	4,025,245
Sales and marketing	1,670,041	1,809,434
Engineering, research and development	1,531,245	3,764,816
Total operating expenses	8,193,947	12,001,224
LOSS FROM OPERATIONS	(4,852,694)	(9,566,639)
OTHER (EXPENSE) INCOME:		
Interest expense	(761,231)	(362,069)
Gain (loss) on extinguishment of debt	80,706	(422,435)
Fair value adjustment of warrants	63,034	594,949
Loss on impairment of long-lived assets	—	(50,285)
Other	(9,066)	(14,146)
NET LOSS	$ (5,479,251)	$ (9,820,625)
BASIC AND DILUTED NET LOSS PER COMMON SHARE	$ (0.65)	$ (1.23)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING	8,384,708	7,998,662

See accompanying notes to financial statements.

LUCID, INC.
STATEMENTS OF STOCKHOLDERS' DEFICIT
FOR THE YEARS ENDED DECEMBER 31, 2013 AND 2012

	Common Stock		Additional Paid-In	Accumulated	
	Shares	Amount	Capital	Deficit	Total
BALANCE—Jan. 1, 2012	7,840,477	$ 78,405	35,907,806	$ (36,651,431)	$ (665,220)
Stock-based compensation	—	—	1,795,794	—	1,795,794
Stock option exercises	161,400	1,614	18,806	—	20,420
Issuance of common units	5,300	53	20,204	—	20,257
Issuance of common shares	296,933	2,969	573,899	—	576,868
Forfeiture of restricted stock	(18,500)	(185)	185	—	—
Reclassification of warrants to equity	54,600	546	30,277	—	30,823
Issuance of common stock upon placement of long-term debt, related party	167,164	1,672	332,656	—	334,328
Net loss			—	(9,820,625)	(9,820,625)
BALANCE—Dec. 31, 2012	8,507,374	85,074	38,679,627	(46,472,056)	(7,707,355)
Stock-based compensation	—	—	321,676	—	321,676
Issuance of warrants for services	—	—	374,702	—	374,702
Issuance of warrants in connection with anti-dilution adjustments	—	—	(2,943)	—	(2,943)
Dissolution of subsidiary	—	—	(100)	—	(100)
Net loss	—	—	—	(5,479,251)	(5,479,251)
BALANCE—Dec. 31, 2013	8,507,374	$ 85,074	$ 39,372,962	$ (51,951,307)	$ (12,493,271)

See accompanying notes to financial statements.

LUCID, INC.
STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31, 2013 AND 2012

	2013	2012
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (5,479,251)	$ (9,820,625)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	35,499	41,687
Loss on disposal of fixed assets	—	3,890
Loss on impairment of long-lived assets	—	50,285
Stock-based compensation	321,676	1,795,794
Warrants issued for services	374,702	—
Fair value adjustment of warrants	(63,034)	(594,949)
(Gain) loss on extinguishment of debt	(80,706)	422,435
Accretion of debt discount	59,464	138,640
Change in:		
Accounts receivable	59,670	(169,442)
Inventories	217,374	(196,361)
Prepaid expenses and other current assets	(241,980)	33,677
Other assets	—	(2,167)
Accounts payable	(419,054)	(438,249)
Accrued expenses and other current liabilities	205,533	352,955
Other liabilities	172,927	677,765
Net cash used in operating activities	(4,837,180)	(7,704,665)
CASH FLOWS FROM INVESTING ACTIVITIES – Purchases of property and equipment	(27,652)	(79,493)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Borrowings on notes payable – related parties	5,000,000	6,652,284
Repayments of debt	(275,106)	(3,448,078)
Loan acquisition costs	—	(64,747)
Issuance of common units	—	20,257
Issuance of common stock	—	654,748
Net cash provided by financing activities	4,724,894	3,814,464
NET DECREASE IN CASH	(139,938)	(3,969,694)
CASH – Beginning of year	926,447	4,896,141
CASH – End of year	$ 786,509	$ 926,447
SUPPLEMENTAL CASH FLOW DATA – Cash paid for interest	$ —	$ 62,939
SUPPLEMENTAL SCHEDULE OF NONCASH INVESTING AND FINANCING ACTIVITIES:		
Issuance of warrants in connection with anti-dilution adjustments	$ 2,943	$ —
Refinance of loan acquisition costs with note payable	$ —	$ 26,162
Refinance of debt discount with note payable	$ —	$ 36,633

See accompanying notes to financial statements.

1. NATURE OF OPERATIONS

Lucid, Inc., operating as Caliber Imaging & Diagnostics, or Caliber I.D., (the "Company" or "Lucid"), is a medical device company that develops, manufactures, markets and sells point-of-care cellular imaging systems. The Company's patented and FDA-cleared VivaScope® technology provides physicians with real-time images of the epidermis and superficial dermis of the skin, as well as other epithelial tissues at a cellular level that can be interpreted by the physician at the bedside and/or transferred securely to a pathologist on VivaNet®, the Company's HIPAA-compliant private telepathology network for remote diagnosis. With sensitivity and specificity that can rival the current "gold standard", clinical histopathology, but without all of the associated costs of a traditional biopsy, the Company's platform imaging technology has the potential to significantly improve patient outcomes while simultaneously reducing costs. The Company sells its products in the United States and numerous foreign countries and is headquartered in Rochester, New York.

As a cost-saving measure, in January 2013, the Company dissolved its wholly-owned subsidiary Lucid International, Inc. The dissolution of Lucid International, Inc. did not have a significant impact on the Company's financial position or results of operations. All information regarding periods prior to January 2013 were presented on a consolidated basis.

2. LIQUIDITY, CAPITAL RESOURCES AND MANAGEMENT PLANS

As of December 31, 2013, the Company had cash and cash equivalents of $0.8 million and a working capital deficit of $5.1 million. In 2013, cash used in operating activities totaled $4.8 million. As a result of its limited cash resources and working capital deficit, the Company is delinquent in paying a number of its creditors. Unless the Company obtains additional financing in the coming months, it will need to substantially curtail operations and may be unable to continue its business.

The Company engaged H.C. Wainwright & Co., LLC ("H.C. Wainwright") in August 2013 to identify, originate and develop potential strategic partnerships, assist in merger and acquisition transactions and to raise capital. The Company terminated its engagement with H.C. Wainwright in March 2014 and hired R.F. Lafferty & Co., Inc. ("Lafferty") to provide general investment banking services. See Note 17 - Subsequent Events for further information.

The Company anticipates to continue to generate losses for at least the next year as it develops and expands its products and offerings and seek to commercialize its products and expand its corporate infrastructure. The Company will continue to require significant amounts of additional capital to fund its operations, and such capital may not be available when it needs it on terms that it finds favorable, if at all. The Company is seeking to raise these funds as described above, though it may seek additional debt financings, credit facilities, partnering or other corporate collaborations and licensing arrangements. If adequate funds are not available or are not available on acceptable terms, the Company's ability to fund its operations, take advantage of opportunities, develop products and technologies, and otherwise respond to competitive pressures could be significantly delayed or limited, and the Company may need to downsize or halt its operations. Prevailing market conditions may not allow for such a fundraising or new investors may not be prepared to purchase the Company's securities at prices that are greater than the current market price.

There can be no assurance that the Company will be successful in attracting alternative debt or equity financing. These conditions raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates—The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expenses during the reporting period. On an ongoing basis, the Company evaluates its estimates, including those related to revenue recognition, allowances for doubtful accounts, inventories, impairment of long-lived assets, accrued expenses, income taxes including the valuation allowance for deferred tax assets, valuation of warrants, and stock-based compensation. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Due to the inherent uncertainty involved in making estimates, actual results reported in future periods may differ from those estimates.

Revenue Recognition—The Company recognizes revenue when evidence of an arrangement exists, title has passed (generally upon shipment) or services have been rendered, the selling price is fixed or determinable and collectability is reasonable assured. When transactions include multiple deliverables, the Company applies the accounting guidance for multiple element arrangements to determine if those deliverables constitute separate units of accounting. Revenue on arrangements that include multiple elements is allocated to each element based on the relative fair value of each element. Each element's allocated revenue is recognized when the revenue recognition criteria for that element have been met. Multiple element arrangements have not been material through December 31, 2013. When allocating arrangement consideration, fair value is generally determined by objective evidence, which is based on the price charged when each element is sold separately.

All costs related to product shipment are recognized at time of shipment and included in cost of revenue. The Company does not provide for rights of return to customers on product sales. Certain direct sales contracts require installation at the customer's location prior to acceptance. As such, revenue recognition on these contracts is typically delayed until all aspects of delivery, including installation, are complete. In addition, should the contract include training, revenue recognition is delayed until training is complete.

Product Warranty—Medical devices sold are covered by a warranty for up to two years, for which estimated contractual warranty obligations are recorded as an expense at the time of shipment.

Concentrations of Credit Risk—Financial instruments that subject the Company to concentrations of credit risk consist primarily of cash and accounts receivable. The Company maintains its cash in demand deposit and money market accounts at financial institutions. The cash balances are insured by the FDIC up to $250,000 per depositor with unlimited insurance for funds in noninterest-bearing transaction accounts through December 31, 2013. At times, the amounts in these accounts may exceed the federally insured limits. The Company has not experienced any losses in these accounts and believes it is not exposed to any significant credit risk with respect to cash.

The Company provides credit in the normal course of business to the majority of its customers. Accounts for which no payments have been received for several months are considered delinquent and customary collection efforts are initiated. After all collection efforts are exhausted the account is written-off. Allowance for doubtful accounts is based on estimates of probable losses related to accounts receivable balances. At December 31, 2013 and 2012, management has determined that no allowance is required.

For the year ended December 31, 2013, the Company had sales of approximately $1.4 million and $0.5 million to two distributors, respectively. These two distributors accounted for 42% and 15%, respectively, of the Company's revenues in 2013. For the year ended December 31, 2013, the Company had $0.4 million of accounts receivable related to two distributors and two customers, representing 84% of the Company's total accounts receivable.

Cash and Cash Equivalents—The Company defines cash and cash equivalents as money market funds and other highly liquid investments with original maturities of 90 days or less. Cash and cash equivalents are stated at cost, which approximates fair value. Cash equivalents are subject to credit risk and are primarily maintained in a money market fund.

Inventories—Inventories are stated at the lower of cost, determined on a first-in, first-out (FIFO) method, or market. Excess, obsolete or expired inventory are adjusted to net realizable value, based primarily on how long the inventory has been held as well as the Company's estimate of forecasted net sales of that product. A significant change in the timing or level of demand for our products may result in recording additional adjustments to the net realizable value of excess, obsolete or expired inventory in the future.

Property and Equipment—Property and equipment is stated at cost, less accumulated depreciation. Repairs and maintenance are expensed as incurred. Depreciation is computed using the straight-line method over the estimated useful lives of the related assets as follows:

Computer hardware and software	2 - 3 years
Furniture and fixtures	5 years
Machinery and equipment	2 - 5 years
Office equipment	5 years
Vehicle	5 years

Impairment of Long-Lived Assets—The Company assesses the impairment of definite lived assets when events or changes in circumstances indicate that the carrying value of the assets may not be recoverable. Factors that are considered in deciding when to perform an impairment review include significant under-performance of a business or product line in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in the use of the assets.

Recoverability potential is measured by comparing the carrying amount of the asset group to the asset group's related total future undiscounted cash flows. If an asset group's carrying value is not recoverable through its related cash flows, the asset group is considered to be impaired. Impairment is measured by comparing the asset group's carrying amount to its fair value.

When it is determined that useful lives of assets are shorter than originally estimated, and there are sufficient cash flows to support the carrying value of the assets, the rate of depreciation is accelerated in order to fully depreciate the assets over their new shorter useful lives. The Company recognized an impairment loss on long-lived assets of approximately $50,000 in 2012 and no impairment losses in 2013.

Deferred Financing Costs, Net—Deferred financing costs, net, represents amounts incurred in connection with the Company's 2013 Term Loan and 2012 Term Loan. These amounts are amortized over the period from the date of issuance to the contractual maturity date or conversion date if earlier. The Company expensed deferred fees of approximately $1,000 and $8,000 for the years ended December 31, 2013 and 2012, respectively, which are included in depreciation and amortization in the statement of cash flows, and as interest expense within the statement of operations.

Fair Value Measurements—Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (i.e. the "exit price") in an orderly transaction between market participants at the measurement date. The guidance establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the assets or liability developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the assumptions market participants would use in pricing the asset or liability developed based on the best information available in the circumstances. The hierarchy is broken down into three levels based on the reliability of inputs as follows:

Level 1—Valuations based on quoted prices in active markets for identical assets or liabilities that the Company has the ability to access. Since valuations are based on quoted prices that are readily and regularly available in an active market, valuation of these products does not entail a significant degree of judgment.

Level 2—Valuation is determined from quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar instruments in markets that are not active or by model-based techniques in which all significant inputs are observable in the market.

Level 3—Valuations based on inputs that are unobservable and significant to the overall fair value measurement. The degree of judgment exercised in determining fair value is greatest for instruments categorized in Level 3.

The availability of observable inputs can vary and is affected by a wide variety of factors, including, the type of asset/liability, whether the asset/liability is established in the marketplace, and other characteristics particular to the transaction. To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy.

In such cases, for disclosure purposes the appropriate level in the fair value hierarchy is determined based on the lowest level input that is significant to the fair value measurement in its entirety.

Fair value is a market-based measure considered from the perspective of a market participant rather than an entity-specific measure. Therefore, even when market assumptions are not readily available, assumptions are required to reflect those that market participants would use in pricing the asset or liability at the measurement date.

The Company's cash equivalents are classified as Level I because they are valued using quoted market prices.

The Company considers warrants that are not indexed to the Company's own stock to be classified as Level 3. The following table presents the change in Level 3 liabilities:

	2013	2012
Balance at January 1	$ 61,808	$ 687,580
Warrants issued for anti-dilution adjustment	2,943	—
Reclassification to equity	—	(30,823)
Fair value adjustment	(63,034)	(594,949)
Balance at December 31	$ 1,717	$ 61,808

The fair value of these warrants is derived using the Black-Scholes pricing model using the same assumptions and methodology utilized in the valuation of common stock options described below. (See Note 13-Equity for assumptions used to value warrants.)

The Company's financial instruments consist principally of accounts receivable, accounts payable and debt. The Company believes the recorded values for accounts receivable and accounts payable approximate current values as of December 31, 2013 because of their nature and respective durations. Management estimates the carrying value of its debt instruments approximates fair value as of December 31, 2013. This estimate is based on acceptable valuation methodologies which use market data of similarly sized and situated debt issuers.

Engineering, Research and Development Costs—Engineering, research and development costs are expensed as incurred.

Stock-Based Compensation Plans—The Company measures compensation cost for stock awards at fair value and recognizes compensation over the service period for awards expected to vest. The fair value of each option grant is estimated on the date of grant using the Black-Scholes pricing model and straight-line amortization of compensation expense over the requisite service period of the grant. The determination of fair value using the Black-Scholes model requires a number of complex and subjective variables. Key assumptions in the Black-Scholes pricing model include the fair value of common stock, the expected term, expected volatility of the common stock, the risk-free interest rate, and estimated forfeitures. Management determined the fair value of the Company's common stock largely on recent trading history and volumes on the OTCQB. The expected term is estimated by using the contractual term of the awards and the length of time for the recipient to exercise the awards. Management based expected volatilities on a volatility factor computed based on the historical equity volatilities of the common stock of public comparable firms. The risk-free interest rate was based on the implied yield available at the time the options were granted on U.S. Treasury zero coupon issues with a remaining term equal to the expected term of the option. Estimated forfeitures are based on management's current expectations. The expected dividend yield is 0% for all periods presented, based upon the Company's historical practice of not paying cash dividends on its common stock.

Warrants—The Company accounts for warrants issued that are indexed to the Company's own stock as a component of equity and records the warrants at estimated fair value computed at the date of grant. Warrants issued that are not indexed to the Company's own stock are treated as a liability and are initially recorded at estimated fair value computed at the date of grant. This liability is adjusted to fair value at each period presented. The fair value of warrants is derived using the Black-Scholes pricing model. The Company believes that the Black-Scholes pricing model results in a value that is not materially different from the value determined using a binomial pricing model.

Debt—When common stock has been issued together with debt, the Company allocates the proceeds between the debt and common stock based on the relative fair value of each financial instrument, resulting in a debt discount to be amortized to interest expense over the term of the debt.

Income Taxes—Income taxes are provided for the tax effects of transactions reported in the financial statements and consist of taxes currently due and deferred taxes related primarily to differences between the financial statement and tax basis of assets and liabilities and operating loss and tax credit carryforwards measured by the enacted tax rates that are anticipated to be in effect in the respective jurisdiction when those differences reverse. The deferred tax provision generally represents the net change in the deferred tax assets and liabilities. A valuation allowance is established when it is necessary to reduce deferred tax assets to amounts that more likely than not will be realized.

The Company accounts for uncertain tax positions in accordance with Accounting Standards Codification (ASC) Topic 740 – *Income Taxes*. As such, tax positions are recognized only when it is more likely than not (likelihood of greater than 50%) that the position would be sustained upon examination based solely on the technical merits of the position. Tax positions that meet the more likely than not threshold are measured using a probability-weighted approach as the largest amount of tax benefit that is greater than 50% likely of being realized upon settlement. The Company recognizes accrued interest and penalties related to income tax liabilities as a component of income tax expense.

Net Loss Per Common Share—Basic net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the reporting period. Diluted net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted-average number of dilutive common shares outstanding during the period. Dilutive common shares outstanding are calculated by adding to the weighted average number of common shares outstanding any potential (unissued) shares of common stock assuming conversion, exercise or issuance from the Company's outstanding warrants, stock options and restricted stock. Since the Company reported a net loss attributable to common stockholders in the years ended December 31, 2013 and 2012, all potential common stock are excluded from the calculation because they would have an anti-dilutive effect, meaning the loss per common share would be reduced. Therefore, in periods when a loss is reported, the calculation of basic and dilutive loss per common share results in the same value. The Company's nonvested restricted stockholders have the right to participate with common stockholders in dividends and unallocated earnings. Net losses are not allocated to the nonvested restricted stockholders. Therefore, when applicable, basic and diluted earnings per share are computed using the two-class method, under which the Company's undistributed earnings are allocated to the common and vested restricted stockholders.

Recently Issued Accounting Pronouncements—In the normal course of business, Management evaluates all new accounting pronouncements issued by the Financial Accounting Standards Board, Securities and Exchange Commission, Emerging Issues Task Force, American Institute of Certified Public Accountants and other authoritative accounting bodies to determine the potential impact they may have on the Company's Financial statements. Based upon this review, Management does not expect any of the recently issued accounting pronouncements to have a material impact on the Company's financial statements.

Reclassifications—Certain immaterial reclassification adjustments have been made to the prior year financial statements to reclassify certain operating costs from General and administrative and Sales and marketing to Engineering, research and development in the accompanying statements of operations to conform to the current year presentation.

4. INVENTORIES

The components of inventories are as follows at December 31:

	2013	2012
Raw materials	$ 426,996	$ 659,149
Finished goods	288,068	334,026
Offsite demo equipment	125,669	96,566
Less inventory reserve	(131,871)	(163,505)
	$ 708,862	$ 926,236

Offsite demo equipment represents the cost of products physically located at customer locations, during an orientation period for which the Company retains title. As such, no depreciation expense has been recorded on these units. The Inventory reserve at December 31, 2013 includes amounts necessary to adjust the Company's inventory and offsite demo equipment to net realizable value following the Company's release of newly redesigned products in 2013.

5. PREPAID EXPENSES AND OTHER CURRENT ASSETS

The components of prepaid expenses and other current liabilities are as follows at December 31:

	2013	2012
Prepaid inventory	$ 168,768	$ 195
Other current assets	88,342	—
Prepaid expenses	34,025	48,960
	$ 291,135	$ 49,155

6. PROPERTY AND EQUIPMENT

Property and equipment consists of the following at December 31:

	2013	2012
Machinery and equipment	$ 402,889	$ 407,039
Computer hardware and software	100,245	89,971
Leasehold improvements	46,891	46,891
Furniture and fixtures	29,484	29,484
Vehicle	18,680	18,680
Office equipment	3,869	3,869
	602,058	595,934
Less accumulated depreciation and amortization	(501,275)	(488,525)
	$ 100,783	$ 107,409

Depreciation expense totaled approximately $34,000 and $33,000 for the years ended December 31, 2013 and 2012, respectively.

7. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consisted of the following at December 31:

	2013	2012
Compensation and benefits	$ 679,556	$ 635,039
Interest – related party	240,958	265,719
Product warranty liability	384,126	263,000
Other accrued expenses	259,206	211,130
Customer deposits	105,816	79,384
Rent	41,705	39,674
Professional fees	9,500	21,388
	$ 1,720,867	$ 1,515,334

In 2012, the Company and certain officers of the Company mutually agreed to terminate their employment relationships. At December 31, 2013 and 2012, the remaining severance was $0.6 million and $0.4 million, respectively, which is included in "Compensation and benefits" in the table above for the current portion of these liabilities.

Customer deposits represent advances paid to the Company by customers for the purchase of equipment.

8. NOTES PAYABLE—RELATED PARTIES

In July 2012, the Company borrowed $7.0 million from an affiliate of the Company pursuant to a Loan and Security Agreement (the "2012 Term Loan"). On October 7, 2013, the Company entered into a letter agreement modifying the 2012 Term Loan by (i) extending the maturity date by three years to July 5, 2020, (ii) providing that interest will be payable only on maturity, and (iii) providing that the events of default will only be nonpayment at maturity or the Company's insolvency (the "Modification"). The 2012 Term Loan refinanced a previous loan, may be prepaid at any time subject to certain notice requirements, bears interest at a rate of 7% per annum and is secured by all of the Company's assets. The Company had recorded accrued interest of $0.7 million and $0.3 million at December 31, 2013 and 2012, respectively, in connection with the 2012 Term Loan. As a result of the Modification, accrued interest on the 2012 Term Loan was classified as long-term at December 31, 2013 and is included in Other Long-Term Liabilities on the Company's financial statements. In connection with the closing of the 2012 Term Loan, the Company issued 167,164 shares of the Company's common stock to the affiliate. The Company allocated the debt proceeds between the debt and common stock based on the relative fair value of each financial instrument, resulting in a debt discount of $0.3 million which is being amortized to interest expense over the term of the loan. Debt discount was $(0.2) million and $(0.3) million at December 31, 2013 and 2012, respectively, and is included in Notes Payable – Related Party – net.

The 2012 Term Loan contains customary affirmative and negative covenants, including covenants restricting the incurrence of debt, imposition of liens, the payment of dividends, and entering into affiliate transactions. At December 31, 2013 the Company was in compliance with all covenants. The 2012 Term Loan, as modified by the Modification contains events of default consisting of nonpayment at maturity and the Company's insolvency. If an event of default occurs and is continuing under the 2012 Term Loan, the entire outstanding balance may become immediately due and payable.

In May 2013, the Company borrowed an additional $5.0 million from the same affiliate of the Company under the 2013 Term Loan. The 2013 Term Loan matures in November 2014 and may be prepaid at any time. The 2013 Term Loan bears interest at a rate of 7% per annum, payable upon maturity and is secured by all of the Company's assets. The Company had recorded accrued interest of approximately $0.2 million at December 31, 2013 in connection with the 2013 Term Loan. The 2013 Term Loan includes cross default provisions with the existing 2012 Term Loan. On October 7, 2013, the Company entered into a letter agreement with the holder of the 2013 Term Loan pursuant to which the holder agreed that upon closing of an offering by the Company in which it raises at least $6 million, all outstanding amounts of principal and interest under the 2013 Term Loan will convert into the Company's common stock on the same terms as such shares sold to other investors in the offering. In exchange for this recapitalization, upon closing, the Company will issue to the holder warrants to purchase 150,000 shares of the Company's common stock at an exercise price equal to the higher of $1.00 per share or the price paid by the other investors in this offering.

Interest expense on Notes Payable – Related Party totaled $0.7 million and $0.3 million for the years ended December 31, 2013 and 2012, respectively. Debt discount amortization of $0.1 million and approximately $33,000 was charged to interest expense for the years ended December 31, 2013 and 2012, respectively.

9. DEBT

As of December 31, 2012, promissory notes outstanding totaled $0.4 million on two notes which do not accrue interest. In May 2013, the outstanding balance of one of the promissory notes was settled in full, resulting in a gain on extinguishment of debt of approximately $81,000 for the year ended December 31, 2013.

As of December 31, 2013 the remaining promissory note totaled approximately $24,000 and was classified as a current liability.

10. INCOME TAXES

Because the Company has incurred net losses, and has provided a full valuation allowance against deferred tax assets, its tax provision is zero for the years ended December 31, 2013 and 2012.

The differences between income taxes computed using the statutory U.S. federal income tax rate and the provision (benefit) for income taxes were as follows:

	2013	2012
Pre-tax net loss	$ (5,479,251)	$ (9,820,625)
Amount computed using the Statutory U.S. federal rate	$ (1,862,946)	$ (3,339,012)
State taxes – net of federal benefit	(364,605)	—
Increase (reduction) in taxes resulting from valuation allowance	1,942,560	3,186,987
Fair value adjustment of warrants	(21,432)	(202,283)
Interest on debt treated as equity	20,217	13,284
Stock-based compensation—ISO	39,056	131,221
Warrants	127,399	—
Other	119,751	209,803
Provision (benefit) for income taxes	$ —	$ —

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and liabilities as of December 31, 2013 and 2012 are as follows:

	2013	2012
Current deferred tax asset:		
Compensation Reserves	$ 203,937	$ 302,196
Deferred revenue	—	—
Prepaid fees	47,565	56,523
Warranty reserve	134,482	89,420
Other	46,190	55,613
	432,174	503,752
Valuation allowance	(432,174)	(503,752)
Net current deferred tax asset	$ —	$ —
Noncurrent deferred tax asset:		
Stock based compensation	1,733,564	1,613,248
Net operating loss	10,464,281	8,580,265
Other	10,949	1,143
	12,208,794	10,194,656
Valuation allowance	(12,208,794)	(10,194,656)
Net noncurrent deferred tax asset	$ —	$ —
Total	$ —	$ —

The Company has performed the required assessment of positive and negative evidence regarding the realization of deferred tax assets. This assessment included the evaluation of scheduled reversals of deferred income tax assets and liabilities, estimates of projected future taxable income and tax planning strategies.

In assessing the realizability of deferred tax assets, the Company considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Based on the Company's historical net losses, management does not believe that it is more likely than not that the Company will realize the benefits of these deferred tax assets and, accordingly, a full valuation allowance has been recorded against the deferred tax assets as of December 31, 2013 and 2012.

As a result of certain realization requirements of ASC Topic 718, *Compensation—Stock Compensation*, the Company's deferred tax assets at December 31, 2013 do not include approximately $0.5 million of excess tax benefits from the exercise of nonqualified options that are a component of the Company's NOL carryovers. Equity will be increased by approximately $0.2 million if and when such deferred tax assets are ultimately realized for federal income tax purposes. The Company uses ordering pursuant to ASC Topic 740, *Income Taxes*, for purposes of determining when excess tax benefits have been realized.

The Company has federal and state net operating loss carryforwards of approximately $30 million to offset future taxable income which expire between 2014 and 2034. The Company has undergone several equity transactions which may have resulted in an ownership change or changes as defined by Internal Revenue Code Sec. 382. If an ownership change occurred, the use of the Company's net operating losses (NOLs) may be limited. Because of the Company's current tax loss position, the Company's NOLs are not being utilized at this time. The Company will determine whether or not an ownership change has occurred under IRC Sec. 382 before utilizing its NOLs in the future. Also, any future equity raise by the Company may result in an ownership change which would also need to be analyzed under IRC Sec. 382.

As discussed in Note 3, the Company accounts for uncertain tax positions in accordance with ASC Topic 740. The amount of unrecognized tax benefits for uncertain tax positions as of December 31, 2013, was insignificant. Amounts related to uncertain tax positions that may change within the next 12 months are not expected to be material.

The Company files income tax returns with the U.S. government and various states. The Company is not presently under audit by the Internal Revenue Service or any state. The Company's tax matters for 2006 through 2012 remain subject to examination by the respective federal and state tax authorities.

11. NET LOSS PER COMMON SHARE DATA

The following table sets forth the computation of basic and diluted net loss attributable to common stockholders per common share, as well as a reconciliation of the numerator and denominator used in the computation:

	Year Ended December 31,	
	2013	2012
Net loss	$ (5,479,251)	$ (9,820,625)
Weighted-average common shares outstanding	8,384,708	7,998,662
Basic and diluted net loss per common share	$ (0.65)	$ (1.23)

The following equivalent shares were excluded from the calculation of diluted loss per share as their impact would have been anti-dilutive:

	Year Ended December 31,	
	2013	2012
Options to purchase common stock	3,511,000	625,000
Warrants	4,280,553	1,981,661
Restricted stock	122,666	122,666

12. COMMITMENTS AND CONTINGENCIES

Leases **–** Rent expense was approximately $0.3 million for the years ended December 31, 2013 and 2012, under the terms of the Company's lease agreements. Minimum future lease payments are as follows at December 31, 2013:

2014	$ 134,513
2015	97,600
2016	99,552
2017	101,543
2018	103,574
Thereafter	231,422
	$ 768,204

Minimum future lease payments in the chart above include a new lease agreement executed in March 2014 for the Company's principal executive office which replaced a previous lease for the Company's former principal executive office.

Product Warranty – Changes in the product warranty accrual for the year ended December 31, 2013 and 2012 were as follows:

	Year Ended December 31,	
	2013	2012
Product warranty liability at beginning of period	$ 263,000	$ 140,000
Additions to warranty accrual (including changes in estimates)	269,211	385,625
Warranty expenses during the period	(148,085)	(262,625)
Product warranty liability at end of period	$ 384,126	$ 263,000

Legal Proceedings – The Company is not currently subject to any material legal proceedings, nor, to its knowledge, is any material legal proceeding threatened against it. From time to time, the Company may be a party to certain legal proceedings, incidental to the normal course of business. While the outcome of these legal proceedings cannot be predicted with certainty, the Company does not expect that these proceedings will have a material effect upon its financial condition or results of operations.

13. EQUITY

Common Stock **–** The holders of our common stock are entitled to one vote for each share standing in the holder's name,and holders vote together as a single class on all matters requiring the vote of the stockholders. Common stock holders have no preemptive, subscription or redemption rights. Subject to law and the provisions of our Certificate of Incorporation, our Board of Directors may declare dividends on our stock, payable upon such dates as the Board of Directors may designate. No dividend may be paid on common stock unless all declared but unpaid dividends, if any, on the Preferred Stock have been paid. Under Section 510 of the New York Business Corporation Law ("NYBCL"), the net assets of the corporation upon declaration or distribution of a dividend must remain at least equal to the amount of the corporation's stated capital.

As part of a restructuring of the board of directors of the Company, five members resigned in February 2012. As a result, the individuals forfeited 18,500 shares of unvested restricted stock, in aggregate.

In December 2012, the Company's Chairman and his spouse purchased 214,286 shares of common stock in a private transaction with the Company at a price of $1.40 per share.

Stock-Based Awards—In July 2012, the Board of Directors adopted, subject to stockholder approval at the next stockholder meeting, the 2012 Stock Option and Incentive Plan ("the 2012 Plan"). If approved by the stockholders, 1,775,000 shares of common stock will be available for issuance upon the grant or exercise of awards under the 2012 Plan. The 2012 Plan has a ten-year term and provides flexibility to the Executive Compensation Committee to use various equity-based incentive awards, including stock options (both incentive and non-qualified options), stock appreciation rights, restricted stock, restricted stock units, unrestricted stock, performance shares, dividend equivalent rights and cash-based awards, as compensation tools to motivate the Company's workforce. The maximum number of shares of common stock to be issued under the 2012 Plan is 2,030,221, which includes an additional 255,221 shares of common stock available for issuance upon grant or exercise of awards. The additional shares was based on January 1, 2013 and each January 1 thereafter, a number of shares of common stock equal to 3 percent of the number of shares of common stock outstanding on the prior December 31. The shares of common stock underlying any awards that are forfeited, canceled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without any issuance of stock, expire or are otherwise terminated (other than by exercise) under the 2012 Plan are added back to the shares of common stock available for issuance under the 2012 Incentive Plan. As of December 31, 2013, there were options for the purchase of up to 1,770,500 shares outstanding under the 2012 Plan, leaving 259,721 shares reserved for future grants.

In June of 2010, the Company's stockholders approved a Stock Option Plan (the 2010 Plan), pursuant to which options including incentive and nonqualified options for its common stock and shares of restricted stock may be granted to employees, directors and consultants of the Company. The 2010 Plan also allows for stock awards to be granted a right to receive shares of stock in the future. The Company reserved 2,000,000 common shares for the 2010 Plan and at December 31, 2012, there were 501,000 shares reserved for future grants and 1,480,500 stock options outstanding. Under the terms of the awards, stock-based awards generally have 10-year contractual terms, equity grants for employees generally vest based on three years of continuous service and equity grants for directors and consultants vest over their respective remaining term as of the date of grant. The Company does not capitalize any expense related to the stock option awards.

The Company also has options and restricted stock outstanding under a Stock Option Plan approved by stockholders during 2007 (the 2007 Plan) and options to purchase common shares outstanding under a Stock Option Plan approved by stockholders during 2000 (the 2000 Plan). Under the terms of the awards under these two plans, equity grants for employees generally vest based on three years of continuous service and equity grants for directors and consultants vest over their respective remaining term as of the date of grant. As of December 31, 2013, options to purchase common shares of 102,500 and 157,500 were outstanding under the 2007 Plan and the 2000 Plan, respectively, with an additional 137,500 shares of restricted stock outstanding under the 2007 Plan. As of December 31, 2013, no shares were reserved for future grants under the 2007 Plan or the 2000 Plan.

On September 30, 2012, certain employees and directors of the Company voluntarily forfeited an aggregate of 625,000 stock options with a weighted average exercise price of $7.48. In October 2012, the Company issued approximately 55,000 shares of common stock (at a value of $2.00 per share) in an equal exchange for approximately 234,000 common stock warrants. The value of the exchanged warrants was determined using the Black-Scholes pricing model, with an assumed common stock value of $2.00 per share.

The Company recognizes the expense related to stock option awards on a straight-line basis over the service period. Stock-based compensation expense recognized in the statement of operations is as follows:

	Year Ended December 31,	
	2013	2012
Cost of revenue	$ 8,293	$ 13,698
General and administrative	184,539	979,547
Sales and marketing	31,663	88,282
Engineering, research and development	97,181	714,267
	$ 321,676	$ 1,795,794

A summary of option activity under the Plans and changes during the periods ended are presented below:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2012	2,201,774	$ 5.78		
Granted	317,500	2.00		
Exercised	(161,400)	0.13		
Forfeited or expired	(1,732,874)	6.51		
Outstanding at December 31, 2012	625,000	$ 3.32		
Granted	2,919,500	1.01		
Exercised	—	—		
Forfeited or expired	(33,500)	3.89		
Outstanding at December 31, 2013	3,511,000	$ 1.39	8.8 years	$ —
Vested or expected to vest at December 31, 2013	3,440,780	$ 1.39	8.8 years	$ —
Exercisable at December 31, 2013	523,333	$ 3.38	4.1 years	$ —

There were no stock options exercised during the year ended December 31, 2013. The total intrinsic value of stock options exercised during the year ended December 31, 2012 was approximately $0.2 million.

The following table summarizes information about stock options outstanding and exercisable at December 31, 2013:

	Options Outstanding			Options Exercisable		
Exercise Price ($)	Number of Options	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number of Options	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price
1.00 – 1.41	2,918,500	9.7 years	$ 1.01	—	—	$ —
2.00 - 2.50	315,000	4.5 years	$ 2.00	251,666	4.4 years	$ 2.00
4.00 - 4.30	220,000	3.1 years	$ 4.09	220,000	3.1 years	$ 4.09
6.58	40,000	6.5 years	$ 6.58	40,000	6.5 years	$ 6.58
8.60 - 8.88	17,500	7.5 years	$ 8.66	11,667	7.5 years	$ 8.66
	3,511,000			523,333		

The weighted-average grant date fair value of options granted during the year ended December 31, 2013 and 2012 was $0.46 and $2.00, respectively. The following assumptions were used to estimate the grant date fair value of options granted using the Black-Scholes option pricing model.

	2013	2012
Risk free interest rate	0.31% - 1.86%	0.31% - 0.94%
Expected dividend yield	0%	0%
Expected term (in years)	2.5 – 6.5	2.5 – 6.5
Expected volatility	70%	70%
Pre-vesting forfeiture rate	2%	2%

As of December 31, 2013 there was $1.3 million of total unrecognized compensation cost related to stock option arrangements granted under the Company's plans. As of December 31, 2013, the unrecognized cost is expected to be recognized over a weighted average period of 9.5 years.

The Company determines fair value of its restricted stock based on the common stock value on the date of grant. The following table summarizes the Company's restricted stock activity:

	Number of Shares	Weighted-Average Fair Value
Nonvested at January 1, 2012	191,166	$ 8.16
Granted	—	$ —
Vested	(50,000)	$ 7.62
Forfeited	(18,500)	$ 8.41
Nonvested at December 31, 2012	122,666	$ 8.34
Granted	—	$ —
Vested	—	$ —
Forfeited	—	$ —
Nonvested at December 31, 2013	122,666	$ 8.34

There was no intrinsic value of nonvested restricted stock as of December 31, 2013 and 2012. At December 31, 2013 there was approximately $0.1 million of total unrecognized compensation cost related to restricted stock granted under the Plan. As of December 31, 2013, the unrecognized cost is expected to be recognized over a weighted average period of 1.2 years. As of December 31, 2013, the Company had 137,500 shares of restricted stock outstanding.

Warrants **-** At December 31, 2013, there were warrants to purchase up to 4,280,553 shares of the Company's common stock outstanding at a weighted average exercise price of $3.17.

In September 2013, the Company issued to a financial advisor common stock warrants to purchase up to 2,125,000 shares of the Company's common stock, at an exercise price of $1.00 per share. These warrants expire in February 2019. The estimated fair value was computed using the Black-Scholes option pricing model with the following assumptions: an expected term of 5.5 years; a risk-free interest rate of 1.55%; a dividend yield of zero; and expected volatility of 70%. A portion of the warrant's estimated fair value of $0.4 million was charged to general and administrative expenses during the third quarter of 2013 at which time one-third of the warrants became exercisable and non-forfeitable, in accordance with Accounting Standards Codification ("ASC") 505-50 "Equity-Based Payments to Non-Employees." The remaining unvested two-thirds of the warrants were forfeited and returned to the Company in March 2014, when the Company terminated its engagement with the advisor. See Note 17 – Subsequent Events for further information..

In December, 2013 the Company issued to a public relations firm common stock warrants to purchase up to 42,500 shares of the Company's common stock, at an exercise price of $1.00 per share. These warrants expire in August 2016. The estimated fair value was computed using the Black-Scholes option pricing model with the following assumptions: an expected term of 2.50 years; a risk-free interest rate of 0.58%; a dividend yield of zero; and expected volatility of 70%. A portion of the warrant's estimated fair value of approximately $2,000 was charged to general and administrative expenses during the year ended December 31, 2013. The warrants vest monthly during the term of the contract which expires in August 2014 at which time the warrants became exercisable and non-forfeitable, in accordance with Accounting Standards Codification ("ASC") 505-50 "Equity-Based Payments to Non-Employees."

During 2013, the Company issued warrants to purchase 132,583 shares of common stock as a result of anti-dilution adjustments triggered by the issuances of shares of common stock and warrants. The value at the date of issuance of $2,943 was recorded to reflect these additional warrants.

In October 2013, the holder of the 2013 Term Loan agreed that contingent upon the closing of an offering of at least $6.0 million to convert the 2013 Term Loan into the Company's common stock on the same terms as such shares are sold to other investors in the offering. In exchange for this recapitalization, upon such closing, the Company will issue to the holder of the 2013 Term Loan warrants to purchase 150,000 shares of the Company's common stock at an exercise price equal to the higher of $1.00 per share or the price paid by the other investors in an offering.

Under the terms of various agreements, the Company has issued warrants for the purchase of common shares. Warrants are exercisable at the grant date and generally expire 5 to 10 years from the date of the grant.

Changes in the status of outstanding warrants are summarized as follows:

	Warrants	Warrants Weighted-Average Exercise Price
Outstanding at January 1, 2012	2,219,546	$ 5.84
Issued	5,300	$ 5.04
Exercised	—	$ —
Expired	(9,166)	$ 6.30
Conversion to Common Stock	(234,019)	$ 6.77
Outstanding at January 1, 2013	1,981,661	$ 5.75
Issued	2,167,500	$ 1.00
Exercised	—	$ —
Expired	(1,191)	$ 6.30
Anti-dilution additional warrants issued	132,583	$ 6.69
Outstanding at December 31, 2013	4,280,553	$ 3.17

The following table summarizes information about common stock warrants outstanding at December 31, 2013:

	Warrants Outstanding		
Exercise Price ($)	Number of Warrants	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price
1.00	2,167,500	5.1 years	$ 1.00
2.12 – 2.50	86,205	1.6 years[1]	$ 2.30
4.00 – 5.04	1,384,911	2.9 years[2]	$ 4.98
6.30 – 6.50[3]	500,048	1.9 years	$ 6.50
7.12 – 9.22[4]	141,889	1.9 years	$ 7.35
	4,280,553		

(1) Weighted average remaining contractual life excludes 40,000 warrants with no expiration date.
(2) Weighted average remaining contractual life excludes 35,261 warrants with no expiration date.
(3) Includes 104,527 warrants issued as a result of anti-dilution adjustments triggered by the issuances of shares of common stock or warrants. This adjustment changed the range of exercise price from $6.30 – $8.22 to $6.30 - $6.50 and the weighted average exercise price from $8.22 to $6.50.
(4) Includes 28,056 warrants issued as a result of anti-dilution adjustments triggered by the issuances of shares of common stock or warrants. This adjustment changed the range of exercise price from $9.04 – $10.14 to $7.12 - $9.22 and the weighted average exercise price from $9.17 to $7.35.

At the measurement date, the Company estimated the fair value of each warrant using the Black-Scholes option pricing model. The following assumptions were used:

	2013	2012
Risk free interest rate	0.58% - 1.55%	0.25% - 0.36%
Expected dividend yield	0%	0%
Expected term (in years)	2.5 – 5.5	2.0 - 3.0
Expected volatility	70%	70%

14. RETIREMENT PLAN

The Company sponsors a defined contribution plan. All contributions are at the discretion of the Company. No Company contributions were made during the years ended 2013 and 2012.

15. SEGMENT INFORMATION

The Company operates in one reportable segment—the research, development and sale of medical devices to diagnose skin cancer. The Company's chief operating decision maker reviews financial information for the Company as a whole for purposes of allocating resources and evaluating financial performance. Substantially all long-lived assets of the Company are in the United States. Sales for each significant geographical area are as follows:

	Year Ended December 31,			
	2013		2012	
	Product Sales	Percent	Product Sales	Percent
	(in millions)		*(in millions)*	
North America	$ 0.9	27%	$ 0.5	23%
Europe	1.3	41%	1.0	39%
Asia	0.7	23%	0.6	25%
Latin America	0.3	7%	0.2	8%
Australia	0.1	2%	0.1	5%
Total	$ 3.3	100%	$ 2.4	100%

16. SELECTED QUARTERLY FINANCIAL INFORMATION (UNAUDITED)

A summary of selected quarterly financial information is as follows:

	Quarter Ended			
	March 31, 2013	June 30, 2013	September 30, 2013	December 31, 2013
Revenue	$ 1,058,610	$ 515,814	$ 691,732	$ 1,075,097
Cost of revenue	748,397	583,544	596,800	758,656
General and administrative	450,188	430,773	818,462	605,841
Sales and marketing	338,789	345,713	547,802	437,737
Engineering, research and development	454,825	340,023	356,594	379,803
Loss from Operations	(933,589)	(1,184,239)	(1,627,926)	(1,106,940)
Net Loss	(1,052,795)	(1,272,027)	(1,855,044)	(1,299,385)
Net loss per common share	$ (0.13)	$ (0.15)	$ (0.22)	$ (0.16)

	Quarter Ended			
	March 31, 2012	June 30, 2012	September 30, 2012	December 31, 2012
Revenue	$ 317,809	$ 571,749	$ 413,509	$ 1,131,518
Cost of revenue	495,297	611,649	644,619	1,124,568
General and administrative	1,388,400	1,176,185	1,001,123	(350,691)
Sales and marketing	709,937	332,097	439,808	417,239
Engineering, research and development	776,897	1,103,691	1,211,142	919,262
Loss from Operations	(3,052,722)	(2,651,873)	(2,883,183)	(978,861)
Net Loss	(3,380,644)	(2,338,538)	(3,059,137)	(1,042,306)
Net loss per common share	$ (0.43)	$ (0.30)	$ (0.38)	$ (0.13)

17. SUBSEQUENT EVENTS

The Company has evaluated subsequent events after the balance sheet date through the date of filing of these financial statements with the Securities and Exchange Commission for appropriate accounting and disclosure and concluded that there were no subsequent events, other than that described below, requiring adjustment or disclosure in these financial statements.

In March 2014, the Company terminated its engagement with its financial advisor, H.C. Wainwright. As a result of this termination, H.C. Wainwright forfeited and returned to the Company the unvested two-thirds of the warrant to purchase 2,125,000 shares of the Company's common stock.

In March 2014, the Company engaged Lafferty to provide general investment banking services. In addition to paying a $2,000 monthly retainer for the 6-month term of the engagement, which is creditable against a cash fee at the time of a funding, the Company has agreed to pay Lafferty a transaction fee of 8% of the gross proceeds from the placement of any securities and a fee for unallocated expenses of 1.5% of the gross proceeds. In connection with the placement of any securities, the Company has agreed to issue Lafferty common stock warrants equal to 10% of the number of shares of common stock underlying the securities issued in the financing. Such 10% will only be on the actual common stock issued and shall not apply to any derivative securities. The warrants shall have an exercise price equal to 120% of the price of the securities issued to the investors, except that if the price of the securities issued to investors reaches $0.80 then the exercise price will then become 110% of the price of the securities issued to investors. Additionally, the Company will issue 100,000 shares of its common stock to Lafferty in the event that Lafferty places a minimum of $3 million in escrow by June 1, 2014. Lafferty will receive no fees on monies invested by its directors, employees, stockholders or friends.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934) as of December 31, 2013. Based on that evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures as of December 31, 2013 are not fully effective in providing reasonable assurance that the information required to be disclosed by us in reports filed under the Securities Exchange Act of 1934 is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding disclosures. A controls system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Our internal control system was designed to, in general, provide reasonable assurance to our management and Board of Directors regarding the preparation and fair presentation of published financial statements, but because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements.

In connection with the filing of our Annual Report on Form 10-K for the period ended December 31, 2013, the Company's management, under the supervision of and with the participation of our chief executive officer and chief financial officer evaluated the effectiveness of our internal control over financial reporting as of December 31, 2013. Based on that evaluation, management concluded that our internal control over financial reporting was not fully effective. The senior management team and other key personnel perform monitoring and other key control activities to ensure the accuracy of the Company's filings; however, these procedures are not fully documented or tested in a manner that supports a conclusion that these procedures are designed and operating effectively.

The framework used by management in making that assessment was the criteria set forth in the document entitled "Internal Control – Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on the evaluation, our management, including our chief executive officer and chief financial officer, concluded that our internal control environment was not fully effective. The senior management team and other key personnel perform monitoring and other key control activities to ensure the accuracy of the Company's filings; however, these procedures are not fully documented or tested in a manner that supports a conclusion that these procedures are designed and operating effectively.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. In its assessment of the effectiveness of internal control over our financial reporting as of December 31, 2013, the Company determined that our internal control environment was not fully effective due to the limited documentation of significant accounting policies, internal controls, management's estimates and judgments and assessment of recent accounting pronouncements. Due to the size of the accounting department and the lack of financial resources of the company, the opportunities to document and test the internal control environment has been limited.

Management intends to remediate these weaknesses as soon as practicable after the Company's financial position improves.

Changes in Internal Control Over Financial Reporting

As required by Rule 13a-15(f) of the Exchange Act, our management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the internal control over financial reporting to determine whether any changes occurred during the last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Based on that evaluation, our principal executive officer and principal financial officer concluded no such changes during the last fiscal quarter materially affected, or were reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

On March 10, 2014, we entered into a Termination Agreement to terminate our engagement with our financial advisor, H.C. Wainwright. As a result of this termination, H.C. Wainwright forfeited and returned to us the unvested two-thirds of the warrant to purchase 2,125,000 shares of our common stock.

On March 10, 2014, we entered into a Letter Agreement to engage Lafferty to provide general investment banking services. In addition to paying a $2,000 monthly retainer for the 6-month term of the engagement, which is creditable against a cash fee at the time of funding, we have agreed to pay Lafferty a transaction fee of 8% of the gross proceeds from the placement of any securities and a fee for unallocated expenses of 1.5% of the gross proceeds. In connection with the placement of any securities, we have agreed to issue Lafferty common stock warrants equal to 10% of the number of shares of common stock underlying the securities issued in the financing. Such 10% will only be on the actual common stock issued and shall not apply to any derivative securities. The warrants shall have an exercise price equal to 120% of the price of the securities issued to the investors, except that if the price of the securities issued to investors reaches $0.80 then the exercise price will then become 110% of the price of the securities issued to investors. Additionally, we will issue 100,000 shares of our common stock to Lafferty in the event that Lafferty places a minimum of $3 million in escrow by June 1, 2014. Lafferty will receive no fees on monies invested by our directors, employees, stockholders or friends.

The description of terms and conditions of the agreement set forth above do not purport to be complete and are qualified in their entirety by the full text of the agreements which are attached hereto as Exhibits 10.28 and 10.29 and incorporated herein by reference.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item is incorporated by reference from the Company's Proxy Statement for the 2014 Annual Meeting of Shareholders to be filed with the Securities and Exchange Commission within 120 days of the end of the Company's fiscal year ended December 31, 2013 (the "Proxy Statement").

Item 11. Executive Compensation

The Information required by this Item is incorporated by reference from the Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The Information required by this Item is incorporated by reference from the Proxy Statement.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The Information required by this Item is incorporated by reference from the Proxy Statement.

Item 14. Principal Accountant Fees and Services

The Information required by this Item is incorporated by reference from the Proxy Statement.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a)(1) The following Financial Statements, Notes thereto and Reports of Independent Registered Public Accounting Firms are set forth under Item 8:

Report of Independent Registered Public Accounting Firm
Balance Sheets
Statements of Operations
Statements of Stockholders' Deficit
Statements of Cash Flows
Notes to Financial Statements

(a)(2) Financial Statement Schedules

All schedules are omitted because they are not applicable or the required information is shown in the Financial Statements or notes thereto.

(a)(3) The following is a complete list of Exhibits filed or incorporated by reference as part of this report:

Exhibit No.	Description of Document
3.1	Restated Certificate of Incorporation of Lucid Inc., as filed with the New York Department of State on May 6, 2011 (Incorporated by reference to Exhibit 3.4 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
3.2	Certificate of Amendment to Certificate of Incorporation of Lucid Inc., as filed with the New York Department of State on December 6, 2011 (Incorporated by reference to Exhibit 3.5 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
3.3	Amended and Restated Bylaws of Lucid, Inc., as adopted December 14, 2010 (Incorporated by reference to Exhibit 3.3 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
4.1	Specimen Common Stock Certificate (Incorporated by reference to Exhibit 4.1 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
4.2	Warrant to Purchase Convertible Preferred Stock, issued to the New York State Foundation for Science, Technology, and Innovation—Small Business Technology Investment Fund, as successor in interest by statute to New York Urban Development Corporation d/b/a Empire State Development—Small Business Technology Investment Fund, on February 1, 2007, as modified by the Second Modification and Extension Agreement, dated December 31, 2008 (Incorporated by reference to Exhibit 4.8 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
4.3	Form of Amended and Restated Common Stock Purchase Warrant—2007 (Incorporated by reference to Exhibit 4.9 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
4.4	Form of 2008 Common Stock Warrant (Incorporated by reference to Exhibit 4.10 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
4.5	Form of 2009 Common Stock Warrant (Incorporated by reference to Exhibit 4.11 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
4.6	Form of 2010/2011 Common Stock Warrant (Incorporated by reference to Exhibit 4.15 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
4.7	Common Stock Warrant Issued to Maxim Partners, LLC on November 15, 2010 (Incorporated by reference to Exhibit 4.16 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
4.8	Form of Stock Option Agreement under the Lucid, Inc. 2010 Long-Term Equity Incentive Plan (Incorporated by reference to Exhibit 4.18 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
4.9	Form of April 2007 Fixed Quantity Common Stock Warrant (Incorporated by reference to Exhibit 4.19 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
4.10	Form of August 2008 Fixed Price Common Stock Warrant (Incorporated by reference to Exhibit 4.20 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))

4.11	Warrant to Purchase Stock, issued to Square 1 Bank on July 20, 2011 (Incorporated by reference to Exhibit 4.21 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
4.12	Common Stock Warrant issued to Maxim Partners, LLC on July 27, 2011 (Incorporated by reference to Exhibit 4.26 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
4.13	Form of November 2008 Fixed Price Common Stock Warrant (Incorporated by reference to Exhibit 4.27 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
4.14	Form of Warrant included in the Units (Incorporated by reference to Exhibit 4.29 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
4.15	Warrant Agreement, dated December 30, 2011, between Lucid, Inc. and American Stock Transfer & Trust Company, LLC, as warrant agent (Incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on January 4, 2012 (File No. 001-35379))
4.16	Form of Common Stock Purchase Warrant (Incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K/A filed with the SEC on October 3, 2013 (File No. 001-35379))
†10.1	Lucid, Inc. 2010 Long-Term Equity Incentive Plan (Incorporated by reference to Exhibit 10.1 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
†10.2	Lucid, Inc. 2007 Long-Term Equity Incentive Plan (Incorporated by reference to Exhibit 10.2 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
†10.3	Lucid, Inc. Year 2000 Stock Option Plan (Incorporated by reference to Exhibit 10.3 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
†10.4	Lucid, Inc. 2012 Stock Option and Incentive Plan (Incorporated by reference to Exhibit 10.39 of the Company's Annual Report on Form 10-K filed with the SEC on March 29, 2013 (File No. 001-35379))
10.5	Colocation License Agreement, by and between the Company and PAETEC Communications, Inc., dated September 4, 2007 (Incorporated by reference to Exhibit 10.4 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
10.6	Joint Venture Agreement, by and between the Company and Mavig Austria GmbH, an Austrian limited liability company, dated October 2006 (Incorporated by reference to Exhibit 10.5 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
10.7	Supply Agreement, by and between the Company and Mavig Austria GmbH, an Austrian limited liability company, dated December 2006, and letter amendment thereto, dated May 25, 2011 (Incorporated by reference to Exhibit 10.6 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
†10.8	Form of Indemnification Agreement by and between the Company and its directors and executive officers (Incorporated by reference to Exhibit 10.8 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
†10.9	Employment Agreement between the Company and Mr. Hone, dated October 1, 2012 (Incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K/A filed with the SEC on October 5, 2012 (File No. 001-35379))
†10.10	Employment Agreement between the Company and Mr. Fox, dated January 11, 2011 (Incorporated by reference to Exhibit 10.23 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
†10.11	Employment Agreement between the Company and Mr. Pulsifer, dated October 1, 2012 (Incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K/A filed with the SEC on October 5, 2012 (File No. 001-35379))
10.12	Form of Lucid, Inc. Employee Invention, Copyright, Proprietary Information and Conflicts of Interest Agreement (Incorporated by reference to Exhibit 10.26 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
10.13	Distributor Agreement, dated September 1, 2004, by and between the Company and Integral Corporation (Incorporated by reference to Exhibit 10.27 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
10.14	Distributor Agreement, dated February 8, 2008, by and between the Company and ConBio (China) Co., Ltd. (Incorporated by reference to Exhibit 10.28 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))

10.15	Promissory Note, given by the Company in favor of Dale Crane, dated December 31, 2010 (Incorporated by reference to Exhibit 10.32 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
10.16	Agreement of Lease, dated August 18, 2011, by and between the Company, as Tenant, and 95 Methodist Hill Drive LLC, as Landlord (Incorporated by reference to Exhibit 10.33 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
†10.17	Separation Agreement, Including Release and Waiver of Claims, dated January 30, 2012, between Lucid, Inc. and Marcy Davis-McHugh (Incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on February 3, 2012 (File No. 001-35379))
10.18	Secured Demand Promissory Note, dated as of May 7, 2012, issued by Lucid, Inc. to Northeast LCD Capital, LLC (Incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on May 11, 2012 (File No. 001-35379))
10.19	Security Agreement, dated as of May 7, 2012, by and between Lucid, Inc. and Northeast LCD Capital, LLC (Incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on May 11, 2012 (File No. 001-35379))
10.20	Guaranty, dated as of May 7, 2012, by L. Michael Hone in favor of Northeast LCD Capital, LLC (Incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K filed with the SEC on May 11, 2012 (File No. 001-35379))
10.21	Loan and Security Agreement, by and between the Company and Northeast LCD Capital, LLC dated July 5, 2012 (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on July 11, 2012 (File No. 001-35379))
10.22	Subsequent Term Note, by and between the Company and Northeast LCD Capital, LLC dated May 20, 2013 (Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 20, 2013 (File No. 001-35379))
10.23	Intercreditor and Participation Agreement, by and between the Company and Northeast LCD Capital, LLC dated May 20, 2013 (Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 20, 2013 (File No. 001-35379))
10.24	Letter agreement dated as of October 7, 2013 by and between Caliber I.D. and Northeast LCD Capital, LLC (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on October 11, 2013 (File No. 001-35379))
†10.25	Separation Agreement by and between the Company and Martin Joyce, dated July 9, 2011 (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on July 13, 2012 (File No. 001-35379))
†10.26	Resignation Agreement by and between the Company and Jay Eastman, effective September 30, 2012 (Incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2012 (File No. 001-35379))
10.27	Letter Agreement dated as of August 22, 2013 by and between the Company and H.C. Wainwright & Co., LLC (Incorporated by reference to Exhibit 1.1 of the Company's Current Report on Form 8-K filed on August 27, 2013 (File No. 001-35379))
*10.28	Termination Agreement dated as of March 10, 2014 by and between the Company and H.C. Wainwright & Co., LLC
*10.29	Letter Agreement dated as of March 10, 2014 by and between the Company and R.F. Lafferty & Co., Inc.
14.1	Code of Ethics (Incorporated by reference to Exhibit 14.1 to the Company's Current Report on Form 8-K filed with the SEC on October 5, 2012 (File No. 001-35379))
16.1	Letter from Deloitte & Touche LLP (Incorporated by reference to Exhibit 16.1 to the Company's Current Report on Form 8-K filed with the SEC on August 30, 2012 (File No. 001-35379))
*23.1	Consent of Independent Registered Public Accounting Firm
24.1	Power of Attorney (included in signature page)
*31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
*31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
**32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

**32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
††101	The following material from Lucid Inc.'s Annual Report on Form 10-K, for the year ended December 31, 2013, formatted in XBRL (Extensible Business Reporting Language): (i) the Balance Sheets; (ii) the Statements of Operations; (iii) the Statements of Stockholders' Deficit; (iv) the Statements of Cash Flows; and (v) the Notes to Financial Statements.

---

* Filed herewith.
** Furnished herewith.
† Management contract or compensatory plan or arrangement.
†† *XBRL information is furnished and not filed for purposes of Sections 11 and 12 of the Securities Act of 1933, as amended, and Section 18 of the Securities Exchange Act of 1934, as amended, and is not subject to liability under those sections, is not part of any registration statement or prospectus to which it relates and is not incorporated or deemed to be incorporated by reference into any registration statement, prospectus or other document.*

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 12, 2014.

LUCID, INC.

By: /s/ L. Michael Hone
Name: L. Michael Hone
Title: Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS that each individual whose signature appears below constitutes and appoints each of L. Michael Hone and Richard J. Pulsifer such person's true and lawful attorney-in-fact and agent with full power of substitution and resubstitution, for such person and in such person's name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and all documents in connection therewith, with the Securities and Exchange Commission, granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that any said attorney-in-fact and agent, or any substitute or substitutes of any of them, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ L. Michael Hone **L. Michael Hone**	Chief Executive Officer (Principal Executive Officer)	March 12, 2014
/s/ Richard J. Pulsifer **Richard J. Pulsifer**	Chief Financial Officer (Principal Financial and Accounting Officer)	March 12, 2014
/s/ William J. Shea **William J. Shea**	Chairman of the Board of Directors	March 12, 2014
/s/ Brian Carty **Brian Carty**	Director	March 12, 2014
/s/ Kevin M. Cronin **Kevin M. Cronin**	Director	March 12, 2014
/s/ Rocco Maggiotto **Rocco Maggiotto**	Director	March 12, 2014
/s/ Ruben King-Shaw, Jr. **Ruben King-Shaw, Jr.**	Director	March 12, 2014
/s/ Daniel M. Siegel, M.D. **Daniel M. Siegel, M.D.**	Director	March 12, 2014
/s/ Paul Stuka **Paul Stuka**	Director	March 12, 2014

EXHIBIT INDEX

Exhibit No.	Description of Document
3.1	Restated Certificate of Incorporation of Lucid Inc., as filed with the New York Department of State on May 6, 2011 (Incorporated by reference to Exhibit 3.4 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
3.2	Certificate of Amendment to Certificate of Incorporation of Lucid Inc., as filed with the New York Department of State on December 6, 2011 (Incorporated by reference to Exhibit 3.5 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
3.3	Amended and Restated Bylaws of Lucid, Inc., as adopted December 14, 2010 (Incorporated by reference to Exhibit 3.3 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
4.1	Specimen Common Stock Certificate (Incorporated by reference to Exhibit 4.1 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
4.2	Warrant to Purchase Convertible Preferred Stock, issued to the New York State Foundation for Science, Technology, and Innovation—Small Business Technology Investment Fund, as successor in interest by statute to New York Urban Development Corporation d/b/a Empire State Development—Small Business Technology Investment Fund, on February 1, 2007, as modified by the Second Modification and Extension Agreement, dated December 31, 2008 (Incorporated by reference to Exhibit 4.8 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
4.3	Form of Amended and Restated Common Stock Purchase Warrant—2007 (Incorporated by reference to Exhibit 4.9 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
4.4	Form of 2008 Common Stock Warrant (Incorporated by reference to Exhibit 4.10 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
4.5	Form of 2009 Common Stock Warrant (Incorporated by reference to Exhibit 4.11 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
4.6	Form of 2010/2011 Common Stock Warrant (Incorporated by reference to Exhibit 4.15 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
4.7	Common Stock Warrant Issued to Maxim Partners, LLC on November 15, 2010 (Incorporated by reference to Exhibit 4.16 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
4.8	Form of Stock Option Agreement under the Lucid, Inc. 2010 Long-Term Equity Incentive Plan (Incorporated by reference to Exhibit 4.18 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
4.9	Form of April 2007 Fixed Quantity Common Stock Warrant (Incorporated by reference to Exhibit 4.19 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
4.10	Form of August 2008 Fixed Price Common Stock Warrant (Incorporated by reference to Exhibit 4.20 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
4.11	Warrant to Purchase Stock, issued to Square 1 Bank on July 20, 2011 (Incorporated by reference to Exhibit 4.21 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
4.12	Common Stock Warrant issued to Maxim Partners, LLC on July 27, 2011 (Incorporated by reference to Exhibit 4.26 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
4.13	Form of November 2008 Fixed Price Common Stock Warrant (Incorporated by reference to Exhibit 4.27 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
4.14	Form of Warrant included in the Units (Incorporated by reference to Exhibit 4.29 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
4.15	Warrant Agreement, dated December 30, 2011, between Lucid, Inc. and American Stock Transfer & Trust Company, LLC, as warrant agent (Incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on January 4, 2012 (File No. 001-35379))
4.16	Form of Common Stock Purchase Warrant (Incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K/A filed with the SEC on October 3, 2013 (File No. 001-35379))

†10.1	Lucid, Inc. 2010 Long-Term Equity Incentive Plan (Incorporated by reference to Exhibit 10.1 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
†10.2	Lucid, Inc. 2007 Long-Term Equity Incentive Plan (Incorporated by reference to Exhibit 10.2 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
†10.3	Lucid, Inc. Year 2000 Stock Option Plan (Incorporated by reference to Exhibit 10.3 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
†10.4	Lucid, Inc. 2012 Stock Option and Incentive Plan (Incorporated by reference to Exhibit 10.39 of the Company's Annual Report on Form 10-K filed with the SEC on March 29, 2013 (File No. 001-35379))
10.5	Colocation License Agreement, by and between the Company and PAETEC Communications, Inc., dated September 4, 2007 (Incorporated by reference to Exhibit 10.4 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
10.6	Joint Venture Agreement, by and between the Company and Mavig Austria GmbH, an Austrian limited liability company, dated October 2006 (Incorporated by reference to Exhibit 10.5 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
10.7	Supply Agreement, by and between the Company and Mavig Austria GmbH, an Austrian limited liability company, dated December 2006, and letter amendment thereto, dated May 25, 2011 (Incorporated by reference to Exhibit 10.6 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
†10.8	Form of Indemnification Agreement by and between the Company and its directors and executive officers (Incorporated by reference to Exhibit 10.8 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
†10.9	Employment Agreement between the Company and Mr. Hone, dated October 1, 2012 (Incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K/A filed with the SEC on October 5, 2012 (File No. 001-35379))
†10.10	Employment Agreement between the Company and Mr. Fox, dated January 11, 2011 (Incorporated by reference to Exhibit 10.23 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
†10.11	Employment Agreement between the Company and Mr. Pulsifer, dated October 1, 2012 (Incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K/A filed with the SEC on October 5, 2012 (File No. 001-35379))
10.12	Form of Lucid, Inc. Employee Invention, Copyright, Proprietary Information and Conflicts of Interest Agreement (Incorporated by reference to Exhibit 10.26 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
10.13	Distributor Agreement, dated September 1, 2004, by and between the Company and Integral Corporation (Incorporated by reference to Exhibit 10.27 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
10.14	Distributor Agreement, dated February 8, 2008, by and between the Company and ConBio (China) Co., Ltd. (Incorporated by reference to Exhibit 10.28 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
10.15	Promissory Note, given by the Company in favor of Dale Crane, dated December 31, 2010 (Incorporated by reference to Exhibit 10.32 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
10.16	Agreement of Lease, dated August 18, 2011, by and between the Company, as Tenant, and 95 Methodist Hill Drive LLC, as Landlord (Incorporated by reference to Exhibit 10.33 of the Company's Registration Statement on Form S-1, as amended (File No. 333-173555))
†10.17	Separation Agreement, Including Release and Waiver of Claims, dated January 30, 2012, between Lucid, Inc. and Marcy Davis-McHugh (Incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on February 3, 2012 (File No. 001-35379))
10.18	Secured Demand Promissory Note, dated as of May 7, 2012, issued by Lucid, Inc. to Northeast LCD Capital, LLC (Incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on May 11, 2012 (File No. 001-35379))
10.19	Security Agreement, dated as of May 7, 2012, by and between Lucid, Inc. and Northeast LCD Capital, LLC (Incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on May 11, 2012 (File No. 001-35379))

10.20	Guaranty, dated as of May 7, 2012, by L. Michael Hone in favor of Northeast LCD Capital, LLC (Incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K filed with the SEC on May 11, 2012 (File No. 001-35379))
10.21	Loan and Security Agreement, by and between the Company and Northeast LCD Capital, LLC dated July 5, 2012 (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on July 11, 2012 (File No. 001-35379))
10.22	Subsequent Term Note, by and between the Company and Northeast LCD Capital, LLC dated May 20, 2013 (Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 20, 2013 (File No. 001-35379))
10.23	Intercreditor and Participation Agreement, by and between the Company and Northeast LCD Capital, LLC dated May 20, 2013 (Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 20, 2013 (File No. 001-35379))
10.24	Letter agreement dated as of October 7, 2013 by and between Caliber I.D. and Northeast LCD Capital, LLC (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on October 11, 2013 (File No. 001-35379))
†10.25	Separation Agreement by and between the Company and Martin Joyce, dated July 9, 2011 (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on July 13, 2012 (File No. 001-35379))
†10.26	Resignation Agreement by and between the Company and Jay Eastman, effective September 30, 2012 (Incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2012 (File No. 001-35379))
10.27	Letter Agreement dated as of August 22, 2013 by and between the Company and H.C. Wainwright & Co., LLC (Incorporated by reference to Exhibit 1.1 of the Company's Current Report on Form 8-K filed on August 27, 2013 (File No. 001-35379))
*10.28	Termination Agreement dated as of March 10, 2014 by and between the Company and H.C. Wainwright & Co., LLC
*10.29	Letter Agreement dated as of March 10, 2014 by and between the Company and R.F. Lafferty & Co., Inc.
14.1	Code of Ethics (Incorporated by reference to Exhibit 14.1 to the Company's Current Report on Form 8-K filed with the SEC on October 5, 2012 (File No. 001-35379))
16.1	Letter from Deloitte & Touche LLP (Incorporated by reference to Exhibit 16.1 to the Company's Current Report on Form 8-K filed with the SEC on August 30, 2012 (File No. 001-35379))
*23.1	Consent of Independent Registered Public Accounting Firm
24.1	Power of Attorney (included in signature page)
*31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
*31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
**32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
**32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
††101	The following material from Lucid Inc.'s Annual Report on Form 10-K, for the year ended December 31, 2013, formatted in XBRL (Extensible Business Reporting Language): (i) the Balance Sheets; (ii) the Statements of Operations; (iii) the Statements of Stockholders' Deficit; (iv) the Statements of Cash Flows; and (v) the Notes to Financial Statements.

---

* Filed herewith.
** Furnished herewith.
† Management contract or compensatory plan or arrangement.
†† *XBRL information is furnished and not filed for purposes of Sections 11 and 12 of the Securities Act of 1933, as amended, and Section 18 of the Securities Exchange Act of 1934, as amended, and is not subject to liability under those sections, is not part of any registration statement or prospectus to which it relates and is not incorporated or deemed to be incorporated by reference into any registration statement, prospectus or other document.*

Exhibit 10.28

Lucid, Inc.
95 Methodist Hill Dr. Suite 500
Rochester, NY 14623
T (585) 239 - 9800
F (585) 239 - 9806
www.lucid-tech.com

BY FEDERAL EXPRESS

March 10, 2014

H.C. Wainwright & Co., LLC
570 Lexington Avenue
New York, NY 10022
Attn: Head of Investment Banking

Dear Sir/Madam:

Reference is made to the agreement (the "Agreement") between Lucid, Inc., d/b/a Caliber Imaging and Diagnostics, ("Caliber") and H.C. Wainwright & Co., LLC ("HCW") dated as of August 22, 2013 and as amended on February 20, 2014 and February 28, 2014. In accordance with Section 1 of the Agreement, Caliber hereby terminates the Agreement. This notice shall be deemed to be the 6-Month Termination Notice referred to in the Agreement.

LUCID, INC.

By: /s/ Richard J. Pulsifer
Richard J. Pulsifer, Chief Financial Officer

Exhibit 10.29

Caliber Imaging & Diagnostics
March 10, 2014

Caliber Imaging & Diagnostics (Lucid, Inc.)
10 Post Office Square
North Tower, 11th Floor - Suite 1150
Boston, MA 02109

Dear Mr. Hone,

We are pleased that Lucid, Inc., operating as Caliber Imaging & Diagnostics, ("**Caliber**" or the "**Company**") has decided to retain R.F. Lafferty & Co., Inc. ("**Lafferty**") to provide general investment banking services to the Company as set forth herein. This letter agreement ("**Agreement**") will confirm Lafferty's acceptance of such retention and set forth the terms of our engagement.

1. Retention. The Company hereby retains Lafferty as its exclusive investment banker to provide general investment banking services, and Lafferty accepts such retention on the terms and conditions set forth in this Agreement. In connection with this Agreement, Lafferty may provide certain or all of the following services in connection with a potential transaction(s) (collectively referred to as the "**Advisory Services**"):

a. Assist the Company in raising capital activity as provided herein

b. Provide a valuation analysis of the Company, which may include certain or all of the following analysis:

- Pro-forma financing analysis;
- Comparable company analysis;
- Precedent transaction analysis;
- Discounted cash flow analysis;
- Analyses of exchange ratios for any proposed stock splits of the Company.

c. Analyze and advise the Company on potential corporate finance activities, which may include the following:

- Analysis of raising capital privately versus publicly;
- Potential uses of existing cash.

d. Advise the Company with respect to its ongoing strategic planning process and business plans, including an analysis of markets, positioning, financial models, organizational structure, potential strategic alliances and capital requirements. Work closely with the Company's management to develop a set of long and short-term goals with special focus on enhancing corporate and shareholder value.

e. Provide such other financial advisory and investment banking services upon which the parties may mutually agree.

It is expressly understood and agreed that Lafferty shall be required to perform only such tasks as may be necessary or desirable in connection with the rendering of its services hereunder and therefore may not perform all of the tasks enumerated above during the term of this Agreement. Moreover, it is further understood that Lafferty need not perform each of the above-referenced tasks in order to receive the fees described in Section 3. It is further understood that Lafferty's tasks may not be limited to those enumerated in this paragraph.

2. Information. In connection with Lafferty's activities hereunder, the Company will cooperate with Lafferty and furnish Lafferty upon request with all information regarding the business, operations, properties, historical and projected financials (in GAAP format), management and prospects of the Company (all such information so furnished being the "**Information**") which Lafferty deems appropriate and will provide Lafferty with access to the Company's officers, directors, employees, independent accountants and legal counsel. The Company represents and warrants to Lafferty that all Information made available to Lafferty hereunder will be complete and correct in all material respects and will not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein not misleading in light of the circumstances under which such statements are or will be made. The Company further represents and warrants that any projections and other forward-looking information provided by it to Lafferty will have been prepared in good faith and will be based upon assumptions which, in light of the circumstances under which they are made, are reasonable. The Company recognizes and confirms that Lafferty: (i) will use and rely primarily on the Information and on information available from generally recognized public sources in performing the services contemplated by this Agreement without having independently verified the same; (ii) does not assume responsibility for the accuracy or completeness of the Information and such other information; and (iii) will not make an appraisal of any assets of the Company. Any advice rendered by Lafferty pursuant to this Agreement may not be disclosed publicly without Lafferty's prior written consent. Lafferty hereby acknowledges that certain of the Information received by Lafferty may be confidential and/or proprietary, including Information with respect to the Company's technologies, products, business plans, marketing, and other Information which must be maintained by Lafferty as confidential. Lafferty agrees that it will not disclose such confidential and/or proprietary Information to any other companies in the industry in which the Company is involved without the prior consent of the Company.

3. Compensation. As consideration for Lafferty's services rendered pursuant to this Agreement, Lafferty shall receive, and the Company agrees to pay Lafferty, the following compensation:

a. In the event that Lafferty places a minimum of $3 million in escrow by June 1, 2014, the Company shall be obligated to deliver One Hundred thousand Shares (100,000 shares) of the Company's common stock in one 100,000 share certificate at the time such money place in escrow is released to the Company. Such certificate will be a 100,000 share certificate and shall bear the standard unregistered restriction with the following additional language:

In any circumstance, these shares may not be sold, transferred, hypothecated or pledged in any event prior to December 31, 2014

b. The Company and Lafferty acknowledge and agree that, in the course of performing services hereunder, Lafferty may advise and work with the Company in identifying third parties who may be interested in providing financing to the Company (a "**Financing**"). Lafferty's compensation in connection with a Financing is enumerated in **Exhibit B**.

The Company agrees that if within twelve (12) months from the effective date of the termination of this Agreement either the Company or any party to whom the Company was introduced by Lafferty or who was contacted by Lafferty in connection with its services for the Company hereunder proposes a Financing involving the Company, and Lafferty is not engaged as the Company's exclusive financial advisor, agent and/or investment banker in connection with such Financing pursuant to Section 6 hereof, then, if any such Financing is consummated, the Company shall pay to Lafferty fees in accordance with the Fee Schedule detailed in Exhibit B. Such fees shall be payable to Lafferty in cash at the closing or closings of the Financing to which it relates.

Notwithstanding anything in this Agreement, any monies invested by directors, employees, stockholders and friends of the Company will be done so without any fees to Lafferty.

4. Expenses. In addition to payment to Lafferty of the compensation set forth in Section 3 hereof, the Company shall promptly upon request from time to time reimburse Lafferty for all reasonable expenses (including, without limitation, fees and disbursements of counsel and all travel and other out-of-pocket expenses) incurred by Lafferty in connection with its engagement hereunder.

5. Indemnification. The Company agrees to indemnify Lafferty in accordance with the indemnification and other provisions attached to this Agreement as Exhibit A (the "**Indemnification Provisions**"), which provisions are incorporated herein by reference and shall survive the termination or expiration of this Agreement.

6. Future Rights. As additional consideration for its services hereunder and as an inducement to cause Lafferty to enter into this Agreement, if at any time during the term of this Agreement or within twelve (12) months from the effective date of the successful Financing by Lafferty of an agreed upon amount, the Company proposes to effect a Financing (other than during the term of this Agreement the services to be provided by Lafferty hereunder), the Company shall offer to retain Lafferty as an advisor, agent and/or investment banker in connection with such Financing, upon such terms as the parties may mutually agree, such terms to be set forth in a separate engagement letter or other agreement between the parties. Such offer shall be made in writing in order to be effective. If Lafferty should decline such retention, the Company shall have no further obligations to Lafferty, except as specifically provided for herein.

7. Other Activities. The Company acknowledges that Lafferty has been, and may in the future be, engaged to provide services as an underwriter, placement agent, finder, advisor and investment banker to other companies in the industry in which the Company is involved. Subject to the confidentiality provisions of Lafferty contained in Section 2 hereof, the Company acknowledges and agrees that nothing contained in this Agreement shall limit or restrict the right of Lafferty or of any member, manager, officer, employee, agent or representative of Lafferty, to be a member, manager, partner, officer, director, employee, agent or representative of, investor in, or to engage in, any other business, whether or not of a similar nature to the Company's business, nor to limit or restrict the right of Lafferty to render services of any kind to any other corporation, firm, individual or association. Lafferty may, but shall not be required to, present opportunities to the Company.

8. Termination; Survival of Provisions. Either Lafferty or the Company may terminate this Agreement at any time after September 3, 2014. In the event of such termination, the Company shall pay and deliver to Lafferty: (i) all compensation earned through the date of such termination ("**Termination Date**") pursuant to any provision of Section 3 hereof, and (ii) all compensation which may be earned by Lafferty after the Termination Date pursuant to Section 3 hereof, and shall reimburse Lafferty for all expenses incurred by Lafferty in connection with its services hereunder pursuant to Section 4 hereof. All such fees and reimbursements due to Lafferty pursuant to the immediately preceding sentence shall be paid to Lafferty on or before the Termination Date (in the event such fees and reimbursements are earned or owed as of the Termination Date) or upon the closing of a Financing or any applicable portion thereof (in the event such fees are due pursuant to the terms of Section 3 hereof). Notwithstanding anything expressed or implied herein to the contrary: (i) any other agreement entered into between Lafferty and the Company may only be terminated in accordance with the terms thereof, notwithstanding an actual or purported termination of this Agreement, and (ii) the terms and provisions of Sections 3, 4, 5 (including, but not limited to, the Indemnification Provisions attached to this Agreement and incorporated herein by reference), 6, 8, 9, 10 and 15 shall survive the termination of this Agreement.

9. Notices. All notices will be in writing and will be effective when delivered in person or sent via facsimile and confirmed by letter, to the party to whom it is addressed at the following addresses or such other address as such party may advise the other in writing:

To the Company:
Caliber Imaging & Diagnostics
Attn: Michael Hone
50 Methodist Hill Drive, Suite 1000
Rochester, NY 14623

To Lafferty:
R.F. Lafferty & Co., Inc.
40 Wall Street, 19th Floor
New York, NY 10004
Telephone: (212) 293-9090
Facsimile: (212) 344-0138

10. Governing Law; Jurisdiction; Waiver of Jury Trial. This Agreement shall be enforced, governed by and construed in accordance with the laws of New York without regard to principles of conflict of laws. Any controversy between the parties to this Agreement, or out of shall be resolved by arbitration before the Financial Industry Regulatory Authority ("FINRA") in New York City. The following arbitration agreement should be read in conjunction with these disclosures:

(a) ARBITRATION IS FINAL AND BINDING ON THE PARTIES;
(b) THE PARTIES ARE WAIVING THEIR RIGHT TO SEEK REMEDIES IN COURT, INCLUDING THE RIGHT TO JURY TRIAL;
(c) PRE-ARBITRATION DISCOVERY IS GENERALLY MORE LIMITED THAN AND DIFFERENT FROM COURT PROCEEDING;
(d) THE ARBITRATORS' AWARD IS NOT REQUIRED TO INCLUDE FACTUAL FINDING OR LEGAL REASONING AND ANY PARTY'S RIGHT TO APPEAL OR TO SEEK MODIFICATION OF RULINGS BY THE ARBITRATORS IS STRICTLY LIMITED; AND

ARBITRATION AGREEMENT ANY AND ALL CONTROVERSIES, DISPUTES OR CLAIMS BETWEEN THE UNDERSIGNED AND YOU OR YOUR AGENTS, REPRESENTATIVES, EMPLOYEES, DIRECTORS, OFFICERS OR CONTROL PERSONS, ARISING OUT OF, IN CONNECTION WITH, FROM OR WITH RESPECT TO (a) ANY PROVISIONS OF OR THE VALIDITY OF THIS AGREEMENT OR ANY RELATED AGREEMENTS, (b) THE RELATIONSHIP OF THE PARTIES HERETO, OR (c) ANY CONTROVERSY ARISING OUT OF YOUR BUSINESS SHALL BE CONDUCTED PURSUANT TO THE CODE OF ARBITRATION PROCEDURE OF THE AAA. ARBITRATION MUST BE COMMENCED BY SERVICE OF A WRITTEN DEMAND FOR ARBITRATION OR A WRITTEN NOTICE OF INTENTION TO ARBITRATE. IF YOU ARE A PARTY TO SUCH ARBITRATION, TO THE EXTENT PERMITTED BY THE RULES OF THE APPLICABLE ARBITRATION TRIBUNAL, THE ARBITRATION SHALL BE CONDUCTED IN NEW YORK, NEW YORK. THE DECISION AND AWARD OF THE ARBITRATORS(S) SHALL BE CONCLUSIVE AND BINDING UPON ALL PARTIES, AND ANY JUDGMENT UPON ANY AWARD RENDERED MAY BE ENTERED IN A COURT HAVING JURISDICTION THEREOF, AND NEITHER PARTY SHALL OPPOSE SUCH ENTRY.

11. Amendments. This Agreement may not be modified or amended except in a writing duly executed by the parties hereto.

12. Headings. The section headings in this Agreement have been inserted as a matter of reference and are not part of this Agreement.

13. Successors and Assigns. The benefits of this Agreement shall inure to the parties hereto, their respective successors and assigns and to the indemnified parties hereunder and their respective successors and assigns, and the obligations and liabilities assumed in this Agreement shall be binding upon the parties hereto and their respective successors and assigns. Notwithstanding anything contained herein to the contrary, neither Lafferty nor the Company shall assign any of its obligations hereunder without the prior written consent of the other party.

14. No Third Party Beneficiaries. This Agreement does not create, and shall not be construed as creating, any rights enforceable by any person or entity not a party hereto, except those entitled to the benefits of the Indemnification Provisions. Without limiting the foregoing, the Company acknowledges and agrees that Lafferty is not being engaged as, and shall not be deemed to be, an agent or fiduciary of the Company's stockholders or creditors or any other person by virtue of this Agreement or the retention of Lafferty hereunder, all of which are hereby expressly waived.

15. Waiver. Any waiver or any breach of any of the terms or conditions of this Agreement shall not operate as a waiver of any other breach of such terms or conditions or of any other term or condition, nor shall any failure to insist upon strict performance or to enforce any provision hereof on any one occasion operate as a waiver of such provision or of any other provision hereof or a waiver of the right to insist upon strict performance or to enforce such provision or any other provision on any subsequent occasion. Any waiver must be in writing.

16. Counterparts. This Agreement may be executed in any number of counterparts and by facsimile transmission, each of which shall be deemed to be an original instrument, but all of which taken together shall constitute one and the same agreement. Facsimile signatures shall be deemed to be original signatures for all purposes.

17. Hold Harmless. Lafferty and the Company agree that neither Lafferty nor any of its affiliates or any of their respective officers, directors, controlling persons (within the meaning of Section 15 of the Act or Section 20 of the Exchange Act of 1934), employees or agents shall have any liability to the Company, its security holders or creditors, or any person asserting claims on behalf of or in the right of the Company (whether direct, indirect, in contract, tort, for an act of negligence or otherwise) for any losses, fees, damages, liabilities, costs, expenses or equitable relief arising out of or relating to this Agreement or the Advisory Services rendered hereunder, except for losses, fees, damages, liabilities, costs or expenses that arise out of or are based on any action of or failure of Lafferty and that are finally and judicially determined to have resulted primarily and directly from the negligence or willful misconduct of Lafferty. This Section 17 is separate and distinct from the indemnification afforded to Lafferty pursuant to the Indemnification Provisions enumerated in Exhibit A.

18. Entire Agreement. This Agreement and the schedules hereto sets forth the entire understandings of the parties relating to the subject matter hereof and supersedes and cancels any prior or contemporaneous communications, understandings or agreements between the parties hereto.

19. Review by Counsel. This Agreement has been reviewed by the signatories hereto and their counsel. There shall be no construction of any provision against Lafferty because this Agreement was drafted by Lafferty, and the parties waive any statute or rule of law to such effect.

20. Severability. In the event that any term or provision of this Agreement shall be held to be illegal or unenforceable, the entire Agreement shall not fail on account thereof. It is further agreed that if any one or more of such paragraphs or provisions shall be judged to be void as going beyond what is reasonable in all of the circumstances for the protection of the interests of the Company, but would be valid if part of the wording thereof were deleted or the period thereof reduced or the range of activities covered thereby reduced in scope, the said reduction shall be deemed to apply with such modifications as may be necessary to make them valid and effective and any such modification shall not thereby affect the validity of any other paragraph or provisions contained in this Agreement.

(Signature Page to Follow)

Caliber Imaging & Diagnostics
March 10, 2014

If the terms of our engagement as set forth in this letter are satisfactory to you, please confirm by signing and returning one copy of this letter. Your signature below shall indicate the Company's agreement to the terms hereof.

Very truly yours,

R.F. LAFFERTY & CO., INC.

By: /s/ Robert Hackel

Agreed to and accepted this 10 day of March, 2014

Caliber Imaging & Diagnostics

By: /s/ Richard J. Pulsifer

Members FINRA & SIPC
40 Wall Street * New York, NY 10005 * tel (212) 293-9090 * fax (212) 344-0138 *
www.RFlafferty.com

Exhibit A

INDEMNIFICATION PROVISIONS

Capitalized terms used in this Exhibit shall have the meanings ascribed to such terms in the Agreement to which this Exhibit is attached.

The Company agrees to indemnify and hold harmless Lafferty and each of the other Indemnified Parties (as hereinafter defined) from and against any and all losses, claims, damages, obligations, penalties, judgments, awards, liabilities, costs, expenses and disbursements, and any and all actions, suits, proceedings and investigations in respect thereof and any and all legal and other costs, expenses and disbursements in giving testimony or furnishing documents in response to a subpoena or otherwise (including, without limitation, the costs, expenses and disbursements, as and when incurred, of investigating, preparing, pursing or defending any such action, suit, proceeding or investigation (whether or not in connection with litigation in which any Indemnified Party is a party)) (collectively, "**Losses**"), directly or indirectly, caused by, relating to, based upon, arising out of, or in connection with, Lafferty's acting for the Company, including, without limitation, any act or omission by Lafferty in connection with its acceptance of or the performance or non-performance of its obligations under the Agreement between the Company and Lafferty to which these indemnification provisions are attached and form a part (the "**Agreement**"), any breach by the Company of any representation, warranty, covenant or agreement contained in the Agreement (or in any instrument, document or agreement relating thereto, including any Agency Agreement), or the enforcement by Lafferty of its rights under the Agreement or these indemnification provisions, except to the extent that any such Losses are found in a final judgment by a court of competent jurisdiction (not subject to further appeal) to have resulted primarily and directly from the negligence or willful misconduct of the Indemnified Party seeking indemnification hereunder. The Company also agrees that no Indemnified Party shall have any liability (whether direct or indirect, in contract or tort or otherwise) to the Company for or in connection with the engagement of Lafferty by the Company or for any other reason, except to the extent that any such liability is found in a final judgment by a court of competent jurisdiction (not subject to further appeal) to have resulted primarily and directly from such Indemnified Party's gross negligence or willful misconduct.

These Indemnification Provisions shall extend to the following persons (collectively, the "**Indemnified Parties**"): Lafferty, its present and former affiliated entities, managers, members, officers, employees, legal counsel, agents and controlling persons (within the meaning of the federal securities laws), and the officers, directors, partners, stockholders, members, managers, employees, legal counsel, agents and controlling persons of any of them. These indemnification provisions shall be in addition to any liability which the Company may otherwise have to any Indemnified Party.

If any action, suit, proceeding or investigation is commenced, as to which an Indemnified Party proposes to demand indemnification, it shall notify the Company with reasonable promptness; provided, however, that any failure by an Indemnified Party to notify the Company shall not relieve the Company from its obligations hereunder. The Company shall be liable for any settlement of any claim against any Indemnified Party made with the Company's written consent. The Company shall not, without the prior written consent of Lafferty, settle or compromise any claim, or permit a default or consent to the entry of any judgment in respect thereof, unless such settlement, compromise or consent (i) includes, as an unconditional term thereof, the giving by the claimant to all of the Indemnified Parties of an unconditional release from all liability in respect of such claim, and (ii) does not contain any factual or legal admission by or with respect to an Indemnified Party or an adverse statement with respect to the character, professionalism, expertise or reputation of any Indemnified Party or any action or inaction of any Indemnified Party.

In order to provide for just and equitable contribution, if a claim for indemnification pursuant to these indemnification provisions is made but it is found in a final judgment by a court of competent jurisdiction (not subject to further appeal) that such indemnification may not be enforced in such case, even though the express provisions hereof provide for indemnification in such case, then the Company shall contribute to the Losses to which any Indemnified Party may be subject (i) in accordance with the relative benefits received by the Company and its stockholders, subsidiaries and affiliates, on the one hand, and the Indemnified Party, on the other hand, and (ii) if (and only if) the allocation provided in clause (i) of this sentence is not permitted by applicable law, in such proportion as to reflect not only the relative benefits, but also the relative fault of the Company, on the one hand, and the Indemnified Party, on the other hand, in connection with the statements, acts or omissions which resulted in such Losses as well as any relevant equitable considerations. No person found liable for a fraudulent misrepresentation shall be entitled to contribution from any person who is not also found liable for fraudulent misrepresentation. The relative benefits received (or anticipated to be received) by the Company and its stockholders, subsidiaries and affiliates shall be deemed to be equal to the aggregate consideration payable or receivable by such parties in connection with the transaction or transactions to which the Agreement relates relative to the amount of fees actually received by Lafferty in connection with such transaction or transactions. Notwithstanding the foregoing, in no event shall the amount contributed by all Indemnified Parties exceed the compensation previously received by Lafferty pursuant to the Agreement.

Neither termination nor completion of the Agreement shall affect these Indemnification Provisions which shall remain operative and in full force and effect. The Indemnification Provisions shall be binding upon the Company and its successors and assigns and shall inure to the benefit of the Indemnified Parties and their respective successors, assigns, heirs and personal representatives.

Exhibit B

Compensation

In consideration of rendering such services, the Company agrees to pay R.F. Lafferty & Co., Inc. on the following basis:

For investment banking services--

i. A $ 2,000.00 monthly retainer for a period of six months to be paid monthly upon execution of this agreement. Such retainer is creditable against the cash fee at the time of a funding.

ii. A cash fee of 8% of the capital raised or invested.

iii. A cash fee for unallocated expenses of 1.5% of the amount of capital raised or invested.

iv. Delivery of warrant to Lafferty (the "**Agent Warrant**") to purchase shares of the Company's common stock (the "**Common Stock**") equal to the following percentage of the number of shares of Common Stock underlying the securities issued in the Financing: 10% of the number of shares of Common Stock underlying the securities issued in the Financing. Such 10% will only be on the actual common stock issued and under no circumstances shall be applied to any derivative securities (i.e. warrants). Such Agent Warrant will be issued at each Closing and shall provide, among other things, that the Agent Warrant shall (i) be exercisable at an exercise price equal to 120% of the price of the securities (or the exercise price of the securities) issued to the investors in the Financing except that if the price of the securities issued to investors reaches $0.80 then such Agent Warrant price will then become 110% of the price of the security issued to the investors, (ii) expire five (5) years from the date of issuance, (iii) contain standard anti-dilution protection and such other anti-dilution protection provided to the investors in the Financing, (iv) include customary registration rights consistent with the registration rights provided to the investors, (v) contain provisions for cashless exercise and (vi) include such other terms as are normal and customary for warrants of this type.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to incorporation by reference in Registration Statement No. 333-182752 on Form S-8 of our report dated March 12, 2014, relating to the 2013 and 2012 financial statements of Lucid, Inc. (which report expresses an unqualified opinion and includes an explanatory paragraph relating to substantial doubt regarding the Company's ability to continue as a going concern), appearing in the Annual Report on Form 10-K of Lucid, Inc. for the year ended December 31, 2013.

/s/ Marcum LLP
Boston, Massachusetts
March 12, 2014

Exhibit 31.1

CERTIFICATION PURSUANT TO
SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, L. Michael Hone, certify that:

1. I have reviewed this Annual Report on Form 10-K of Lucid, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 12, 2014

/s/ L. Michael Hone
L. Michael Hone
Chief Executive Officer

Exhibit 31.2

CERTIFICATION PURSUANT TO
SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Richard J. Pulsifer, certify that:

1. I have reviewed this Annual Report on Form 10-K of Lucid, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 12, 2014

/s/ Richard J. Pulsifer
Richard J. Pulsifer
Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE
SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Lucid, Inc. (the "Company") on Form 10-K for the year ended December 31, 2013 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, L. Michael Hone, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 12, 2014

/s/ L. Michael Hone
L. Michael Hone
Chief Executive Officer

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE
SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Lucid, Inc. (the "Company") on Form 10-K for the year ended December 31, 2013 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Richard J. Pulsifer, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 12, 2014

/s/ Richard J. Pulsifer
Richard J. Pulsifer
Chief Financial Officer

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:96931 Tracking Number BB1 Original Specialty Recommended RVU: **0.90**
Presented Recommended RVU: **0.80**
Global Period: XXX RUC Recommended RVU: **0.80**

CPT Descriptor: Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; image acquisition and interpretation and report, first lesion

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A 55-year-old male with a history of non-melanoma skin cancer and melanoma and multiple atypical moles is found to have a lesion with one or more clinical and/or historical characteristics highly suggestive of melanoma or other non-melanoma skin cancer. Reflectance confocal microscopy is ordered by the examining dermatologist.

Percentage of Survey Respondents who found Vignette to be Typical: 92%

Site of Service (Complete for 010 and 090 Globals Only)

Percent of survey respondents who stated they perform the procedure; In the hospital 0% , In the ASC 0%, In the office 0%

Percent of survey respondents who stated they typically perform this procedure in the hospital, stated the patient is; Discharged the same day 0% , Overnight stay-less than 24 hours 0% , Overnight stay-more than 24 hours 0%

Percent of survey respondents who stated that if the patient is typically kept overnight also stated that they perform an E&M service later on the same day 0%

Moderate Sedation

Is moderate sedation inherent to this procedure in the Hospital/ASC setting?
Percent of survey respondents who stated moderate sedation is typical in the Hospital/ASC setting? 0%

Is moderate sedation inherent to this procedure in the office setting?
Percent of survey respondents who stated moderate sedation is typical in the office setting? 0%

Description of Pre-Service Work: The physician reviews the clinical history and referral information.

Description of Intra-Service Work: The imaged lesion appears in a list in the software. The lesion is selected for interpretation by the physician. The physician logs into the HIPAA compliant software using a computer with a high resolution graphics card and significant memory for rapid image loading and positioning, clicks on a photo of the lesion, and reviews the pictures and the clinical information. He/she opens up the confocal images in software optimized for viewing RCM images and reviews each mosaic (up to five 8x8mm slices).A diagnostic report is completed. The report would include, in addition to a narrative description, a database link to RCM features related to the diagnosis. These terms can easily be searched to locate specific patients, diseases/condition types, diagnoses, or lesion locations (for example, if a physician wanted to pull up all patient records for lesions on the face diagnosed as melanoma, this would be possible) to optimize the physician's participation in registries that are evolving to meet requirements for quality and outcome measures that are becoming part of the practice of medicine. Finally, representative images are added to the report as appropriate. It is electronically signed and is ready for the interpreting physician to print and discuss with the referring physician. The report is digitally linked to the patient and the specific lesion/images that it corresponds to and is stored as a file at the datacenter for future retrieval.

Description of Post-Service Work:

SURVEY DATA

RUC Meeting Date (mm/yyyy)	10/2015		
Presenter(s):	Mark Kaufmann, MD; Harold Rabinovitz, MD; Jane Grant-Kels, MD		
Specialty(s):	AAD		
CPT Code:	96931		
Sample Size:	72	**Resp N:** 38	**Response:** 52.7 %
Description of Sample:	List of trained users supplied by the manufacturer.		

	Low	25th pctl	Median*	75th pctl	High
Service Performance Rate	0.00	1.00	**11.00**	58.00	500.00
Survey RVW:	0.45	0.90	**1.15**	2.00	25.00
Pre-Service Evaluation Time:			**10.00**		
Pre-Service Positioning Time:			**0.00**		
Pre-Service Scrub, Dress, Wait Time:			**0.00**		
Intra-Service Time:	10.00	20.00	**25.00**	34.00	120.00

Immediate Post Service-Time:	**10.00**	
Post Operative Visits	**Total Min****	**CPT Code and Number of Visits**
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.00** 99239x **0.00** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

**Physician standard total minutes per E/M visit: 99291 (70); 99292 (30); 99231 (20); 99232 (40); 99233 (55); 99238(38); 99239 (55); 99217 (38); 99211 (7); 99212 (16); 99213 (23); 99214 (40); 99215 (55); 99224 (20); 99225 (40); 99226 (55); 99354 (60); 99355 (30); 99356 (60); 99357 (30)

Specialty Society Recommended Data

Please, pick the pre-service time package that best corresponds to the data which was collected in the survey process. (Note: your recommended pre time should not exceed your survey median time for any category)

XXX Global Code

CPT Code:	96931	**Recommended Physician Work RVU: 0.80**		
		Specialty Recommended Pre-Service Time	**Specialty Recommended Pre Time Package**	**Adjustments/Recommended Pre-Service Time**
Pre-Service Evaluation Time:		**3.00**	**0.00**	**3.00**
Pre-Service Positioning Time:		**0.00**	**0.00**	**0.00**
Pre-Service Scrub, Dress, Wait Time:		**0.00**	**0.00**	**0.00**
Intra-Service Time:		**25.00**		

Please, pick the post-service time package that best corresponds to the data which was collected in the survey process: (Note: your recommended post time should not exceed your survey median time)

XXX Global Code

	Specialty Recommended Post-Service Time	**Specialty Recommended Post Time Package**	**Adjustments/Recommended Post-Service Time**
Immediate Post Service-Time:	**0.00**	**0.00**	**0.00**

Post-Operative Visits	Total Min**	CPT Code and Number of Visits
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.0** 99239x **0.0** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

Modifier -51 Exempt Status

Is the recommended value for the new/revised procedure based on its modifier -51 exempt status?

New Technology/Service:

Is this new/revised procedure considered to be a new technology or service? Yes

TOP KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
88305	XXX	0.75	**RUC Time**

CPT Descriptor Level IV - Surgical pathology, gross and microscopic examination

SECOND HIGHEST KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
17315	XXX	0.87	**RUC Time**

CPT Descriptor Mohs micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histopathologic preparation including routine stain(s) (eg, hematoxylin and eosin, toluidine blue), each additional block after the first 5 tissue blocks, any stage

KEY MPC COMPARISON CODES:

Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU	Time Source	Most Recent Medicare Utilization
92002	XXX	0.88	**RUC Time**	223,037

CPT Descriptor 1 Ophthalmological services: medical examination and evaluation with initiation of diagnostic and treatment program; intermediate, new patient

MPC CPT Code 2	Global	Work RVU	Time Source	Most Recent Medicare Utilization
99202	XXX	0.93	**RUC Time**	3,126,033

CPT Descriptor 2 Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 20 minutes are spent face-to-face with the patient and/or family.

Other Reference CPT Code	Global	Work RVU	Time Source
93925	XXX	0.80	**RUC Time**

CPT Descriptor Duplex scan of lower extremity arteries or arterial bypass grafts; complete bilateral study

---

RELATIONSHIP OF CODE BEING REVIEWED TO TOP TWO KEY REFERENCE SERVICES:
Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the top two chosen key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Top Key Reference Code: 10 **% of respondents:** 26.3 **%**

Number of respondents who choose 2nd Key Reference Code: 5 **% of respondents:** 13.1 **%**

TIME ESTIMATES (Median)

	CPT Code: 96931	Top Key Reference CPT Code: 88305	2nd Key Reference CPT Code: 17315
Median Pre-Service Time	3.00	0.00	0.00
Median Intra-Service Time	25.00	25.00	30.00
Median Immediate Post-service Time	0.00	0.00	0.00
Median Critical Care Time	0.0	0.00	0.00
Median Other Hospital Visit Time	0.0	0.00	0.00
Median Discharge Day Management Time	0.0	0.00	0.00
Median Office Visit Time	0.0	0.00	0.00
Prolonged Services Time	0.0	0.00	0.00
Median Subsequent Observation Care Time	0.0	0.00	0.00
Median Total Time	**28.00**	**25.00**	**30.00**
Other time if appropriate			

INTENSITY/COMPLEXITY MEASURES
(of those that selected Key Reference codes)

Survey respondents are rating the survey code relative to the key reference code.

Intensity & Complexity Rating Scale: (much less= -2.00, somewhat less= -1.00, identical= 0.00, somewhat more= 1.00, much more= 2.00)

	Top Key Ref Code	2nd Key Ref Code
Mental Effort and Judgment (Mean)		
The number of possible diagnosis and/or the number of management options that must be considered	0.90	1.20
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed	1.20	0.80
Urgency of medical decision making	0.80	0.00

Technical Skill/Physical Effort (Mean)

Technical skill required	1.10	0.20
Physical effort required	1.30	0.40

Psychological Stress (Mean)

The risk of significant complications, morbidity and/or mortality	0.50	0.20
Outcome depends on the skill and judgment of physician	1.10	0.40
Estimated risk of malpractice suit with poor outcome	0.80	0.80

INTENSITY/COMPLEXITY MEASURES	Top Key Ref Code	2nd Key Ref Code
Time Segment (Mean)		
Overall intensity/complexity	1.30	0.80

Additional Rationale and Comments

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

THE ADDITIONAL RATIONALE BELOW IS THE ORIGINAL RATIONALE SUBMITTED BY THE SPECIALTY SOCIETY(IES) PRIOR TO THE RUC MEETING AND DOES NOT NECESSARILY REPRESENT THE RATIONALE FOR THE RUC RECOMMENDATION. TO VIEW THE RUC'S RATIONALE, PLEASE REVIEW THE SEPARATE RUC RECOMMENDATION DOCUMENT.

The AAD convened an expert panel to review the survey results and to develop recommendations. It was decided that 93925 is a good additional reference code because it is an imaging code that allows for a PE crosswalk/comparison. The specialty was advised by AMA staff to use an imaging code for PE comparison.

The 25th percentile RVU is 0.90, which seems appropriate, as confirmed with an IWPUT of 0.032, with a 25 minute intra-service time and 5 minutes pre-time. This is consistent with comparable pathology codes and with endomicroscopy code 88375.

Regarding the question of expected frequency that this service will be provided, a subset of dermatologists and dermatopathologists will probably acquire the technology and will frequently perform the service. It is expected that patients will usually be referred to those physicians for RCM, so they will not be providing an E/M on the day of service.

The College of American Pathologists did not get any usable responses using a random survey.

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions:

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   ☐ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.

- ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
- ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
- ☐ Multiple codes are used to maintain consistency with similar codes.
- ☐ Historical precedents.
- ☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) 96999

How often do physicians in your specialty perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty Dermatology How often? Sometimes

Specialty How often?

Specialty How often?

Estimate the number of times this service might be provided nationally in a one-year period? 13000
If the recommendation is from multiple specialties, please provide the frequency and percentage for each specialty. Please explain the rationale for this estimate.

Specialty Frequency Percentage %

Specialty Frequency Percentage %

Specialty Frequency Percentage %

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? 10 If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty. Please explain the rationale for this estimate.

Specialty Frequency Percentage %

Specialty Frequency Percentage %

Specialty Frequency 0 Percentage 0.00 %

Do many physicians perform this service across the United States?

Berenson-Eggers Type of Service (BETOS) Assignment

Please pick the appropriate BETOS classification that best corresponds to the clinical nature of this CPT code. Please select the main BETOS classification and sub-classification to the greatest level of specificity possible.

Main BETOS Classification:

Other

BETOS Sub-classification:
NA

BETOS Sub-classification Level II:
NA

Professional Liability Insurance Information (PLI)

If the surveyed code is an existing code and the specialty believes the specialty utilization mix will not change, enter the surveyed existing CPT code number

If this code is a new/revised code or an existing code in which the specialty utilization mix will change, please select another crosswalk based on a similar specialty mix. 17315

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:96933 Tracking Number BB3 Original Specialty Recommended RVU: **0.90**
Presented Recommended RVU: **0.80**
Global Period: XXX RUC Recommended RVU: **0.80**

CPT Descriptor: Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; interpretation and report only, first lesion

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A 55-year-old male with a history of non-melanoma skin cancer and melanoma and multiple atypical moles is found to have a lesion with one or more clinical and/or historical characteristics highly suggestive of melanoma or other non-melanoma skin cancer. Reflectance confocal microscopy is ordered by the examining dermatologist.

Percentage of Survey Respondents who found Vignette to be Typical: 92%

Site of Service (Complete for 010 and 090 Globals Only)

Percent of survey respondents who stated they perform the procedure; In the hospital 0% , In the ASC 0%, In the office 0%

Percent of survey respondents who stated they typically perform this procedure in the hospital, stated the patient is; Discharged the same day 0% , Overnight stay-less than 24 hours 0% , Overnight stay-more than 24 hours 0%

Percent of survey respondents who stated that if the patient is typically kept overnight also stated that they perform an E&M service later on the same day 0%

Moderate Sedation

Is moderate sedation inherent to this procedure in the Hospital/ASC setting?
Percent of survey respondents who stated moderate sedation is typical in the Hospital/ASC setting? 0%

Is moderate sedation inherent to this procedure in the office setting?
Percent of survey respondents who stated moderate sedation is typical in the office setting? 0%

Description of Pre-Service Work: The physician reviews the clinical history and referral information.

Description of Intra-Service Work: The imaged lesion appears in a list in the software. The lesion is selected for interpretation by the physician. The physician logs into the HIPAA compliant software using a computer with a high resolution graphics card and significant memory for rapid image loading and positioning, clicks on a photo of the lesion, and reviews the pictures and the clinical information. He/she opens up the confocal images in software optimized for viewing RCM images and reviews each mosaic (up to five 8x8mm slices).A diagnostic report is completed. The report would include, in addition to a narrative description, a database link to RCM features related to the diagnosis. These terms can easily be searched to locate specific patients, diseases/condition types, diagnoses, or lesion locations (for example, if a physician wanted to pull up all patient records for lesions on the face diagnosed as melanoma, this would be possible) to optimize the physician's participation in registries that are evolving to meet requirements for quality and outcome measures that are becoming part of the practice of medicine. Finally, representative images are added to the report as appropriate. It is electronically signed and is ready for the interpreting physician to print and discuss with the referring physician. The report is digitally linked to the patient and the specific lesion/images that it corresponds to and is stored as a file at the datacenter for future retrieval.

Description of Post-Service Work:

SURVEY DATA

RUC Meeting Date (mm/yyyy)	10/2015				
Presenter(s):	Mark Kaufmann, MD; Harold Rabinovitz, MD; Jane Grant-Kels, MD				
Specialty(s):	AAD				
CPT Code:	96933				
Sample Size:	72	**Resp N:**	38	**Response:** 52.7 %	
Description of Sample:	List of trained users supplied by the manufacturer.				

	Low	**25th pctl**	**Median***	**75th pctl**	**High**
Service Performance Rate	0.00	0.00	**5.00**	90.00	500.00
Survey RVW:	0.22	0.80	**1.00**	1.84	25.00
Pre-Service Evaluation Time:			**10.00**		
Pre-Service Positioning Time:			**0.00**		
Pre-Service Scrub, Dress, Wait Time:			**0.00**		
Intra-Service Time:	5.00	16.00	**20.00**	29.00	120.00

Immediate Post Service-Time:	**10.00**	
Post Operative Visits	**Total Min****	**CPT Code and Number of Visits**
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.00** 99239x **0.00** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

**Physician standard total minutes per E/M visit: 99291 (70); 99292 (30); 99231 (20); 99232 (40); 99233 (55); 99238(38); 99239 (55); 99217 (38); 99211 (7); 99212 (16); 99213 (23); 99214 (40); 99215 (55); 99224 (20); 99225 (40); 99226 (55); 99354 (60); 99355 (30); 99356 (60); 99357 (30)

Specialty Society Recommended Data

Please, pick the pre-service time package that best corresponds to the data which was collected in the survey process. (Note: your recommended pre time should not exceed your survey median time for any category)

XXX Global Code

CPT Code:	96933	**Recommended Physician Work RVU: 0.80**		
		Specialty Recommended Pre-Service Time	**Specialty Recommended Pre Time Package**	**Adjustments/Recommended Pre-Service Time**
Pre-Service Evaluation Time:		**3.00**	**0.00**	**3.00**
Pre-Service Positioning Time:		**0.00**	**0.00**	**0.00**
Pre-Service Scrub, Dress, Wait Time:		**0.00**	**0.00**	**0.00**
Intra-Service Time:		**25.00**		

Please, pick the post-service time package that best corresponds to the data which was collected in the survey process: (Note: your recommended post time should not exceed your survey median time)

XXX Global Code

	Specialty Recommended Post-Service Time	**Specialty Recommended Post Time Package**	**Adjustments/Recommended Post-Service Time**
Immediate Post Service-Time:	**0.00**	**0.00**	**0.00**

Post-Operative Visits	Total Min**	CPT Code and Number of Visits
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.0** 99239x **0.0** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

Modifier -51 Exempt Status
Is the recommended value for the new/revised procedure based on its modifier -51 exempt status?

New Technology/Service:
Is this new/revised procedure considered to be a new technology or service? Yes

TOP KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
88305	XXX	0.75	**RUC Time**

CPT Descriptor Level IV - Surgical pathology, gross and microscopic examination

SECOND HIGHEST KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
88325	XXX	2.50	**RUC Time**

CPT Descriptor Consultation, comprehensive, with review of records and specimens, with report on referred material

KEY MPC COMPARISON CODES:
Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU	Time Source	Most Recent Medicare Utilization
92002	XXX	0.88	**RUC Time**	223,037

CPT Descriptor 1 Ophthalmological services: medical examination and evaluation with initiation of diagnostic and treatment program; intermediate, new patient

MPC CPT Code 2	Global	Work RVU	Time Source	Most Recent Medicare Utilization
99202	XXX	0.93	**RUC Time**	3,126,033

CPT Descriptor 2 Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 20 minutes are spent face-to-face with the patient and/or family.

Other Reference CPT Code	Global	Work RVU	Time Source
93925	XXX	0.80	**RUC Time**

CPT Descriptor Duplex scan of lower extremity arteries or arterial bypass grafts; complete bilateral study

RELATIONSHIP OF CODE BEING REVIEWED TO TOP TWO KEY REFERENCE SERVICES:
Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the top two chosen key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Top Key Reference Code: 11 **% of respondents:** 28.9 **%**

Number of respondents who choose 2nd Key Reference Code: 5 **% of respondents:** 13.1 **%**

TIME ESTIMATES (Median)

	CPT Code: 96933	**Top Key Reference CPT Code:** 88305	**2nd Key Reference CPT Code:** **88325**
Median Pre-Service Time	3.00	0.00	0.00
Median Intra-Service Time	25.00	25.00	80.00
Median Immediate Post-service Time	0.00	0.00	0.00
Median Critical Care Time	0.0	0.00	0.00
Median Other Hospital Visit Time	0.0	0.00	0.00
Median Discharge Day Management Time	0.0	0.00	0.00
Median Office Visit Time	0.0	0.00	0.00
Prolonged Services Time	0.0	0.00	0.00
Median Subsequent Observation Care Time	0.0	0.00	0.00
Median Total Time	**28.00**	**25.00**	**80.00**
Other time if appropriate			

INTENSITY/COMPLEXITY MEASURES
(of those that selected Key Reference codes)

Survey respondents are rating the survey code relative to the key reference code.

Intensity & Complexity Rating Scale: (much less= -2.00, somewhat less= -1.00, identical= 0.00, somewhat more= 1.00, much more= 2.00)

	Top Key Ref Code	**2nd Key Ref Code**
Mental Effort and Judgment (Mean)		
The number of possible diagnosis and/or the number of management options that must be considered	1.27	0.40
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed	1.36	0.60
Urgency of medical decision making	1.18	0.60
Technical Skill/Physical Effort (Mean)		
Technical skill required	1.09	1.20

Physical effort required	1.09	1.20

Psychological Stress (Mean)

The risk of significant complications, morbidity and/or mortality	0.91	0.20
Outcome depends on the skill and judgment of physician	1.09	0.60
Estimated risk of malpractice suit with poor outcome	1.18	0.80

INTENSITY/COMPLEXITY MEASURES	**Top Key Ref Code**	**2nd Key Ref Code**

Time Segment (Mean)

Overall intensity/complexity	1.18	1.40

Additional Rationale and Comments

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

THE ADDITIONAL RATIONALE BELOW IS THE ORIGINAL RATIONALE SUBMITTED BY THE SPECIALTY SOCIETY(IES) PRIOR TO THE RUC MEETING AND DOES NOT NECESSARILY REPRESENT THE RATIONALE FOR THE RUC RECOMMENDATION. TO VIEW THE RUC'S RATIONALE, PLEASE REVIEW THE SEPARATE RUC RECOMMENDATION DOCUMENT.

The AAD convened an expert panel to review the survey results and to develop recommendations. It was decided that 93925 is a good additional reference code because it is an imaging code that allows for a PE crosswalk/comparison. The specialty was advised by AMA staff to use an imaging code for PE comparison.

Since the physician work involved in 96931 and 96933 is the same, the panel concluded that the work RVU and the times for the two codes should also be identical. The difference between the two codes is the technical component, which involves only direct PE. This is between the 25th percentile and the median work RVU estimates found in the survey. Times or RVUs other than those assigned to 96931 will result in a rank order anomaly.

Regarding the question of expected frequency that this service will be provided, a subset of dermatologists and dermatopathologists will probably acquire the technology and will frequently perform the service. It is expected that patients will usually be referred to those physicians for RCM, so they will not be providing an E/M on the day of service.

The College of American Pathologists did not get any usable responses using a random survey.

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions:

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☐ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.

☐ Historical precedents.
☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) 96999

How often do physicians in your specialty perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty Dermatology How often? Sometimes

Specialty How often?

Specialty How often?

Estimate the number of times this service might be provided nationally in a one-year period? 13000
If the recommendation is from multiple specialties, please provide the frequency and percentage for each specialty. Please explain the rationale for this estimate.

Specialty Frequency Percentage %

Specialty Frequency Percentage %

Specialty Frequency Percentage %

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? 10 If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty. Please explain the rationale for this estimate.

Specialty Frequency Percentage %

Specialty Frequency Percentage %

Specialty Frequency 0 Percentage 0.00 %

Do many physicians perform this service across the United States?

Berenson-Eggers Type of Service (BETOS) Assignment
Please pick the appropriate BETOS classification that best corresponds to the clinical nature of this CPT code. Please select the main BETOS classification and sub-classification to the greatest level of specificity possible.

Main BETOS Classification:
Other

BETOS Sub-classification:
NA

BETOS Sub-classification Level II:
NA

Professional Liability Insurance Information (PLI)

If the surveyed code is an existing code and the specialty believes the specialty utilization mix will not change, enter the surveyed existing CPT code number

If this code is a new/revised code or an existing code in which the specialty utilization mix will change, please select another crosswalk based on a similar specialty mix. 17315

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:96934 Tracking Number BB4 Original Specialty Recommended RVU: **0.79**
Presented Recommended RVU: **0.76**
Global Period: ZZZ RUC Recommended RVU: **0.76**

CPT Descriptor: Reflectance confocal microscopy (rcm) for cellular and sub-cellular imaging of skin; image acquisition and interpretation and report, each additional lesion (list separately in addition to primary procedure) / (use 96934 in conjunction with 96931)

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A 55-year-old male with a history of non-melanoma skin cancer and melanoma and multiple atypical moles is found to have five lesions with one or more clinical and/or historical characteristics highly suggestive of melanoma or other non-melanoma skin cancer. Following imaging of the first lesion, additional imaging is requested on an additional to obtain data for the high-risk lesions in question in an effort to confirm or to rule out melanoma or other non-melanoma skin cancer.

Percentage of Survey Respondents who found Vignette to be Typical: 94%

Site of Service (Complete for 010 and 090 Globals Only)

Percent of survey respondents who stated they perform the procedure; In the hospital 0% , In the ASC 0%, In the office 0%

Percent of survey respondents who stated they typically perform this procedure in the hospital, stated the patient is; Discharged the same day 0% , Overnight stay-less than 24 hours 0% , Overnight stay-more than 24 hours 0%

Percent of survey respondents who stated that if the patient is typically kept overnight also stated that they perform an E&M service later on the same day 0%

Moderate Sedation

Is moderate sedation inherent to this procedure in the Hospital/ASC setting?
Percent of survey respondents who stated moderate sedation is typical in the Hospital/ASC setting? 0%

Is moderate sedation inherent to this procedure in the office setting?
Percent of survey respondents who stated moderate sedation is typical in the office setting? 0%

Description of Pre-Service Work:

Description of Intra-Service Work: The imaged lesion appears in a list in the software. The lesion is selected for interpretation by the physician. The physician logs into the HIPAA compliant software using a computer with a high resolution graphics card and significant memory for rapid image loading and positioning, clicks on a photo of the lesion, and reviews the pictures and the clinical information. He/she opens up the confocal images in software optimized for viewing RCM images and reviews each mosaic (up to five 8x8mm slices).A diagnostic report is completed. The report would include, in addition to a narrative description, a database link to RCM features related to the diagnosis. These terms can easily be searched to locate specific patients, diseases/condition types, diagnoses, or lesion locations (for example, if a physician wanted to pull up all patient records for lesions on the face diagnosed as melanoma, this would be possible) to optimize the physician's participation in registries that are evolving to meet requirements for quality and outcome measures that are becoming part of the practice of medicine. Finally, representative images are added to the report as appropriate. It is electronically signed and is ready for the interpreting physician to print and discuss with the referring physician. The report is digitally linked to the patient and the specific lesion/images that it corresponds to and is stored as a file at the datacenter for future retrieval.

Description of Post-Service Work:

SURVEY DATA

RUC Meeting Date (mm/yyyy)	10/2015		
Presenter(s):	Mark Kaufmann, MD; Harold Rabinovitz, MD; Jane Grant-Kels, MD		
Specialty(s):	AAD		
CPT Code:	96934		
Sample Size:	72	**Resp N:** 36	**Response:** 50.0 %
Description of Sample:	List of trained users supplied by the manufacturer.		

	Low	25th pctl	Median*	75th pctl	High
Service Performance Rate	0.00	0.00	**5.00**	53.00	500.00
Survey RVW:	0.40	0.79	**1.00**	2.00	25.00
Pre-Service Evaluation Time:			**0.00**		
Pre-Service Positioning Time:			**0.00**		
Pre-Service Scrub, Dress, Wait Time:			**0.00**		
Intra-Service Time:	10.00	20.00	**25.00**	39.00	90.00

Immediate Post Service-Time:	**0.00**	
Post Operative Visits	**Total Min****	**CPT Code and Number of Visits**
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.00** 99239x **0.00** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

**Physician standard total minutes per E/M visit: 99291 (70); 99292 (30); 99231 (20); 99232 (40); 99233 (55); 99238(38); 99239 (55); 99217 (38); 99211 (7); 99212 (16); 99213 (23); 99214 (40); 99215 (55); 99224 (20); 99225 (40); 99226 (55); 99354 (60); 99355 (30); 99356 (60); 99357 (30)

Specialty Society Recommended Data

Please, pick the pre-service time package that best corresponds to the data which was collected in the survey process. (Note: your recommended pre time should not exceed your survey median time for any category)

ZZZ Global Code

CPT Code:	96934	**Recommended Physician Work RVU: 0.76**		
		Specialty Recommended Pre-Service Time	**Specialty Recommended Pre Time Package**	**Adjustments/Recommended Pre-Service Time**
Pre-Service Evaluation Time:		**0.00**	**0.00**	**0.00**
Pre-Service Positioning Time:		**0.00**	**0.00**	**0.00**
Pre-Service Scrub, Dress, Wait Time:		**0.00**	**0.00**	**0.00**
Intra-Service Time:		**25.00**		

Please, pick the post-service time package that best corresponds to the data which was collected in the survey process: (Note: your recommended post time should not exceed your survey median time)

ZZZ Global Code

	Specialty Recommended Post-Service Time	**Specialty Recommended Post Time Package**	**Adjustments/Recommended Post-Service Time**
Immediate Post Service-Time:	**0.00**	**0.00**	**0.00**

Post-Operative Visits	Total Min**	CPT Code and Number of Visits
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.0** 99239x **0.0** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

Modifier -51 Exempt Status
Is the recommended value for the new/revised procedure based on its modifier -51 exempt status?

New Technology/Service:
Is this new/revised procedure considered to be a new technology or service? Yes

TOP KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
88305	XXX	0.75	**RUC Time**

CPT Descriptor Level IV - Surgical pathology, gross and microscopic examination

SECOND HIGHEST KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
88325	XXX	2.50	**RUC Time**

CPT Descriptor Consultation, comprehensive, with review of records and specimens, with report on referred material

KEY MPC COMPARISON CODES:
Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU	Time Source	Most Recent Medicare Utilization
99231	XXX	0.76	**RUC Time**	10,805,487

CPT Descriptor 1 Subsequent hospital care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A problem focused interval history; A problem focused examination; Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is stable, recovering or improving. Typically, 15 minutes are spent at the bedside and on the patient's hospital floor or unit.

MPC CPT Code 2	Global	Work RVU	Time Source	Most Recent Medicare Utilization
51797	ZZZ	0.80	**RUC Time**	142,263

CPT Descriptor 2 Voiding pressure studies, intra-abdominal (ie, rectal, gastric, intraperitoneal) (List separately in addition to code for primary procedure)

Other Reference CPT Code	Global	Work RVU	Time Source
93925	XXX	0.80	**RUC Time**

CPT Descriptor Duplex scan of lower extremity arteries or arterial bypass grafts; complete bilateral study

RELATIONSHIP OF CODE BEING REVIEWED TO TOP TWO KEY REFERENCE SERVICES:
Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the top two chosen key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Top Key Reference Code: 11 **% of respondents:** 30.5 **%**

Number of respondents who choose 2nd Key Reference Code: 5 **% of respondents:** 13.8 **%**

TIME ESTIMATES (Median)

	CPT Code: 96934	Top Key Reference CPT Code: 88305	2nd Key Reference CPT Code: **88325**
Median Pre-Service Time	0.00	0.00	0.00
Median Intra-Service Time	25.00	25.00	80.00
Median Immediate Post-service Time	0.00	0.00	0.00
Median Critical Care Time	0.0	0.00	0.00
Median Other Hospital Visit Time	0.0	0.00	0.00
Median Discharge Day Management Time	0.0	0.00	0.00
Median Office Visit Time	0.0	0.00	0.00
Prolonged Services Time	0.0	0.00	0.00
Median Subsequent Observation Care Time	0.0	0.00	0.00
Median Total Time	**25.00**	**25.00**	**80.00**
Other time if appropriate			

INTENSITY/COMPLEXITY MEASURES
(of those that selected Key Reference codes)

Survey respondents are rating the survey code relative to the key reference code.

Intensity & Complexity Rating Scale: (much less= -2.00, somewhat less= -1.00, identical= 0.00, somewhat more= 1.00, much more= 2.00)

	Top Key Ref Code	2nd Key Ref Code
Mental Effort and Judgment (Mean)		
The number of possible diagnosis and/or the number of management options that must be considered	1.27	0.40
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed	1.36	0.60
Urgency of medical decision making	1.18	0.60
Technical Skill/Physical Effort (Mean)		
Technical skill required	1.09	1.20

Physical effort required	1.09	1.20

Psychological Stress (Mean)

The risk of significant complications, morbidity and/or mortality	0.91	0.20
Outcome depends on the skill and judgment of physician	1.09	0.60
Estimated risk of malpractice suit with poor outcome	1.18	0.80

INTENSITY/COMPLEXITY MEASURES	**Top Key Ref Code**	**2nd Key Ref Code**
Time Segment (Mean)		
Overall intensity/complexity	1.18	1.40

Additional Rationale and Comments

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

THE ADDITIONAL RATIONALE BELOW IS THE ORIGINAL RATIONALE SUBMITTED BY THE SPECIALTY SOCIETY(IES) PRIOR TO THE RUC MEETING AND DOES NOT NECESSARILY REPRESENT THE RATIONALE FOR THE RUC RECOMMENDATION. TO VIEW THE RUC'S RATIONALE, PLEASE REVIEW THE SEPARATE RUC RECOMMENDATION DOCUMENT.

The AAD convened an expert panel to review the survey results and to develop recommendations. It was decided that 93925 is a good additional reference code because it is an imaging code that allows for a PE crosswalk/comparison. AMA staff recommended using an imaging code for PE comparison.

Though the intra-service work involved with 96934 is identical to the work in 96931, 96931 involves the 5 minutes of pre-time work for reviewing the clinical history and referral information. The panel concluded that the RVU value of 96934 should be 0.79, which is the 25th percentile of the survey. It is also the value identified using the reverse building block method. 96934 should be less than 96931 by (5 min x 0.0224 RVU/min) = 0.11 RVU.

Regarding the question of expected frequency that this service will be provided, a subset of dermatologists and dermatopathologists will probably acquire the technology and will frequently perform the service. It is expected that patients will usually be referred to those physicians for RCM, so they will not be providing an E/M on the day of service.

The College of American Pathologists did not get any usable responses using a random survey.

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions:

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☐ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.

☐ Historical precedents.
☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) 96999

How often do physicians in your specialty perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty Dermatology How often? Sometimes

Specialty How often?

Specialty How often?

Estimate the number of times this service might be provided nationally in a one-year period? 5000
If the recommendation is from multiple specialties, please provide the frequency and percentage for each specialty. Please explain the rationale for this estimate.

Specialty Frequency Percentage %

Specialty Frequency Percentage %

Specialty Frequency Percentage %

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? 10 If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty. Please explain the rationale for this estimate.

Specialty Frequency Percentage %

Specialty Frequency Percentage %

Specialty Frequency 0 Percentage 0.00 %

Do many physicians perform this service across the United States?

Berenson-Eggers Type of Service (BETOS) Assignment
Please pick the appropriate BETOS classification that best corresponds to the clinical nature of this CPT code. Please select the main BETOS classification and sub-classification to the greatest level of specificity possible.

Main BETOS Classification:
Other

BETOS Sub-classification:
NA

BETOS Sub-classification Level II:
NA

Professional Liability Insurance Information (PLI)

If the surveyed code is an existing code and the specialty believes the specialty utilization mix will not change, enter the surveyed existing CPT code number

If this code is a new/revised code or an existing code in which the specialty utilization mix will change, please select another crosswalk based on a similar specialty mix. 17315

AMA/SPECIALTY SOCIETY RVS UPDATE PROCESS
SUMMARY OF RECOMMENDATION

CPT Code:96936 Tracking Number BB6 Original Specialty Recommended RVU: **0.79**
Presented Recommended RVU: **0.76**
Global Period: ZZZ RUC Recommended RVU: **0.76**

CPT Descriptor: Reflectance confocal microscopy (rcm) for cellular and sub-cellular imaging of skin; interpretation and report only, each additional lesion (list separately in addition to primary procedure) / (use 96936 in conjunction with 96933)

CLINICAL DESCRIPTION OF SERVICE:

Vignette Used in Survey: A 55-year-old male with a history of non-melanoma skin cancer and melanoma and multiple atypical moles is found to have five lesions with one or more clinical and/or historical characteristics highly suggestive of melanoma or other non-melanoma skin cancer. Following imaging of the first lesion, additional imaging is requested on an additional to obtain data for the high-risk lesions in question in an effort to confirm or to rule out melanoma or other non-melanoma skin cancer.

Percentage of Survey Respondents who found Vignette to be Typical: 94%

Site of Service (Complete for 010 and 090 Globals Only)

Percent of survey respondents who stated they perform the procedure; In the hospital 0% , In the ASC 0%, In the office 0%

Percent of survey respondents who stated they typically perform this procedure in the hospital, stated the patient is; Discharged the same day 0% , Overnight stay-less than 24 hours 0% , Overnight stay-more than 24 hours 0%

Percent of survey respondents who stated that if the patient is typically kept overnight also stated that they perform an E&M service later on the same day 0%

Moderate Sedation

Is moderate sedation inherent to this procedure in the Hospital/ASC setting?
Percent of survey respondents who stated moderate sedation is typical in the Hospital/ASC setting? 0%

Is moderate sedation inherent to this procedure in the office setting?
Percent of survey respondents who stated moderate sedation is typical in the office setting? 0%

Description of Pre-Service Work:

Description of Intra-Service Work: The imaged lesion appears in a list in the software. The lesion is selected for interpretation by the physician. The physician logs into the HIPAA compliant software using a computer with a high resolution graphics card and significant memory for rapid image loading and positioning, clicks on a photo of the lesion, and reviews the pictures and the clinical information. He/she opens up the confocal images in software optimized for viewing RCM images and reviews each mosaic (up to five 8x8mm slices).A diagnostic report is completed. The report would include, in addition to a narrative description, a database link to RCM features related to the diagnosis. These terms can easily be searched to locate specific patients, diseases/condition types, diagnoses, or lesion locations (for example, if a physician wanted to pull up all patient records for lesions on the face diagnosed as melanoma, this would be possible) to optimize the physician's participation in registries that are evolving to meet requirements for quality and outcome measures that are becoming part of the practice of medicine. Finally, representative images are added to the report as appropriate. It is electronically signed and is ready for the interpreting physician to print and discuss with the referring physician. The report is digitally linked to the patient and the specific lesion/images that it corresponds to and is stored as a file at the datacenter for future retrieval.

Description of Post-Service Work:

SURVEY DATA

RUC Meeting Date (mm/yyyy)	10/2015				
Presenter(s):	Mark Kaufmann, MD; Harold Rabinovitz, MD; Jane Grant-Kels, MD				
Specialty(s):	AAD				
CPT Code:	96936				
Sample Size:	72	**Resp N:**	37	**Response:** 51.3 %	
Description of Sample:	List of trained users supplied by the manufacturer.				

	Low	25th pctl	Median*	75th pctl	High
Service Performance Rate	0.00	0.00	**2.00**	35.00	500.00
Survey RVW:	0.22	0.76	**1.00**	1.75	25.00
Pre-Service Evaluation Time:			**0.00**		
Pre-Service Positioning Time:			**0.00**		
Pre-Service Scrub, Dress, Wait Time:			**0.00**		
Intra-Service Time:	5.00	16.00	**25.00**	30.00	60.00

Immediate Post Service-Time:	**0.00**	
Post Operative Visits	**Total Min****	**CPT Code and Number of Visits**
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.00** 99239x **0.00** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

**Physician standard total minutes per E/M visit: 99291 (70); 99292 (30); 99231 (20); 99232 (40); 99233 (55); 99238(38); 99239 (55); 99217 (38); 99211 (7); 99212 (16); 99213 (23); 99214 (40); 99215 (55); 99224 (20); 99225 (40); 99226 (55); 99354 (60); 99355 (30); 99356 (60); 99357 (30)

Specialty Society Recommended Data

Please, pick the pre-service time package that best corresponds to the data which was collected in the survey process. (Note: your recommended pre time should not exceed your survey median time for any category)

ZZZ Global Code

CPT Code:	96936	**Recommended Physician Work RVU: 0.76**		
		Specialty Recommended Pre-Service Time	**Specialty Recommended Pre Time Package**	**Adjustments/Recommended Pre-Service Time**
Pre-Service Evaluation Time:		**0.00**	**0.00**	**0.00**
Pre-Service Positioning Time:		**0.00**	**0.00**	**0.00**
Pre-Service Scrub, Dress, Wait Time:		**0.00**	**0.00**	**0.00**
Intra-Service Time:		**25.00**		

Please, pick the post-service time package that best corresponds to the data which was collected in the survey process: (Note: your recommended post time should not exceed your survey median time)

ZZZ Global Code

	Specialty Recommended Post-Service Time	**Specialty Recommended Post Time Package**	**Adjustments/Recommended Post-Service Time**
Immediate Post Service-Time:	**0.00**	**0.00**	**0.00**

Post-Operative Visits	Total Min**	CPT Code and Number of Visits
Critical Care time/visit(s):	**0.00**	99291x **0.00** 99292x **0.00**
Other Hospital time/visit(s):	**0.00**	99231x **0.00** 99232x **0.00** 99233x **0.00**
Discharge Day Mgmt:	**0.00**	99238x **0.0** 99239x **0.0** 99217x **0.00**
Office time/visit(s):	**0.00**	99211x **0.00** 12x **0.00** 13x **0.00** 14x **0.00** 15x **0.00**
Prolonged Services:	**0.00**	99354x **0.00** 55x **0.00** 56x **0.00** 57x **0.00**
Sub Obs Care:	**0.00**	99224x **0.00** 99225x **0.00** 99226x **0.00**

Modifier -51 Exempt Status
Is the recommended value for the new/revised procedure based on its modifier -51 exempt status?

New Technology/Service:
Is this new/revised procedure considered to be a new technology or service? Yes

TOP KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
88305	XXX	0.75	**RUC Time**

CPT Descriptor Level IV - Surgical pathology, gross and microscopic examination

SECOND HIGHEST KEY REFERENCE SERVICE:

Key CPT Code	Global	Work RVU	Time Source
88321	XXX	1.63	**RUC Time**

CPT Descriptor Consultation and report on referred slides prepared elsewhere

KEY MPC COMPARISON CODES:
Compare the surveyed code to codes on the RUC's MPC List. Reference codes from the MPC list should be chosen, if appropriate that have relative values higher and lower than the requested relative values for the code under review.

MPC CPT Code 1	Global	Work RVU	Time Source	Most Recent Medicare Utilization
99231	XXX	0.76	**RUC Time**	10,805,487

CPT Descriptor 1 Subsequent hospital care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A problem focused interval history; A problem focused examination; Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is stable, recovering or improving. Typically, 15 minutes are spent at the bedside and on the patient's hospital floor or unit.

MPC CPT Code 2	Global	Work RVU	Time Source	Most Recent Medicare Utilization
51797	ZZZ	0.80	**RUC Time**	142,263

CPT Descriptor 2 Voiding pressure studies, intra-abdominal (ie, rectal, gastric, intraperitoneal) (List separately in addition to code for primary procedure)

Other Reference CPT Code	Global	Work RVU	Time Source
93925	XXX	0.80	**RUC Time**

CPT Descriptor Duplex scan of lower extremity arteries or arterial bypass grafts; complete bilateral study

RELATIONSHIP OF CODE BEING REVIEWED TO TOP TWO KEY REFERENCE SERVICES:
Compare the pre-, intra-, and post-service time (by the median) and the intensity factors (by the mean) of the service you are rating to the top two chosen key reference services listed above. **Make certain that you are including existing time data (RUC if available, Harvard if no RUC time available) for the reference code listed below.**

Number of respondents who choose Top Key Reference Code: 14 **% of respondents:** 37.8 **%**

Number of respondents who choose 2nd Key Reference Code: 5 **% of respondents:** 13.5 **%**

TIME ESTIMATES (Median)

	CPT Code: 96936	Top Key Reference CPT Code: 88305	2nd Key Reference CPT Code: **88321**
Median Pre-Service Time	0.00	0.00	0.00
Median Intra-Service Time	25.00	25.00	50.00
Median Immediate Post-service Time	0.00	0.00	0.00
Median Critical Care Time	0.0	0.00	0.00
Median Other Hospital Visit Time	0.0	0.00	0.00
Median Discharge Day Management Time	0.0	0.00	0.00
Median Office Visit Time	0.0	0.00	0.00
Prolonged Services Time	0.0	0.00	0.00
Median Subsequent Observation Care Time	0.0	0.00	0.00
Median Total Time	**25.00**	**25.00**	**50.00**
Other time if appropriate			

INTENSITY/COMPLEXITY MEASURES
(of those that selected Key Reference codes)

Survey respondents are rating the survey code relative to the key reference code.

Intensity & Complexity Rating Scale: (much less= -2.00, somewhat less= -1.00, identical= 0.00, somewhat more= 1.00, much more= 2.00)

	Top Key Ref Code	2nd Key Ref Code
Mental Effort and Judgment (Mean)		
The number of possible diagnosis and/or the number of management options that must be considered	1.14	0.00
The amount and/or complexity of medical records, diagnostic tests, and/or other information that must be reviewed and analyzed	1.36	0.40
Urgency of medical decision making	1.21	0.20
Technical Skill/Physical Effort (Mean)		
Technical skill required	1.00	1.00

Physical effort required	1.21	1.00

Psychological Stress (Mean)

The risk of significant complications, morbidity and/or mortality	0.93	0.40
Outcome depends on the skill and judgment of physician	1.00	0.60
Estimated risk of malpractice suit with poor outcome	1.21	0.80

INTENSITY/COMPLEXITY MEASURES	**Top Key Ref Code**	**2nd Key Ref Code**

Time Segment (Mean)

Overall intensity/complexity	1.14	0.80

Additional Rationale and Comments

Describe the process by which your specialty society reached your final recommendation. *If your society has used an IWPUT analysis, please refer to the Instructions for Specialty Societies Developing Work Relative Value Recommendations for the appropriate formula and format.*

THE ADDITIONAL RATIONALE BELOW IS THE ORIGINAL RATIONALE SUBMITTED BY THE SPECIALTY SOCIETY(IES) PRIOR TO THE RUC MEETING AND DOES NOT NECESSARILY REPRESENT THE RATIONALE FOR THE RUC RECOMMENDATION. TO VIEW THE RUC'S RATIONALE, PLEASE REVIEW THE SEPARATE RUC RECOMMENDATION DOCUMENT.

The AAD convened an expert panel to review the survey results and to develop recommendations. It was decided that 93925 is a good additional reference code because it is an imaging code that allows a PE crosswalk/comparison. AMA staff recommended using an imaging code for PE comparison.

Since the physician work involved in 96934and 96936 is the same, the panel concluded that the work RVU and the times for the two codes should also be identical, 0.79 RVU. This is slightly above the 25th percentile value of 0.76 RVU. The difference between the two codes is the technical component, which involves only direct PE.

Regarding the question of expected frequency that this service will be provided, a subset of dermatologists and dermatopathologists will probably acquire the technology and will frequently perform the service. It is expected that patients will usually be referred to those physicians for RCM, so they will not be providing an E/M on the day of service.

The College of American Pathologists did not get any usable responses using a random survey.

SERVICES REPORTED WITH MULTIPLE CPT CODES

1. Is this code typically reported on the same date with other CPT codes? If yes, please respond to the following questions:

   Why is the procedure reported using multiple codes instead of just one code? (Check all that apply.)

   - ☐ The surveyed code is an add-on code or a base code expected to be reported with an add-on code.
   - ☐ Different specialties work together to accomplish the procedure; each specialty codes its part of the physician work using different codes.
   - ☐ Multiple codes allow flexibility to describe exactly what components the procedure included.
   - ☐ Multiple codes are used to maintain consistency with similar codes.
   - ☐ Historical precedents.

☐ Other reason (please explain)

2. Please provide a table listing the typical scenario where this code is reported with multiple codes. Include the CPT codes, global period, work RVUs, pre, intra, and post-time for each, summing all of these data and accounting for relevant multiple procedure reduction policies. If more than one physician is involved in the provision of the total service, please indicate which physician is performing and reporting each CPT code in your scenario.

FREQUENCY INFORMATION

How was this service previously reported? (if unlisted code, please ensure that the Medicare frequency for this unlisted code is reviewed) 96999

How often do physicians in your specialty perform this service? (ie. commonly, sometimes, rarely)
If the recommendation is from multiple specialties, please provide information for each specialty.

Specialty Dermatology How often? Sometimes

Specialty How often?

Specialty How often?

Estimate the number of times this service might be provided nationally in a one-year period? 5000
If the recommendation is from multiple specialties, please provide the frequency and percentage for each specialty. Please explain the rationale for this estimate.

Specialty Frequency Percentage %

Specialty Frequency Percentage %

Specialty Frequency Percentage %

Estimate the number of times this service might be **provided to Medicare patients** nationally in a one-year period? 10 If this is a recommendation from multiple specialties please estimate frequency and percentage for each specialty. Please explain the rationale for this estimate.

Specialty Frequency Percentage %

Specialty Frequency Percentage %

Specialty Frequency 0 Percentage 0.00 %

Do many physicians perform this service across the United States?

Berenson-Eggers Type of Service (BETOS) Assignment

Please pick the appropriate BETOS classification that best corresponds to the clinical nature of this CPT code. Please select the main BETOS classification and sub-classification to the greatest level of specificity possible.

Main BETOS Classification:
Other

BETOS Sub-classification:
NA

BETOS Sub-classification Level II:
NA

Professional Liability Insurance Information (PLI)

If the surveyed code is an existing code and the specialty believes the specialty utilization mix will not change, enter the surveyed existing CPT code number

If this code is a new/revised code or an existing code in which the specialty utilization mix will change, please select another crosswalk based on a similar specialty mix. 17315

SS Rec Summary

ISSUE: Reflectance Confocal Microscopy (96931 - 96936)

TAB: 6

Source	CPT	DESC	Resp	IWPUT	RVW MIN	RVW 25th	RVW MED	RVW 75th	RVW MAX	Total Time	PRE-TIME EVAL	PRE-TIME POSIT	PRE-TIME SDW	INTRA-TIME MIN	INTRA-TIME 25th	INTRA-TIME MED	INTRA-TIME 75th	INTRA-TIME MAX	IMMD POST	FAC-inpt/same day 91	92	33	32	31	38	39	FAC-obs 26	25	24	17	Office 15	14	13	12	11	Prolonged 54	55	56	57
REF	88305	Level IV - Surgical pa		0.030			0.75			25						25																						
CURRENT				#DIV/0!						0																												
SVY	96931	Reflectance c	38	0.028	0.45	0.90	1.15	2.00	25.00	45	10			10	20	25	34	120	10																			
REC	96931	Reflectance c	38	0.029			0.80			28	3					25																						

Source	CPT	DESC	Resp	IWPUT	RVW MIN	RVW 25th	RVW MED	RVW 75th	RVW MAX	Total Time	PRE-TIME EVAL	PRE-TIME POSIT	PRE-TIME SDW	INTRA-TIME MIN	INTRA-TIME 25th	INTRA-TIME MED	INTRA-TIME 75th	INTRA-TIME MAX	IMMD POST	FAC-inpt/same day 91	92	33	32	31	38	39	FAC-obs 26	25	24	17	Office 15	14	13	12	11	Prolonged 54	55	56	57
REF	88305	Level IV - Surgical pa		0.030			0.75			25						25																						
CURRENT				#DIV/0!						0																												
SVY	96933	Reflectance c	38	0.028	0.22	0.80	1.00	1.84	25.00	40	10			5	16	20	29	120	10																			
REC	96933	Reflectance c	38	0.029			0.80			28	3					25																						

Source	CPT	DESC	Resp	IWPUT	RVW MIN	RVW 25th	RVW MED	RVW 75th	RVW MAX	Total Time	PRE-TIME EVAL	PRE-TIME POSIT	PRE-TIME SDW	INTRA-TIME MIN	INTRA-TIME 25th	INTRA-TIME MED	INTRA-TIME 75th	INTRA-TIME MAX	IMMD POST	FAC-inpt/same day 91	92	33	32	31	38	39	FAC-obs 26	25	24	17	Office 15	14	13	12	11	Prolonged 54	55	56	57
REF	88305	Level IV - Surgical pa		0.030			0.75			25						25																						
CURRENT				#DIV/0!						0																												
SVY	96934	Reflectance c	36	0.040	0.40	0.79	1.00	2.00	25.00	25				10	20	25	39	90																				
REC	96934	Reflectance c	36	0.030			0.76			25						25																						

Source	CPT	DESC	Resp	IWPUT	RVW MIN	RVW 25th	RVW MED	RVW 75th	RVW MAX	Total Time	PRE-TIME EVAL	PRE-TIME POSIT	PRE-TIME SDW	INTRA-TIME MIN	INTRA-TIME 25th	INTRA-TIME MED	INTRA-TIME 75th	INTRA-TIME MAX	IMMD POST	FAC-inpt/same day 91	92	33	32	31	38	39	FAC-obs 26	25	24	17	Office 15	14	13	12	11	Prolonged 54	55	56	57
REF	88305	Level IV - Surgical pa		0.030			0.75			25						25																						
CURRENT				#DIV/0!						0																												
SVY	96936	Reflectance c	37	0.040	0.22	0.76	1.00	1.75	25.00	25				5	16	25	30	60																				
REC	96936	Reflectance c	37	0.030			0.76			25						25																						

16
Tab Number

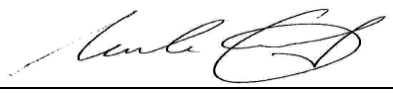
Reflectance Confocal Microscopy
Issue

969XX1, 96XX3, 969XX4 and 969XX6
Code Range

Attestation Statement

This form needs to be completed by any **RUC Advisor** whose specialty society is developing a recommendation to be reviewed by the RUC.

As a RUC Advisor, I attest that the integrity of the RUC survey, summary of recommendation forms and practice expense recommendations are based on accurate and complete data to the best of my knowledge. As a RUC advisor, I acknowledge that violations would be addressed by the executive committee (i.e., RUC Chair , AMA Representative and Alternate AMA Representative.)



Signature

Mark Kaufman, M.D.

Printed Signature

American Academy of Dermatology

Specialty Society

March 31, 2015

Date

AMA/Specialty Society RVS Update Committee (RUC)
Vendor/Company Attestation Statement

This form needs to be completed by an authorized representative of any **Vendor or Company** that makes, markets or distributes a product or device utilized in performing the service being surveyed by the AMA/Specialty Society RVS Update Committee (RUC), as part of its CPT® code survey and valuation process, and which has supplied a list of users of such products or devices in connection with the survey and valuation process.

By submitting to the RUC a list of users of the undersigned's product or device as part of the RUC's CPT® code survey and valuation process, I attest that no employee, affiliate, or agent of the undersigned has contacted, and further covenant that they will not contact, any such user in connection with the survey. I hereby represent and warrant that I have the authority to sign this statement on behalf of the undersigned company and that the information herein is true and accurate. I understand that any false or inaccurate information will render the survey invalid, harming both the undersigned and the physicians who use the product or device.

969XX1, Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin, first lesion; image acquisition and interpretation and report
969XX3, Image acquisition only
969XX4, Interpretation and report only
969XX2, Image acquisition and interpretation and report, each additional lesion (list separately in addition to primary procedure)
969XX5, Image acquisition only, each additional lesion
969XX6, Interpretation and report only, each additional lesion

CPT® Codes

Caliber Imaging and Diagnostics

Vendor/Company Name

By: Christi Alossi Fox

Christi Alossi Fox
Printed Signature

Vice President of Clinical Development
Title

2/23/15
Date

CPT Code: 96931, 96933, 96934, and 96936
Specialty Society('s) _AAD

AMA/Specialty Society Update Process
Practice Expense Summary of Recommendation
Facility Direct Inputs

CPT Long Descriptor:

96931 Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin, first lesion; image acquisition and interpretation and report

96933 Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin, first lesion; interpretation and report only

96934 Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; image acquisition and interpretation and report, each additional lesion (List separately in addition to primary procedure)

96936 Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; interpretation and report only, each additional lesion (List separately in addition to primary procedure)

Global Period: _XXX_and ZZZ___ Meeting Date: __April 2015_____

1. Please provide a brief description of the process used to develop your recommendation and the composition of your Specialty Society Practice Expense Committee:

American Academy of Dermatology convened a consensus panel to finalize the practice expense data for the RCM Codes.

2. You must provide reference code(s) for comparison on your spreadsheet. **If the code you are making recommendations on is a revised code you must use the current PE direct inputs for the code as your comparison.** You must provide an explanation for the selection of reference codes. Reference Code Rationale:

Per AMA staff advise, we selected code 93925 (Duplex scan of lower extremity arteries or arterial bypass grafts; complete bilateral study) as our reference code to compare it with the RCM codes because it is also an imaging code and a similar procedure. The clinical labor activities are similar to the new RCM codes.

3. If you are recommending more minutes than the PE Subcommittee standards you must provide evidence to justify the time:
N/A

4. If you are requesting an increase over the current inputs in clinical staff time, supplies or equipment you must provide compelling evidence:
N/A

5. Please describe in detail the clinical activities of your staff:

Pre-Service Clinical Labor Activities:

The lesion is circled and the patient is moved to a room where the RCM resides. A technician creates a patient record in the RCM software on the dedicated, imaging system workstation, by entering the patient information from the chart supplemented by the patient as needed. The technician creates a lesion record in the software that includes the history of the lesion and the indications for imaging. An RCM-specific tissue stabilization ring is prepared by removing the adhesive backing from the window, aligning it and adhering it to the metal ring. Then, the adhesive backing is removed from the opposite side ("skin side") of the window. It is then placed on a drape on a Mao stand adhesive side up, taking care to not adhere it to anything. The lesion is cleaned with an alcohol swab. A drop (1 cc) of mineral oil is placed on the lesion. The ring/window assembly is placed on the skin, over the lesion in such a fashion as to capture the mineral oil within the ring and not disrupt the adhesive attachment.

Intra-Service Clinical Labor Activities:

An image of the lesion, used to guide the RCM objective lens during mosaicking, is captured through the window. Ultrasound gel (3 ccs) is added to the window, and the RCM's objective lens is aligned to the tissue ring using a magnetic latch. The technician visually locates the surface of the skin during real-time imaging by adjusting the depth of imaging using proprietary software. Using software and a touchscreen, the technician steps the image down into the skin several microns and selects the area around which to create a mosaic by selecting two points around the lesion. The mosaicking function is initiated and a single plane is scanned. This is repeated 3-5 times at different depths sufficient to capture the lesion. The technician must be fully engaged during this process stabilizing the system and cannot perform other tasks during this time.

Post-Service Clinical Labor Activities:
Clean room and equipment. Review the images with the interpreting physician. Archive images. Conduct phone calls.

CPT Code: 96931, 96933, 96934 & 96936
Specialty Society('s) AAD

AMA/Specialty Society Update Process
Practice Expense Summary of Recommendation
Non Facility Direct Inputs

CPT Long Descriptor:
96931 Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin, first lesion; image acquisition and interpretation and report

96933 Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin, first lesion; interpretation and report only

96934 Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; image acquisition and interpretation and report, each additional lesion (List separately in addition to primary procedure)

96936 Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of skin; interpretation and report only, each additional lesion (List separately in addition to primary procedure)

Global Period: XXX and ZZZ Meeting Date: April 2015

1. Please provide a brief description of the process used to develop your recommendation and the composition of your Specialty Society Practice Expense Committee:

American Academy of Dermatology convened a consensus panel to finalize the practice expense data for the RCM Codes.

2. You must provide reference code(s) for comparison on your spreadsheet. **If the code you are making recommendations on is a revised code you must use the current PE direct inputs for the code as your comparison.** You must provide an explanation for the selection of reference codes. Reference Code Rationale:

Per AMA staff advise, we selected code 93925 (Duplex scan of lower extremity arteries or arterial bypass grafts; complete bilateral study) as our reference code to compare it with the RCM codes because it is also an imaging code and a similar procedure. The clinical labor activities are similar to the new RCM codes.

3. If you are recommending more minutes than the PE Subcommittee standards you must provide evidence to justify the time:
N/A

4. If you are requesting an increase over the current inputs in clinical staff time, supplies or equipment you must provide compelling evidence:
N/A

5. Please describe in detail the clinical activities of your staff:

Pre-Service Clinical Labor Activities:

The lesion is circled and the patient is moved to a room where the RCM resides. A technician creates a patient record in the RCM software on the dedicated, imaging system workstation, by entering the patient information from the chart supplemented by the patient as needed. The technician creates a lesion record in the software that includes the history of the lesion and the indications for imaging. An RCM-specific tissue stabilization ring is prepared by removing the adhesive backing from the window, aligning it and adhering it to the metal ring. Then, the adhesive backing is removed from the opposite side ("skin side") of the window. It is then placed on a drape on a Mao stand adhesive side up, taking care to not adhere it to anything. The lesion is cleaned with an alcohol swab. A drop (1 cc) of mineral oil is placed on the lesion. The ring/window assembly is placed on the skin, over the lesion in such a fashion as to capture the mineral oil within the ring and not disrupt the adhesive attachment.

Intra-Service Clinical Labor Activities:

An image of the lesion, used to guide the RCM objective lens during mosaicking, is captured through the window. Ultrasound gel (3 ccs) is added to the window, and the RCM's objective lens is aligned to the tissue ring using a magnetic latch. The technician visually locates the surface of the skin during real-time imaging by adjusting the depth of imaging using proprietary software. Using software and a touchscreen, the technician steps the image down into the skin several microns and selects the area around which to create a mosaic by selecting two points around the lesion. The mosaicking function is initiated and a single plane is scanned. This is repeated 3-5 times at different depths sufficient to capture the lesion. The technician must be fully engaged during this process stabilizing the system and cannot perform other tasks during this time.

Post-Service Clinical Labor Activities:
Clean room and equipment. Review the images with the interpreting physician. Archive images. Conduct phone calls.

	A	B	C	D	E	F	G	H	I	J	K	L	M	N
1				REFERENCE CODE										
2	**Revised on 10/12/2015**			**93925**		**969XX1**		**969XX2**		**969XX3**		**969XX4**		**969**
3	**Meeting Date: April 2015** **Tab: 6** **Specialty: Dermatology**	**CMS Code**	**Staff Type**	Duplex scan of lower extremity arteries or arterial bypass grafts; complete bilateral		Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of		Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of		Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of		Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of		Reflectanc microscopy cellular cellular ir
4	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**
5	**GLOBAL PERIOD**			**XXX**	**XXX**	**XXX**	**XXX**	**XXX**	**XXX**	**XXX**	**XXX**	**ZZZ**	**ZZZ**	**ZZZ**
6	**TOTAL CLINICAL LABOR TIME**			**94.0**	**0.0**	**47.0**	**0.0**	**47.0**	**0.0**	**2.0**	**0.0**	**36.0**	**0.0**	**36.0**
7	**TOTAL PRE-SERV CLINICAL LABOR TIME**			**3.0**	**0.0**	**2.0**	**0.0**	**2.0**	**0.0**	**0.0**	**0.0**	**2.0**	**0.0**	**2.0**
8	**TOTAL SERVICE PERIOD CLINICAL LABOR TIME**			**91.0**	**0.0**	**45.0**	**0.0**	**45.0**	**0.0**	**2.0**	**0.0**	**34.0**	**0.0**	**34.0**
9	**TOTAL POST-SERV CLINICAL LABOR TIME**			**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
10	**PRE-SERVICE**													
11	**Start: Following visit when decision for surgery or procedure made**													
12	Complete pre-service diagnostic & referral forms	LO42A	RN/LPN			**0**		**0**				**0**		**0**
13	Coordinate pre-surgery services	LO42A	RN/LPN			**0**		**0**				**0**		**0**
14	Schedule space and equipment in facility	LO42A	RN/LPN			**0**		**0**				**0**		**0**
15	Provide pre-service education/obtain consent	LO42A	RN/LPN			**0**		**0**				**0**		**0**
16	Follow-up phone calls & prescriptions	LO42A	RN/LPN			**0**		**0**				**0**		**0**
17	Availability of prior images confirmed	LO54A	Vascular Tech	**1**		**0**		**0**				**0**		**0**
18	Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by physician	LO42A	RN/LPN	**2**		**2**		**2**				**2**		**2**
19	Other Clinical Activity - *specify*													
20	**End: When patient enters office/facility for surgery/procedure**													
21	**SERVICE PERIOD**													
22	**Start: When patient enters office/facility for surgery/procedure:**													
23	Greet patient, provide gowning, ensure appropriate medical records are available	LO42A	RN/LPN	**3**		**3**		**3**						
24	Obtain vital signs	LO42A	RN/LPN	**3**		**0**		**0**						
25	Provide pre-service education/obtain consent	LO42A	RN/LPN	**3**		**3**		**3**						
26	Prepare room, equipment, supplies	LO42A	RN/LPN	**2**		**2**		**2**						
27	Setup scope (non facility setting only)	LO42A	RN/LPN			**0**		**0**						
28	Prepare and position patient/ monitor patient/ set up IV	LO42A	RN/LPN	**2**		**2**		**2**				**2**		**2**
29	Sedate/apply anesthesia	LO42A	RN/LPN			**0**		**0**						
30	Other Clinical Activity - specify: Set up US Equipment			**2**										
31	**Intra-service**													
32	Acquire images	LO42A	RN/LPN	**69**		**30**		**30**				**30**		**30**
33	**Post-Service**													
34	Monitor pt. following moderate sedation													

	A	B	C	D	E	F	G	H	I	J	K	L	M	N
1				REFERENCE CODE										
2	**Revised on 10/12/2015**			**93925**		**969XX1**		**969XX2**		**969XX3**		**969XX4**		**969**
3	**Meeting Date: April 2015** **Tab: 6** **Specialty: Dermatology**	**CMS Code**	**Staff Type**	Duplex scan of lower extremity arteries or arterial bypass grafts; complete bilateral		Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of		Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of		Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of		Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of		Reflectanc microscopy cellular cellular ir
4	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**
5	**GLOBAL PERIOD**			**XXX**	**XXX**	**XXX**	**XXX**	**XXX**	**XXX**	**XXX**	**XXX**	**ZZZ**	**ZZZ**	**ZZZ**
35	Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation)													
36	Clean room/equipment by physician staff	LO42A	RN/LPN	**3**		**3**		**3**						
37	Clean Scope	LO42A	RN/LPN			**0**		**0**						
38	Clean Surgical Instrument Package													
39	Complete diagnostic forms, lab & X-ray requisitions													
40	Review/read X-ray, lab, and pathology reports													
41	Check dressings & wound/ home care instructions /coordinate office visits /prescriptions													
42	Technologist QC's images in PACS, checking for all images, reformats, and dose page	LO42A	RN/LPN	**2.0**		**0.0**		**0.0**						
43	Review examination with interpreting MD	LO42A	RN/LPN	**1.0**		**0.0**		**0.0**		**0.0**		**0.0**		**0.0**
44	Exam documents scanned into PACS. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue	LO42A	RN/LPN	**1.0**		**0.0**		**0.0**				**0.0**		**0.0**
45	Other Clinical Activity - Review imaging with interpreting physician	LO42A	RN/LPN			**2**		**2**		**2**		**2**		**2**
46	Other Clinical Activity - Record Patient	LO42A	RN/LPN											
47	Dischrg mgmt same day (0.5 x 99238) (enter 6 min)			**n/a**		**n/a**		**n/a**		**n/a**		**n/a**		**n/a**
48	Dischrg mgmt (1.0 x 99238) (enter 12 min)			**n/a**		**n/a**		**n/a**		**n/a**		**n/a**		**n/a**
49	Dischrg mgmt (1.0 x 99239) (enter 15 min)			**n/a**		**n/a**		**n/a**		**n/a**		**n/a**		**n/a**
50	**End: Patient leaves office**													
51	**POST-SERVICE Period**													
52	**Start: Patient leaves office/facility**													
53	Conduct phone calls/call in prescriptions	LO42A	RN/LPN			**0**		**0**				**0**		**0**
54	***Office visits: List Number and Level of Office Visits***			**# visits**	**# visits**	**# visits**	**# visits**	**# visits**	**3 visits**	**# visits**	**# visits**	**# visits**	**# visits**	**# visits**
55	99211 16 minutes		16											
56	99212 27 minutes		27											
57	99213 36 minutes		36											
58	99214 53 minutes		53											
59	99215 63 minutes		63											
60	**Total Office Visit Time**			**0.0**	**0.0**	**0.0**	**0.0**			**0.0**	**0.0**	**0.0**	**0.0**	
61	Other Clinical Activity - *specify: QA documentation*			**0**										
62	**End: with last office visit before end of global period**													

	A	B	C	D	E	F	G	H	I	J	K	L	M	N
1				REFERENCE CODE										
2	**Revised on 10/12/2015**			**93925**		**969XX1**		**969XX2**		**969XX3**		**969XX4**		**969**
3	**Meeting Date: April 2015** **Tab: 6** **Specialty: Dermatology**	**CMS Code**	**Staff Type**	Duplex scan of lower extremity arteries or arterial bypass grafts; complete bilateral		Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of		Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of		Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of		Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of		Reflectanc microscopy cellular cellular ir
4	**LOCATION**			**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**	**Facility**	**Non Fac**
5	**GLOBAL PERIOD**			**XXX**	**XXX**	**XXX**	**XXX**	**XXX**	**XXX**	**XXX**	**XXX**	**ZZZ**	**ZZZ**	**ZZZ**
63	**MEDICAL SUPPLIES***	**CODE**	**UNIT**											
64	pack, minimum multi-specialty visit	SA048	pack	**1**		**1**		**1**				**0**		**0**
65	Imaging Tray	INVOICE	pack			**1**		**1**				**0**		**0**
66	mineral oil	SJ035	ml			**0**		**0**				**0**		**0**
67	ultrasound transmission gel	SJ062	ml	**60**		**0**		**0**				**0**		**0**
68	swab-pad, alcohol	SJ053	item			**3**		**3**				**3**		**3**
69	razor	SK068	item			**1**		**1**				**1**		**1**
70	gauze, non-sterile 2in x 2in	SG050	item			**3**		**3**				**3**		**3**
71	tissue ring	INVOICE	item			**0**		**0**						
72	tissue window	INVOICE	item			**0**		**0**						
73	adhesive ruler	INVOICE	item			**1**		**1**						
74	wipes, lens cleaning (per wipe) (Kimwipe)	SM027	item			**1**		**1**						
75	drape, non-sterile, sheet 40in x 60in	SB006	item	**1**										
76	cover-condom, transducer or ultrasound probe	SB005	item											
77	film, 8inx10in (ultrasound, MRI)	SK022	item											
78	film, x-ray 14in x 17in	SK034	item											
79	patient education booklet	SK062	item	**1**										
80	video tape, VHS	SK086	item											
81	glutaraldehyde 3.4% (Cidex, Maxicide, Wavicide)	SM018	oz	**0.34**										
82	sanitizing cloth-wipe (surface, instruments, equipment)	SM022	item	**2**										
83														
84														
85														
86	**EQUIPMENT**	**CODE**												
87	table, power	EF031				**43**		**43**				**32**		**32**
88	light, exam	EQ168				**43**		**43**				**32**		**32**
89	reflectance confocal imaging system	INVOICE				**37**		**37**				**32**		**32**
90	camera, 35mm system (medical grade)	ED003				**3**		**3**				**3**		**3**
91	PACS Workstation Proxy	ED050		**69**										
92	room, ultrasound, vascular	EL016		**86**										
93														
94														
95														
96														
97														
98														

	A	B	C	O	P	Q
1						
2	**Revised on 10/12/2015**			**XX5**	**969XX6**	
3	**Meeting Date: April 2015** **Tab: 6** **Specialty: Dermatology**	**CMS Code**	**Staff Type**	e confocal (RCM) for and sub-naging of	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of	
4	**LOCATION**			**Facility**	**Non Fac**	**Facility**
5	**GLOBAL PERIOD**			**ZZZ**	**ZZZ**	**ZZZ**
6	**TOTAL CLINICAL LABOR TIME**			**0.0**	**0.0**	**0.0**
7	**TOTAL PRE-SERV CLINICAL LABOR TIME**			**0.0**	**0.0**	**0.0**
8	**TOTAL SERVICE PERIOD CLINICAL LABOR TIME**			**0.0**	**0.0**	**0.0**
9	**TOTAL POST-SERV CLINICAL LABOR TIME**			**0.0**	**0.0**	**0.0**
10	**PRE-SERVICE**					
11	**Start: Following visit when decision for surgery or procedure made**					
12	Complete pre-service diagnostic & referral forms	LO42A	RN/LPN			
13	Coordinate pre-surgery services	LO42A	RN/LPN			
14	Schedule space and equipment in facility	LO42A	RN/LPN			
15	Provide pre-service education/obtain consent	LO42A	RN/LPN			
16	Follow-up phone calls & prescriptions	LO42A	RN/LPN			
17	Availability of prior images confirmed	LO54A	Vascular Tech			
18	Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by physician	LO42A	RN/LPN			
19	Other Clinical Activity - *specify*					
20	**End: When patient enters office/facility for surgery/procedure**					
21	**SERVICE PERIOD**					
22	**Start: When patient enters office/facility for surgery/procedure:**					
23	Greet patient, provide gowning, ensure appropriate medical records are available	LO42A	RN/LPN			
24	Obtain vital signs	LO42A	RN/LPN			
25	Provide pre-service education/obtain consent	LO42A	RN/LPN			
26	Prepare room, equipment, supplies	LO42A	RN/LPN			
27	Setup scope (non facility setting only)	LO42A	RN/LPN			
28	Prepare and position patient/ monitor patient/ set up IV	LO42A	RN/LPN			
29	Sedate/apply anesthesia	LO42A	RN/LPN			
30	Other Clinical Activity - specify: Set up US Equipment					
31	**Intra-service**					
32	Acquire images	LO42A	RN/LPN			
33	**Post-Service**					
34	Monitor pt. following moderate sedation					

	A	B	C	O	P	Q
1						
2	**Revised on 10/12/2015**			**XX5**	**969XX6**	
3	**Meeting Date: April 2015** **Tab: 6** **Specialty: Dermatology**	**CMS Code**	**Staff Type**	e confocal (RCM) for and sub-naging of	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of	
4	**LOCATION**			**Facility**	**Non Fac**	**Facility**
5	**GLOBAL PERIOD**			**ZZZ**	**ZZZ**	**ZZZ**
35	Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation)					
36	Clean room/equipment by physician staff	LO42A	RN/LPN			
37	Clean Scope	LO42A	RN/LPN			
38	Clean Surgical Instrument Package					
39	Complete diagnostic forms, lab & X-ray requisitions					
40	Review/read X-ray, lab, and pathology reports					
41	Check dressings & wound/ home care instructions /coordinate office visits /prescriptions					
42	Technologist QC's images in PACS, checking for all images, reformats, and dose page	LO42A	RN/LPN			
43	Review examination with interpreting MD	LO42A	RN/LPN		**0.0**	
44	Exam documents scanned into PACS. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue	LO42A	RN/LPN			
45	Other Clinical Activity - Review imaging with interpreting physician	LO42A	RN/LPN			
46	Other Clinical Activity - Record Patient	LO42A	RN/LPN			
47	Dischrg mgmt same day (0.5 x 99238) (enter 6 min)				**n/a**	
48	Dischrg mgmt (1.0 x 99238) (enter 12 min)				**n/a**	
49	Dischrg mgmt (1.0 x 99239) (enter 15 min)				**n/a**	
50	**End: Patient leaves office**					
51	**POST-SERVICE Period**					
52	**Start: Patient leaves office/facility**					
53	Conduct phone calls/call in prescriptions	LO42A	RN/LPN			
54	***Office visits: List Number and Level of Office Visits***			**3 visits**	**# visits**	**# visits**
55	99211 16 minutes		16			
56	99212 27 minutes		27			
57	99213 36 minutes		36			
58	99214 53 minutes		53			
59	99215 63 minutes		63			
60	**Total Office Visit Time**				**0.0**	**0.0**
61	Other Clinical Activity - *specify: QA documentation*					
62	**End: with last office visit before end of global period**					

	A	B	C	O	P	Q
1						
2	**Revised on 10/12/2015**			**XX5**	**969XX6**	
3	**Meeting Date: April 2015** **Tab: 6** **Specialty: Dermatology**	**CMS Code**	**Staff Type**	e confocal (RCM) for and sub-naging of	Reflectance confocal microscopy (RCM) for cellular and sub-cellular imaging of	
4	**LOCATION**			**Facility**	**Non Fac**	**Facility**
5	**GLOBAL PERIOD**			**ZZZ**	**ZZZ**	**ZZZ**
63	**MEDICAL SUPPLIES***	**CODE**	**UNIT**			
64	pack, minimum multi-specialty visit	SA048	pack			
65	Imaging Tray	INVOICE	pack			
66	mineral oil	SJ035	ml			
67	ultrasound transmission gel	SJ062	ml			
68	swab-pad, alcohol	SJ053	item			
69	razor	SK068	item			
70	gauze, non-sterile 2in x 2in	SG050	item			
71	tissue ring	INVOICE	item			
72	tissue window	INVOICE	item			
73	adhesive ruler	INVOICE	item			
74	wipes, lens cleaning (per wipe) (Kimwipe)	SM027	item			
75	drape, non-sterile, sheet 40in x 60in	SB006	item			
76	cover-condom, transducer or ultrasound probe	SB005	item			
77	film, 8inx10in (ultrasound, MRI)	SK022	item			
78	film, x-ray 14in x 17in	SK034	item			
79	patient education booklet	SK062	item			
80	video tape, VHS	SK086	item			
81	glutaraldehyde 3.4% (Cidex, Maxicide, Wavicide)	SM018	oz			
82	sanitizing cloth-wipe (surface, instruments, equipment)	SM022	item			
83						
84						
85						
86	**EQUIPMENT**	**CODE**				
87	table, power	EF031				
88	light, exam	EQ168				
89	reflectance confocal imaging system	INVOICE				
90	camera, 35mm system (medical grade)	ED003				
91	PACS Workstation Proxy	ED050				
92	room, ultrasound, vascular	EL016				
93						
94						
95						
96						
97						
98						

CALIBER I.D

50 Methodist Hill Drive, Suite 1000
Rochester, NY 14623 USA
Phone: 585-239-9800
Fax: 585-239-9806

Invoice #: 20157A
Date: [redacted]
Order #: [redacted]

Sold to:	Ship to:
[redacted]	[redacted]

UPS Tracking # 1Z12983W0356839030, 1Z12983W0355385228

Date Shipped	Ship Via	Shipping Terms	Pmt Terms	Sales Rep
[redacted]	Carrier	Prepay	Credit Card XXX5545	R Kelley

Quantity	Item Code	Description	Unit Price	Extension
20	**04906**	**Imaging Tray**	**$ 34.75**	**$ 695.00**
	04910	- Imaging Tray, 0.5mL Oil Applicator, Qty 2 @ $2.82 = $5.64		
	04911	- Imaging Tray, 1mL Gel Applicator, Qty 2 @ $2.82 = $5.64		
	04764	- 1500 Tissue Ring w/Key Slot, Qty 1 @ $19.77 = $19.77		
	04350	- 1MM Thick Window with Adhesive, Qty 2 @ $1.85 = $3.70		

Subtotal **$ 695.00**

Total Amount Due **$ 695.00**

DELASCO
dermatologic lab & supply, inc.

608 13th Avenue
Council Bluffs, IA 51501 USA
US & Canada (800)831-6273 (712)323-3269
FAX:(800)320-9612 (712)323-1156
questions@delasco.com | www.delasco.com

Invoice Date	Invoice No	Page
3/19/2015	INV00924357	1

Master #:	Batch #
669,674	DOM15-03-18

INV00924357

SOLD TO: LUCID, INC

SHIP TO: [redacted]

Payment Terms: PPD/MASTERCARD

ORDER NO	ORDER DATE	CUSTOMER NO	SLS REP	PURCHASE ORDER NO.	SHIP DATE	SHIP VIA
ORD01312896	3/18/2015	8	AS	LUCID, INC	3/18/2015	UPS GROUND

ITEM NO. / QUANTITY ORDERED	ITEM DESCRIPTION / QUANTITY SHIPPED	STK UNIT	UNIT PRICE	PRICE UNIT	DISCOUNT	EXTENDED PRICE
LP/BLK 1	LABELS,PHOTO,BLACK,RL 500 *NR 1.00	EACH	$9.95000	EACH	$0.00000	$9.95
NR 1	PLEASE NOTE: ITEMS MARKED**N/R**ARE NON-RETURNABLE 1.00	EACH	$0.00000	EACH	$0.00000	$0.00
STMT 1	STATEMENT OF USE ON FILE 1.00	EACH	$0.00000	EACH	$0.00000	$0.00
ORDER INFO: 1	CONTACT: JEREMY BELAIR/585-758-2827 1.00	N/A	$0.00000	N/A	$0.00000	$0.00
PAID BY VISA/MC 1	RICHARD CHRISTOPHER 1.00	N/A	$0.00000	N/A	$0.00000	$0.00
EMAIL 1	EMAIL TO: jwbelair@caliberid.com 1.00	EACH	$0.00000	EACH	$0.00000	$0.00

* Adhesive ruler →

Items marked B/O are temporarily back-ordered and will follow at later date.

Items marked O/S are out of-stock and the order has been cancelled.

PAID IN FULL - MASTERCARD

THANK YOU FOR YOUR ORDER!

SALES AMOUNT:	$9.95
MISC. CHARGES:	$0.00
FREIGHT:	$7.32
SALES TAX:	$0.00
TOTAL:	$17.27
PAYMENT REC'D:	$17.27
BALANCE DUE:	$0.00

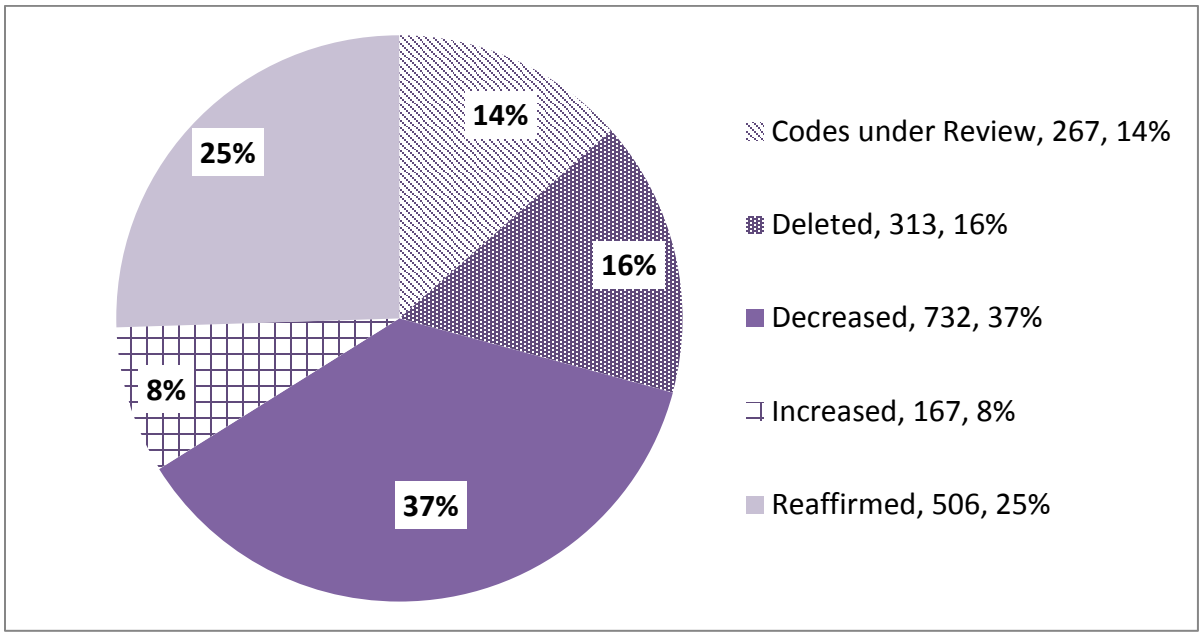
TAXPAYER ID: Delasco is a trade name of Dermatologic Lab & Supply Inc. Incorporated under the laws of the State of Iowa and, as such is exempt from backup withholding and W-9 information reporting. EIN: 42-1232535.

The RUC Relativity Assessment Workgroup Progress Report

In 2006, the AMA/Specialty Society RVS Update Committee (RUC) established the Five-Year Identification Workgroup (now referred to as the Relativity Assessment Workgroup) to identify potentially misvalued services using objective mechanisms for reevaluation prior to the next Five-Year Review. Since the inception of the Relativity Assessment Workgroup, the Workgroup and the Centers for Medicare and Medicaid Services (CMS) have identified nearly 2,000 services through 16 different screening criteria for further review by the RUC. Additionally, the RUC charged the Workgroup with maintaining the "new technology" list of services that will be re-reviewed by the RUC as reporting and cost data become available.

To provide Medicare with reliable data on how physician work has changed over time, the RUC, with more than 300 experts in medicine and research, are examining 1,985 potentially misvalued services accounting for $39 billion in Medicare spending. The update committee has recommended reductions and deletions to 1,045 services, redistributing nearly $4 billion. Here are the outcomes for the committee's review of 1,985 codes:

Potentially Misvalued Services Project



Source: American Medical Association

New Technology

As the RUC identifies new technology services that should be re-reviewed, a list of these services is maintained and forwarded to CMS. Currently, codes are identified as new technology based on recommendations from the appropriate specialty society and consensus among RUC members at the time of the RUC review for these services. RUC members consider several factors to evaluate potential new technology services, including: recent FDA-approval, newness or novelty of the service, use of an existing service in a new or novel way, and migration of the service from a Category III to Category I CPT® code. The Relativity Assessment Workgroup maintains and develops all standards and procedures associated with the list, which currently contains 510 services. In September 2010, the re-review cycle began and since then the RUC has recommended 25 services to be re-examined. The remaining services

are rarely performed (i.e., less than 500 times per year in the Medicare population) and will not be further examined. The Workgroup will continue to review the remaining 221 services every September after three years of Medicare claims data is available for each service.

Methodology Improvements

The RUC recently announced process improvements to methodology following its October 2013 meeting. The process improvements are designed to strengthen the RUC's primary mission of providing the final RVS update recommendations to the Centers for Medicare and Medicaid Services.

In the area of methodology, the RUC is continuously improving its processes to ensure that it is best utilizing reliable, extant data. At its most recent meeting, the RUC increased the minimum number of respondents required for each survey of commonly performed codes:

- For services performed 1 million or more times per year in the Medicare population, at least 75 physicians must complete the survey.
- For services performed from 100,000 to 999,999 times annually, at least 50 physicians will be required.

Further strengthening its methodology, the RUC also announced that specialty societies will move to a centralized online survey process, which will be coordinated by the AMA and will utilize external expertise to ensure survey and reporting improvements.

Site of Service Anomalies

The Workgroup initiated its effort by reviewing services with anomalous sites of service when compared to Medicare utilization data. Specifically, these services are performed less than 50% of the time in the inpatient setting, yet include inpatient hospital Evaluation and Management services within their global period.

The RUC identified 194 services through the site of service anomaly screen. The RUC required the specialties to resurvey 129 services to capture the appropriate physician work involved. These services were reviewed by the RUC between April 2008 and February 2011. CMS implemented 124 of these recommendations in the 2009, 2010 and 2011 Medicare Physician Payment Schedules. The RUC submitted another five recommendations as well as re-reviewed and submitted 44 recommendations to previously reviewed site of service identified codes to CMS for the 2012 Medicare Physician Payment Schedule.

Of the remaining 65 services that were not re-surveyed, the RUC modified the discharge day management for 46 services, maintained three codes and removed two codes from the screen as the typical patient was not a Medicare beneficiary and would be an inpatient. The CPT® Editorial Panel deleted 13 codes and the RUC will re-review two services in the CPT® 2019 cycle after more data is available.

During this review, the RUC uncovered several services that are reported in the outpatient setting, yet, according to several expert panels and survey data from physicians who perform the procedure, the service, typically requires a hospital stay of greater than 23 hours. The RUC maintains that physician work that is typically performed, such as visits on the date of service and discharge work the following day, should be included within the overall valuation. Subsequent observation day visits and discharge day management service are appropriate proxies for this work.

The RUC will reassess the data each year going forward to determine if any new site of service anomalies arise. In 2015, the RUC identified three services in which the Medicare data from 2011-2013 indicated it was performed less than 50% of the time in the inpatient setting, yet included inpatient hospital Evaluation and Management services within the global period. These three services will be reviewed by the RUC for the 2018 Medicare Physician Payment Schedule.

High Volume Growth
The Workgroup assembled a list of all services with a total Medicare utilization of 1,000 or more that have increased by at least 100% from 2004 through 2006. The query initially resulted in the identification of 81 services, but was expanded by 16 services to include the family of services, totaling 97 services. Specialty societies submitted comments to the Workgroup in April 2008 to provide rationales for the growth in reporting. Following this review, the RUC required the specialties to survey 35 services to capture the appropriate work effort and/or direct practice expense inputs. These services were reviewed by the RUC between February 2009 and April 2010.

The RUC recommended removing 22 services from the screen as the volume growth did not impact the resources required to provide these services. The CPT® Editorial Panel deleted 23 codes. The RUC submitted 49 recommendations to CMS for services for the 2012-2015 Medicare Physician Payment Schedules. In September 2011, the RUC began review of services after two years of utilization data were collected. The RUC will continue to review the remaining three services after additional utilization data is available.

In April 2013, the RUC assembled a list of all services with a total Medicare utilization of 10,000 or more that have increased by at least 100% from 2006 through 2011. The query resulted in the identification of 40 services and expanded to 58 services to include the appropriate family of services. The RUC recommended removing three services from the screen as the volume growth did not impact the resources required to provide these services. The RUC referred seven services to the CPT® Editorial Panel for revision and recommended review of five services after an additional two years of utilization data is collected. The CPT® Editorial Panel deleted six codes and the RUC submitted recommendations for 43 services for the 2015-2016 Medicare Physician Payment Schedule.

In October 2015, the RUC ran this screen again for services based on Medicare utilization of 10,000 or more that have increased by at least 100% from 2008 through 2013. The query resulting in the identification of 23 services and the Relativity Assessment Workgroup will review action plans for these services to determine if the growth is appropriate.

CMS Fastest Growing
In 2008, CMS developed the Fastest Growing Screen to identify all services with growth of at least 10% per year over the course of three years from 2005-2007. Through this screen, CMS identified 114 fastest growing services and the RUC added 69 services to include the family of services, totaling 183. The RUC required the specialties to survey 72 services to capture the appropriate work effort and/or direct practice expense inputs. These services were reviewed by the RUC from February 2008 through April 2010 and submitted to CMS for the Medicare Physician Payment Schedule.

The RUC recommended removing 39 services from the screen as the volume growth did not impact the resources required to provide the service. The CPT® Editorial Panel deleted 34 codes. The RUC submitted 33 recommendations to CMS for the 2012-2016 Medicare Physician Payment Schedules. The RUC will review the remaining five services after additional utilization data is available.

High IWPUT
The Workgroup assembled a list of all services with a total Medicare utilization of 1,000 or more that have an intra-service work per unit of time (IWPUT) calculation greater than 0.14, indicating an outlier intensity. The query resulted in identification of 32 services. Specialty societies submitted comments to the Workgroup in April 2008 for these services. As a result of this screen, the RUC has reviewed and submitted recommendations to CMS for 28 codes, removing four services from the screen as the IWPUT was considered appropriate. The RUC completed review of services under this screen.

Services Surveyed by One Specialty – Now Performed by a Different Specialty
In October 2009, services that were originally surveyed by one specialty, but now performed predominantly by other specialties were identified and reviewed. The RUC identified 21 services by this screen, adding 19 services to address various families of codes. The majority of these services required clarification within CPT®. The CPT® Editorial Panel deleted 18 codes. The RUC submitted 22 recommendations for physician work and practice expense to CMS for the 2011-2014 Medicare Physician Payment Schedules. The RUC completed review of services under this screen.

In April 2013, the RUC queried the top two dominant specialties performing services based on Medicare utilization more than 1,000 and compared it to who originally surveyed the service. Two services were identified and the RUC recommended that one be removed from the screen since the specialty societies currently performing this service indicated that the service is appropriate and recommended that the other code be referred to CPT® to be revised. The RUC completed review of services under this screen.

Harvard Valued
Utilization over 1 Million
CMS requested that the RUC pay specific attention to Harvard valued codes that have a high utilization. The RUC identified nine Harvard valued services with high utilization (performed over 1 million times per year). The RUC also incorporated an additional 12 Harvard valued codes within the initial family of services identified. The CPT® Editorial Panel deleted one code. The RUC submitted 20 relative value work recommendations to CMS for the 2011 and 2012 Medicare Physician Payment Schedules. The RUC completed review of services under this screen.

Utilization over 100,000
The RUC continued to review Harvard valued codes with significant utilization. The Relativity Assessment Workgroup expanded the review of Harvard codes to those with utilization over 100,000 which totaled 38 services. The RUC expanded this screen by 101 codes to include the family of services, totaling 139 services. The CPT® Editorial Panel deleted 27 codes. The RUC submitted 112 recommendations to CMS for the 2011-2014 Medicare Physician Payment Schedules. The RUC completed review of services under this screen.

Utilization over 30,000
In April 2011, the RUC continued to identify Harvard valued codes with utilization over 30,000, based on 2009 Medicare claims data. The RUC determined that the specialty societies should survey the remaining 36 Harvard codes with utilization over 30,000 for September 2011. The RUC expanded the screen to include the family of services, totaling 65 services. The CPT® Editorial Panel deleted 12 codes. The RUC submitted recommendations for 53 services for the 2013-2014 Medicare Physician Payment Schedules. The RUC completed review of services under this screen.

Medicare Allowed Charges >$10 million
In June 2012, CMS identified 16 services that were Harvard valued with annual allowed charges (2011 data) > $10 million. The RUC expanded this screen to 33 services to include the proper family of services. The RUC removed two services from review as the allowed charges are approximately $1 million and did not meet the screen criteria. The CPT® Editorial Panel deleted one service. The RUC submitted recommendations for 29 services for the 2013-2015 Medicare Physician Payment Schedules. The RUC will review one remaining service for the 2017 Medicare Physician Payment Schedule.

CMS/Other

Utilization over 500,000

In April 2011, the RUC identified 410 codes with a source of "CMS/Other." CMS/Other codes are services which were not reviewed by the Harvard studies or the RUC and were either gap filled, most often via crosswalk by CMS or were part of a radiology fee schedule. "CMS/Other" source codes would not have been flagged in the Harvard only screens, therefore the RUC recommended that a list of all CMS/Other codes be developed and reviewed. The RUC established the threshold for CMS/Other source codes with Medicare utilization of 500,000 or more, which resulted in 19 codes. The RUC expanded this screen to 21 services to include the proper family of services. The CPT® Editorial Panel deleted three services. The RUC submitted recommendations for 16 services for the 2013-2015 Medicare Physician Payment Schedules. The RUC removed one service from the screen and will review one service after additional utilization data is available.

Utilization over 250,000

In April 2013, the RUC lowered the threshold to the CMS/Other source codes with Medicare utilization of 250,000 or more, which resulted in 26 services and was expanded to 47 services to include the family of services. The CPT Editorial Panel deleted eight codes identified under this screen. The RUC referred 10 services to the CPT® Editorial Panel and submitted 36 recommendations to CMS for the 2015 and 2016 Medicare Physician Payment Schedules. The RUC will review one service for the 2017 Medicare Physician Payment Schedule.

Bundled CPT® Services

Reported 95% or More Together

The Relativity Assessment Workgroup solicited data from CMS regarding services inherently performed by the same physician on the same date of service (95% of the time) in an attempt to identify pairings of services that should be bundled together. The CPT® Editorial Panel deleted 31 individual component codes and replaced them with 53 new codes that describe bundles of services. The RUC then surveyed and reviewed work and practice costs associated with these services to account for any efficiencies achieved through the bundling. The RUC completed review of all services under this screen.

Reported 75% or More Together

In February 2010, the Workgroup continued review of services provided on the same day by the same provider, this time lowering the threshold to 75% or more together. The Relativity Assessment Workgroup again analyzed the Medicare claims data and found 151 code pairs which met the threshold. The Workgroup then collected these code pairs into similar "groups" to ensure that the entire family of services would be coordinated under one code bundling proposal. The grouping effort resulted in 20 code groups, totaling 80 codes, and were sent to specialty societies to solicit action plans for consideration at the April 2010 RUC meeting. Resulting from the Relativity Assessment Workgroup review, 81 additional codes were added for review as part of the family of services to ensure duplication of work and practice expense was mitigated throughout the entire set of services. Of the 161 total codes under review, the CPT® Editorial Panel deleted 35 individual component codes and replaced the component coding with 125 new and/or revised codes that described the bundles of services. The CPT® Editorial Panel and the RUC are currently working on one service and expect to complete this screen for final implementation in the 2017 Medicare Physician Payment Schedule.

In August 2011, the Joint CPT®/RUC Workgroup on Codes Reported Together Frequently reconvened to perform its third cycle of analysis of code pairs reported together with 75% or greater frequency. The Workgroup reviewed 30 code pair groups and recommended code bundling for 64 individual codes. In October 2012, the CPT® Editorial Panel started the review of code bundling solutions. Of the 146 total

codes under review, the CPT® Editorial Panel deleted 47 services and is scheduled to review 17 codes in the 2016 cycle. The RUC has submitted 82 code recommendations for the 2014-2016 Medicare Physician Payment Schedules.

In January and April 2015, the Joint CPT/RUC Workgroup on Codes Reported Together Frequently reconvened to perform its fourth cycle analysis of code pairs reported together with 75% or greater frequency. The Workgroup reviewed 8 code pair groups and recommended code bundling for 18 individual codes.

Low Value/Billed in Multiple Units
CMS has requested that services with low work RVUs that are commonly billed with multiple units in a single encounter be reviewed. CMS identified services that are reported in multiples of five or more per day, with work RVUs of less than or equal to 0.50 RVUs.

In October 2010, the Workgroup reviewed 12 CMS identified services and determined that six of the codes were improperly identified as the services were either not reported in multiple units or were reported in a few units and that was considered in the original valuation. The RUC submitted recommendations for the remaining six services for the 2012 Medicare Physician Payment Schedule. The RUC completed review of services under this screen.

Low Value/High Volume Codes
CMS has requested that services with low work RVUs and high utilization be reviewed. CMS has requested that the RUC review 24 services that have low work RVUs (less than or equal to 0.25) and high utilization. The RUC questioned the criteria CMS used to identify these services as it appeared some codes were missing from the screen criteria indicated. The RUC identified codes with a work RVU ranging from 0.01 - 0.50 and Medicare utilization greater than one million. In February 2011, the RUC reviewed the codes identified by this criteria and added 5 codes, totaling 29. The RUC submitted 24 recommendations to CMS for the 2012 Medicare Physician Payment Schedule and five recommendations to CMS for the 2013 Medicare Physician Payment Schedule. The RUC completed review of services under this screen.

Multi-Specialty Points of Comparison List
CMS requested that services on the Multi-Specialty Points of Comparison (MPC) list should be reviewed. CMS prioritized the review of the MPC list to 33 codes, ranking the codes by allowed service units and charges based on CY 2009 claims data as well as those services reviewed by the RUC more than six years ago. The RUC expanded the list to 182 services to include additional codes as part of a family (over 100 of these codes are part of the review of GI endoscopy codes). The CPT® Editorial Panel deleted 25 codes. The RUC submitted recommendations for 157 codes for the 2012-2015 Medicare Physician Payment Schedules. The RUC completed review of services under this screen.

CMS High Expenditure Procedural Codes
In the Proposed Rule for 2012, CMS requested that the RUC review a list of 70 high Medicare Physician Payment Schedule expenditure procedural codes representing services furnished by an array of specialties. CMS selected these codes since they have not been reviewed for at least 6 years, and in many cases the last review occurred more than 10 years ago.

The RUC reviewed the 70 services identified and expanded the list to 145 services to include additional codes as part of the family. The CPT® Editorial Panel deleted 18 codes and will review 11 codes for the 2017 cycle. The RUC submitted 116 recommendations to CMS for the 2013-2016 Medicare Physician Payment Schedules will review utilization data for one service after additional data is available.

In the Proposed Rule for 2016, CMS requested that the RUC review a list of 118 high Medicare Physician Payment Schedule high expenditure services across specialties with Medicare allowed charges of $10 million or more. CMS identified the top 20 codes by specialty in terms of allowed charges, excluding 010 and 090-day global services, anesthesia and Evaluation and Management services and services reviewed since CY 2010. The RUC expanded the list of services to 207 services to include additional codes as part of the family. The RUC requested that 21 of these services be removed because they have been recently reviewed or do not meet the query criteria. The RUC will review the services indicated in the Final Rule for 2016, for the 2018 Medicare Physician Payment schedule.

Services with Stand-Alone PE Procedure Time

In June 2012, CMS proposed adjustments to services with stand-alone procedure time assumptions used in developing non-facility PE RVUs. These assumptions are not based on physician time assumptions. CMS prioritized CPT® codes that have annual Medicare allowed charges of $100,000 or more, include direct equipment inputs that amount to $100 or more, and have PE procedure times greater than five minutes for review. The RUC reviewed 27 services identified through this screen and expanded to 29 services to include additional codes as part of the family. The CPT® Editorial Panel deleted 11 codes. The RUC submitted 18 recommendations for the 2014-2015 Medicare Physician Payment Schedules. The RUC completed review of services under this screen.

Pre-Time Analysis

In January 2014, the RUC reviewed codes that were RUC reviewed prior to April 2008, with pre-time greater than pre-time package 4 *Facility - Difficult Patient/Difficult Procedure* (63 minutes) for services with 2012 Medicare Utilization over 10,000. The screen identified 19 services with more pre-service time than the longest standardized pre-service package and was expanded to 24 to include additional codes as part of the family. The RUC reviewed these services and referred three services to the CPT® Editorial Panel for revision. The CPT Editorial Panel deleted one service. The RUC reviewed 18 services and noted that they were all originally valued by magnitude estimation and therefore readjustments in pre-service time categories did not alter the work values. Additionally, crosswalk references for each service were presented validating the pre-time adjustments. The RUC noted that this screen was useful, however did not reveal any large outliers and therefore the utilization threshold does not need to be lowered to identify more services. The RUC submitted 21 recommendations for the 2016 Medicare Physician Payment Schedule.

Post-Operative Visits

010-Day Global Codes

In January 2014, the RUC reviewed all 477, 010-day global codes to determine any outliers. Many 010-day global period services only include one post-operative office visit. The Relativity Assessment Workgroup pared down the list to 19 services with >1.5 office visits and 2012 Medicare utilization > 1,000. The RUC reviewed the 19 services, which was expanded to 21 services for additional codes in the family of services, identified via this screen. The RUC referred two codes to the CPT Editorial Panel for revision. The RUC submitted recommendations for 20 services for the 2015-2016 Medicare Physician Payment Schedule.

090-Day Global Codes

In January 2014, the RUC reviewed all 3,788, 090-day global codes to determine any outliers. Based on 2012 Medicare utilization data, 10 services were identified, that were reported at least 1,000 times per year and included more than six office visits. The RUC expanded the services identified in this screen to 38 to include additional codes as part of the family. The RUC referred 16 services to the CPT® Editorial Panel, seven of which were deleted. The RUC submitted recommendations for 15 services for the 2015-2016 Medicare Physician Payment Schedule.

High Level E/M in Global Period
In October 2015, the RUC reviewed all services with Medicare utilization greater than 10,000 that have a level 4 (99214) or level 5 (99215) office visit included in the global period. There were no codes with volume greater than 10,000 that had a level 5 office visits included. Seven services were identified that have a level 4 office visit included. The Relativity Assessment Workgroup will review these services to determine if a level 4 office visit is appropriate. The RUC noted that this screen will be complete after the server services are reviewed because the RUC has more rigorously questioned level 4 office visits in the global period in recent years and will continue this process going forward.

Public Comment Requests
In 2011, CMS announced that due to the ongoing identification of potentially misvalued services by CMS and the RUC, the Agency will no longer conduct a separate Five-Year Review. CMS will now call for public comments on an annual basis as part of the comment process on the Final Rule each year.

Final Rule for 2013
In the Final Rule for the 2013 Medicare Physician Payment Schedule, the public and CMS identified 35 potentially misvalued services, which was expanded to 38 services to include the entire code family. The RUC reviewed these services and recommended that eight services be removed from review as two G-codes lacked specialty society interest and six services are not potentially misvalued since there is no reliable way to determine an incremental difference from open thoracotomy to thorascopic procedures. The RUC submitted recommendations for 25 services for the 2014-2016 Medicare Physician Payment Schedules. The RUC referred three services to the CPT® Editorial Panel for revision and will review two services after additional utilization data is available.

Final Rule for 2014
CMS did not receive any publicly nominated potentially misvalued codes for inclusion in the Proposed Rule for 2014. To broaden participation in the process of identifying potentially misvalued codes, CMS sought the input of Medicare contractor medical directors (CMDs). The CMDs have identified over a dozen services which CMS is proposing as potentially misvalued. The RUC reviewed these services and appropriate families, totaling 88 services, at the October 2013 RUC meeting and noted that two services identified were recently reviewed and recommendations were submitted for the 2014 Medicare Payment Schedule. The RUC referred three services to the CPT® Editorial Panel for consideration to delete. The RUC submitted recommendations to CMS for 82 services for the 2015 and 2016 Medicare Physician Payment Schedules and will review one service after additional data is available.

Final Rule for 2015
In the Final Rule for 2015 the public and CMS nominated 26 services as potentially misvalued, which the RUC expanded to 32 services to include additional codes as part of this family. The CPT Editorial Panel deleted five services and will review 14 additional services. The RUC submitted 14 recommendations for the 2016 Medicare Physician Payment Schedule.

Other Issues
In addition to the above screening criteria, the Relativity Assessment Workgroup performed an exhaustive search of the RUC database for services indicated by the RUC to be re-reviewed at a later date. Three codes were found that had not yet been re-reviewed. The RUC recommended a work RVU decrease for two codes and to maintain the work RVU for another code.

CMS also identified 72 services that required further practice expense review. The RUC submitted practice expense recommendations on 67 services and the CPT® Editorial Panel deleted 5 services. The RUC also reviewed special requests for 19 audiology and speech-language pathology services. The RUC submitted recommendations for 10 services for the 2010 Medicare Physician Payment Schedule and the remaining nine services for the 2011 Medicare Physician Payment Schedule.

CMS Requests and RUC Relativity Assessment Workgroup Code Status	
Total Number of Codes Identified*	**1,985**
Codes Completed	**1,718**
Work and PE Maintained	506
Work Increased	167
Work Decreased	616
Direct Practice Expense Revised (beyond work changes)	116
Deleted from CPT®	313
Codes Under Review	**267**
Referred to CPT® Editorial Panel	95
RUC to Review January and April 2016	126
RUC future review after additional data obtained	46

**The total number of codes identified will not equal the number of codes from each screen as some codes have been identified in more than one screen.*

The RUC's efforts for 2009-2015 have resulted nearly $4 billion for redistribution within the Medicare Physician Payment Schedule.

TABLE 16: CY 2016 Interim Final Codes with Direct PE Input Recommendations Accepted With Refinements

HCPCS code	SS to Survey	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min	CMS refine-ment (min or qty)
10035	ACR, ACS, ASBS	Perq dev soft tiss 1st imag	ED050	PACS Works	NF		48	46
			EQ168	light, exam	NF		26	43
			L051B	RN/Diagnost	NF	Review/read X-ray, lab, and pathology	2	0
10036	ACR, ACS, ASBS	Perq dev soft tiss add imag	ED050	PACS Works	NF		26	25
			EQ168	light, exam	NF		21	22
			L051B	RN/Diagnost	NF	Review/read X-ray, lab, and pathology	1	0
41530	AAO-HNS	Tongue base vol reduction	EQ214	radiofrequenc	NF		83	0
			EQ374	radiofrequenc	NF		0	83
47531	ACR, SIR	Injection for cholangiogram	ED050	PACS Works	NF		56	51
			EF018	stretcher	NF		92	87
			EF027	table, instrum	NF		92	87
			EL011	room, angiog	NF		32	29
			EQ011	ECG, 3-chan	NF		92	87
			EQ032	IV infusion p	NF		92	87
			EQ168	light, exam	NF		56	45
			L037D	RN/LPN/MT	NF	Assist physician in performing procedu	20	0
			L041B	Radiologic T	NF	Clean room/equipment by physician sta	6	3
			L051A	RN	NF	Sedate/Apply anesthesia	2	0
47532	ACR, SIR	Injection for cholangiogram	ED050	PACS Works	NF		76	73
			EF018	stretcher	NF		292	289
			EF027	table, instrum	NF		292	289
			EL011	room, angiog	NF		52	49
			EQ011	ECG, 3-chan	NF		292	289
			EQ032	IV infusion p	NF		292	289
			EQ168	light, exam	NF		76	67
			EQ250	ultrasound ur	NF		76	67
			L041B	Radiologic T	NF	Clean room/equipment by physician sta	6	3
			SA019	kit, iv starter	NF		1	0
			SB028	gown, surgica	NF		2	1
			ED050	PACS Works	NF		96	93
			EF018	stretcher	NF		312	309

HCPCS code	SS to Survey	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min	CMS refine-ment (min or qty)
47533	ACR, SIR	Plmt biliary drainage cath	EF027	table, instrum	NF		312	309
			EL011	room, angiog	NF		72	69
			EQ011	ECG, 3-chan	NF		312	309
			EQ032	IV infusion p	NF		312	309
			EQ168	light, exam	NF		96	87
			EQ250	ultrasound ur	NF		96	87
			L041B	Radiologic T	NF	Clean room/equipment by physician sta	6	3
			SA019	kit, iv starter	NF		1	0
			SB028	gown, surgica	NF		2	1
47534	ACR, SIR	Plmt biliary drainage cath	ED050	PACS Works	NF		114	111
			EF018	stretcher	NF		330	327
			EF027	table, instrum	NF		330	327
			EL011	room, angiog	NF		90	87
			EQ011	ECG, 3-chan	NF		330	327
			EQ032	IV infusion p	NF		330	327
			EQ168	light, exam	NF		114	105
			EQ250	ultrasound ur	NF		114	105
			L041B	Radiologic T	NF	Clean room/equipment by physician sta	6	3
			SA019	kit, iv starter	NF		1	0
			SB028	gown, surgica	NF		2	1
47535	ACR, SIR	Conversion ext bil drg cath	ED050	PACS Works	NF		81	78
			EF018	stretcher	NF		297	294
			EF027	table, instrum	NF		297	294
			EL011	room, angiog	NF		57	54
			EQ011	ECG, 3-chan	NF		297	294
			EQ032	IV infusion p	NF		297	294
			EQ168	light, exam	NF		81	72
			L041B	Radiologic T	NF	Clean room/equipment by physician sta	6	3
			SA019	kit, iv starter	NF		1	0
			SB028	gown, surgica	NF		2	1
			ED050	PACS Works	NF		66	63
			EF018	stretcher	NF		162	159
			EF027	table, instrum	NF		162	159

HCPCS code	SS to Survey	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min	CMS refine-ment (min or qty)
47536	ACR, SIR	Exchange biliary drg cath	EL011	room, angiog	NF		42	39
			EQ011	ECG, 3-chan	NF		162	159
			EQ032	IV infusion p	NF		162	159
			EQ168	light, exam	NF		66	57
			L041B	Radiologic T	NF	Clean room/equipment by physician sta	6	3
			SA019	kit, iv starter	NF		1	0
			SB028	gown, surgica	NF		2	1
47537	ACR, SIR	Removal biliary drg cath	ED050	PACS Works	NF		56	51
			EF018	stretcher	NF		92	87
			EF027	table, instrum	NF		92	87
			EL011	room, angiog	NF		32	29
			EQ011	ECG, 3-chan	NF		92	87
			EQ032	IV infusion p	NF		92	87
			EQ168	light, exam	NF		56	45
			L037D	RN/LPN/MT	NF	Assist physician in performing procedu	20	0
			L041B	Radiologic T	NF	Clean room/equipment by physician sta	6	3
			L051A	RN	NF	Sedate/Apply anesthesia	2	0
			ED050	PACS Works	NF		91	88
			EF018	stretcher	NF		307	304
			EF027	table, instrum	NF		307	304
			EL011	room, angiog	NF		67	64
			EQ011	ECG, 3-chan	NF		307	304
			EQ032	IV infusion p	NF		307	304
			EQ168	light, exam	NF		91	82
			L041B	Radiologic T	NF	Clean room/equipment by physician sta	6	3
			SA019	kit, iv starter	NF		1	0
			SB028	gown, surgica	NF		2	1

HCPCS code	SS to Survey	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min	CMS refine-ment (min or qty)
47538	ACR, SIR	Perq plmt bile duct stent	SD150	catheter, ballo	NF		0	2
			SD152	catheter, ballo	NF		2	0
47539	ACR, SIR	Perq plmt bile duct stent	ED050	PACS Works	NF		116	113
			EF018	stretcher	NF		332	329
			EF027	table, instrum	NF		332	329
			EL011	room, angiog	NF		92	89
			EQ011	ECG, 3-chan	NF		332	329
			EQ032	IV infusion p	NF		332	329
			EQ168	light, exam	NF		116	107
			EQ250	ultrasound un	NF		116	107
			L041B	Radiologic T	NF	Clean room/equipment by physician sta	6	3
			SA019	kit, iv starter	NF		1	0
			SB028	gown, surgica	NF		2	1
			SD150	catheter, ballo	NF		0	2
			SD152	catheter, ballo	NF		2	0
			ED050	PACS Works	NF		126	123
			EF018	stretcher	NF		342	339
			EF027	table, instrum	NF		342	339

HCPCS code	SS to Survey	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min	CMS refine-ment (min or qty)
47540	ACR, SIR	Perq plmt bile duct stent	EL011	room, angiog	NF		102	99
			EQ011	ECG, 3-chan	NF		342	339
			EQ032	IV infusion p	NF		342	339
			EQ168	light, exam	NF		126	117
			EQ250	ultrasound ur	NF		126	117
			L041B	Radiologic T	NF	Clean room/equipment by physician sta	6	3
			SA019	kit, iv starter	NF		1	0
			SB028	gown, surgica	NF		2	1
			SD150	catheter, ballo	NF		0	2
			SD152	catheter, ballo	NF		2	0
47541	ACR, SIR	Plmt access bil tree sm bwl	ED050	PACS Works	NF		96	93
			EF018	stretcher	NF		312	309
			EF027	table, instrum	NF		312	309
			EL011	room, angiog	NF		72	69
			EQ011	ECG, 3-chan	NF		312	309
			EQ032	IV infusion p	NF		312	309
			EQ168	light, exam	NF		96	87
			EQ250	ultrasound ur	NF		96	87
			L041B	Radiologic T	NF	Clean room/equipment by physician sta	6	3
			SA019	kit, iv starter	NF		1	0
			SB028	gown, surgica	NF		2	1

HCPCS code	SS to Survey	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min	CMS refine-ment (min or qty)
47542	ACR, SIR	Dilate biliary duct/ampulla	SD150	catheter, ballo	NF		0	1
			SD152	catheter, ballo	NF		1	0
47544	ACR, SIR	Removal duct glbldr calculi	SD150	catheter, ballo	NF		0	1
			SD152	catheter, ballo	NF		1	0
49185	ACR, SIR	Sclerotx fluid collection	EF018	stretcher	NF		60	76
			EF027	table, instrum	NF		99	115
			EQ168	light, exam	NF		39	115
			L037D	RN/LPN/MT	NF	Assist physician in performing procedu	30	0
			SB024	gloves, sterile	NF		4	2
			EF027	table, instrum	NF		46	45
			EL011	room, angiog	NF		46	0

HCPCS code	SS to Survey	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min	CMS refine-ment (min or qty)
50606	SIR, ACR	Endoluminal bx urtr rnl plvs	EL014	room, radiogr	NF		0	47
			EQ011	ECG, 3-chan	NF		46	45
			EQ032	IV infusion p	NF		46	45
			EQ168	light, exam	NF		46	49
50705	SIR, ACR	Ureteral embolization/occl	EF027	table, instrum	NF		61	60
			EL011	room, angiog	NF		61	0
			EL014	room, radiogr	NF		0	62
			EQ011	ECG, 3-chan	NF		61	60
			EQ032	IV infusion p	NF		61	60
			EQ168	light, exam	NF		61	64
			EF027	table, instrum	NF		61	60
			EL011	room, angiog	NF		61	0

HCPCS code	SS to Survey	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min	CMS refine-ment (min or qty)
50706	SIR, ACR	Balloon dilate urtrl strix	EL014	room, radiogr	NF		0	62
			EQ011	ECG, 3-chan	NF		61	60
			EQ032	IV infusion p	NF		61	60
			EQ168	light, exam	NF		61	64
			SD019	catheter, ball	NF		0	1
			SD152	catheter, ball	NF		1	0
65779	AOA	Cover eye w/membrane suture	EQ137	instrument pa	NF		62	56
			L038A	COMT/COT/	F	Dischrg mgmt same day (0.5 x 99238)	6	0
66170	AOA	Glaucoma surgery	EL005	lane, exam (o	F		297	288
			L038A	COMT/COT/	F	99212 27 minutes	3	4
			L038A	COMT/COT/	F	99213 36 minutes	6	5
			SA050	pack, ophthal	F		3	4
			SA082	pack, ophthal	F		6	5
67110	AAO	Repair detached retina	EQ137	instrument pa	NF		52	44
67113	AAO	Repair retinal detach cplx	SA082	pack, ophthal	NF		6	0

HCPCS code	SS to Survey	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min	CMS refine-ment (min or qty)
67228	AAO	Treatment x10sv retinopathy	L038A	COMT/COT/	F	Dischrg mgmt same day (0.5 x 99238)	6	0
73523	AAOS, ACR	X-ray exam hips bi 5/> views	ED050	PACS Works	NF		36	33
			EL012	room, basic r	NF		30	27
			L041B	Radiologic T	NF	Acquire images	21	18
78264	NM, ACR,SNM	Gastric emptying imag study	ED019	computer wo	NF		74	70
			ED050	PACS Works	NF		82	98
			L049A	Nuclear Med	NF	Patient clinical information and questio	4	2
78265	NM, ACR,SNM	Gastric emptying imag study	ED019	computer wo	NF		88	84
			ED050	PACS Works	NF		98	115
			L049A	Nuclear Med	NF	Patient clinical information and questio	4	2
78266	NM, ACR,SNM	Gastric emptying imag study	ED019	computer wo	NF		109	105
			ED050	PACS Works	NF		119	130
			L049A	Nuclear Med	NF	Patient clinical information and questio	4	2
88104	ASC, CAP	Cytopath fl nongyn smears	EP038	solvent recyc	NF		2	0
			L033A	Lab Technici	NF	Recycle xylene from stainer	1	0
			L035A	Lab Tech/His	NF	Order, restock, and distribute specimen	0.5	0

HCPCS code	SS to Survey	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min	CMS refine-ment (min or qty)
			L035A	Lab Tech/His	NF	Prepare specimen containers preload fi	0	0.5
88106	ASC, CAP	Cytopath fl nongyn filter	EP038	solvent recyc	NF		2	0
			L033A	Lab Technici	NF	Recycle xylene from stainer	1	0
			L035A	Lab Tech/His	NF	Order, restock, and distribute specimen	0.5	0
			L035A	Lab Tech/His	NF	Prepare specimen containers preload fi	0	0.5
88108	ASC, CAP	Cytopath concentrate tech	EP038	solvent recyc	NF		2	0
			L033A	Lab Technici	NF	Recycle xylene from stainer	1	0
			L035A	Lab Tech/His	NF	Order, restock, and distribute specimen	0.5	0
			L035A	Lab Tech/His	NF	Prepare specimen containers preload fi	0	0.5
			SB022	gloves, non-s	NF		0.2	2
			SB027	gown, staff, i	NF		0.2	2
			SM016	eye shield, sp	NF		0.2	1
88112	ASC, CAP	Cytopath cell enhance tech	EP038	solvent recyc	NF		2	0
			L033A	Lab Technici	NF	Recycle xylene from stainer	1	0
			L035A	Lab Tech/His	NF	Order, restock, and distribute specimen	0.5	0
			L035A	Lab Tech/His	NF	Prepare specimen containers preload fi	0	0.5
			SB022	gloves, non-s	NF		0.2	2
			SB027	gown, staff, i	NF		0.2	2
			SM016	eye shield, sp	NF		0.2	1
88160	ASC, CAP	Cytopath smear other source	EP038	solvent recyc	NF		2	0
			L033A	Lab Technici	NF	Recycle xylene from stainer	1	0
			L035A	Lab Tech/His	NF	Order, restock, and distribute specimen	0.5	0
			L035A	Lab Tech/His	NF	Prepare specimen containers preload fi	0	0.5
88161	ASC, CAP	Cytopath smear other source	EP038	solvent recyc	NF		2	0
			L033A	Lab Technici	NF	Recycle xylene from stainer	1	0
			L035A	Lab Tech/His	NF	Order, restock, and distribute specimen	0.5	0
			L035A	Lab Tech/His	NF	Prepare specimen containers preload fi	0	0.5
88162	ASC, CAP	Cytopath smear other source	EP038	solvent recyc	NF		2	0
			L033A	Lab Technici	NF	Recycle xylene from stainer	1	0
			L035A	Lab Tech/His	NF	Order, restock, and distribute specimen	0.5	0
			L035A	Lab Tech/His	NF	Prepare specimen containers preload fi	0	0.5

TABLE 1

HCPCS code	Comment	Direct costs change	Specialty Agree/ Disagree	(If Disagree) Specialty Comment
10035	Refined equipment time to conform to established policies for PACS Wo	($0.04)	Disagree	See comment below
	Refined equipment time to conform to established policies for non-highl	$0.07	Agree	
	Clinical labor task redundant with clinical labor task Review examinatio	($1.02)	Disagree	Review and protocol with the radiologist occurs in the pre-service time and is a separate activity than review reports which occurs in the service period time.
10036	Refined equipment time to conform to established policies for PACS Wo	($0.02)	Disagree	See comment below
	Refined equipment time to conform to established policies for non-highl	$0.00	Agree	
	Clinical labor task redundant with clinical labor task Review examinatio	($0.51)	Disagree	Review and protocol with the radiologist occurs in the pre-service time and is a separate activity than review reports which occurs in the service period time.
41530	Equipment item replaced by another item (NEW)	($10.58)	Agree	
	Equipment item replaces another item (EQ374)	$3.29	Agree	
47531	Refined equipment time to conform to established policies for PACS Wo	($0.11)	Agree	
	Refined equipment time to conform to established policies for equipmen	($0.03)	Agree	
	Refined equipment time to conform to established policies for equipmen	($0.01)	Agree	
	Refined equipment time to conform to changes in clinical labor time	($15.76)	Agree	
	Refined equipment time to conform to established policies for equipmen	($0.07)	Agree	
	Refined equipment time to conform to established policies for equipmen	($0.03)	Agree	
	Refined equipment time to conform to established policies for non-highl	($0.05)	Agree	
	Removed clinical labor associated with moderate sedation; moderate sed	($7.40)	Agree	
	Refined time to standard for this clinical labor task	($1.23)	Agree	
	Removed clinical labor associated with moderate sedation; moderate sed	($1.02)	Agree	
47532	Refined equipment time to conform to established policies for PACS Wo	($0.07)	Agree	
	Refined equipment time to conform to established policies for equipmen	($0.02)	Agree	
	Refined equipment time to conform to established policies for equipmen	$0.00	Agree	
	Refined equipment time to conform to changes in clinical labor time	($15.76)	Agree	
	Refined equipment time to conform to established policies for equipmen	($0.04)	Agree	
	Refined equipment time to conform to established policies for equipmen	($0.02)	Agree	
	Refined equipment time to conform to established policies for non-highl	($0.04)	Agree	
	Refined equipment time to conform to established policies for non-highl	($1.05)	Agree	
	Refined time to standard for this clinical labor task	($1.23)	Agree	
	Duplicative; supply is included in conscious sedation pack conscious sed	($1.60)	Agree	
	Duplicative; supply is included in conscious sedation pack conscious sed	($4.67)	Agree	
	Refined equipment time to conform to established policies for PACS Wo	($0.07)	Agree	
	Refined equipment time to conform to established policies for equipmen	($0.02)	Agree	

HCPCS code	Comment	Direct costs change	Specialty Agree/ Disagree	(If Disagree) Specialty Comment
47533	Refined equipment time to conform to established policies for equipmen	$0.00	Agree	
	Refined equipment time to conform to changes in clinical labor time	($15.76)	Agree	
	Refined equipment time to conform to established policies for equipmen	($0.04)	Agree	
	Refined equipment time to conform to established policies for equipmen	($0.02)	Agree	
	Refined equipment time to conform to established policies for non-highl	($0.04)	Agree	
	Refined equipment time to conform to established policies for non-highl	($1.05)	Agree	
	Refined time to standard for this clinical labor task	($1.23)	Agree	
	Duplicative; supply is included in conscious sedation pack conscious sec	($1.60)	Agree	
	Duplicative; supply is included in conscious sedation pack conscious sec	($4.67)	Agree	
47534	Refined equipment time to conform to established policies for PACS Wo	($0.07)	Agree	
	Refined equipment time to conform to established policies for equipmen	($0.02)	Agree	
	Refined equipment time to conform to established policies for equipmen	$0.00	Agree	
	Refined equipment time to conform to changes in clinical labor time	($15.76)	Agree	
	Refined equipment time to conform to established policies for equipmen	($0.04)	Agree	
	Refined equipment time to conform to established policies for equipmen	($0.02)	Agree	
	Refined equipment time to conform to established policies for non-highl	($0.04)	Agree	
	Refined equipment time to conform to established policies for non-highl	($1.05)	Agree	
	Refined time to standard for this clinical labor task	($1.23)	Agree	
	Duplicative; supply is included in conscious sedation pack conscious sec	($1.60)	Agree	
	Duplicative; supply is included in conscious sedation pack conscious sec	($4.67)	Agree	
47535	Refined equipment time to conform to established policies for PACS Wo	($0.07)	Agree	
	Refined equipment time to conform to established policies for equipmen	($0.02)	Agree	
	Refined equipment time to conform to established policies for equipmen	$0.00	Agree	
	Refined equipment time to conform to changes in clinical labor time	($15.76)	Agree	
	Refined equipment time to conform to established policies for equipmen	($0.04)	Agree	
	Refined equipment time to conform to established policies for equipmen	($0.02)	Agree	
	Refined equipment time to conform to established policies for non-highl	($0.04)	Agree	
	Refined time to standard for this clinical labor task	($1.23)	Agree	
	Duplicative; supply is included in conscious sedation pack conscious sec	($1.60)	Agree	
	Duplicative; supply is included in conscious sedation pack conscious sec	($4.67)	Agree	
	Refined equipment time to conform to established policies for PACS Wo	($0.07)	Agree	
	Refined equipment time to conform to established policies for equipmen	($0.02)	Agree	
	Refined equipment time to conform to established policies for equipmen	$0.00	Agree	

HCPCS code	Comment	Direct costs change	Specialty Agree/ Disagree	(If Disagree) Specialty Comment
47536	Refined equipment time to conform to changes in clinical labor time EL	($15.76)	Agree	
	Refined equipment time to conform to established policies for equipmen	($0.04)	Agree	
	Refined equipment time to conform to established policies for equipmen	($0.02)	Agree	
	Refined equipment time to conform to established policies for non-highl	($0.04)	Agree	
	Refined time to standard for this clinical labor task	($1.23)	Agree	
	Duplicative; supply is included in conscious sedation pack conscious sed	($1.60)	Agree	
	Duplicative; supply is included in conscious sedation pack conscious sed	($4.67)	Agree	
47537	Refined equipment time to conform to established policies for PACS W	($0.11)	Agree	
	Refined equipment time to conform to established policies for equipmen	($0.03)	Agree	
	Refined equipment time to conform to established policies for equipmen	($0.01)	Agree	
	Refined equipment time to conform to changes in clinical labor time	($15.76)	Agree	
	Refined equipment time to conform to established policies for equipmen	($0.07)	Agree	
	Refined equipment time to conform to established policies for equipmen	($0.03)	Agree	
	Refined equipment time to conform to established policies for non-highl	($0.05)	Agree	
	Removed clinical labor associated with moderate sedation; moderate sed	($7.40)	Agree	
	Refined time to standard for this clinical labor task	($1.23)	Agree	
	Removed clinical labor associated with moderate sedation; moderate sed	($1.02)	Agree	
	Refined equipment time to conform to established policies for PACS W	($0.07)	Agree	
	Refined equipment time to conform to established policies for equipmen	($0.02)	Agree	
	Refined equipment time to conform to established policies for equipmen	$0.00	Agree	
	Refined equipment time to conform to changes in clinical labor time	($15.76)	Agree	
	Refined equipment time to conform to established policies for equipmen	($0.04)	Agree	
	Refined equipment time to conform to established policies for equipmen	($0.02)	Agree	
	Refined equipment time to conform to established policies for non-highl	($0.04)	Agree	
	Refined time to standard for this clinical labor task	($1.23)	Agree	
	Duplicative; supply is included in conscious sedation pack conscious sed	($1.60)	Agree	
	Duplicative; supply is included in conscious sedation pack conscious sed	($4.67)	Agree	

HCPCS code	Comment	Direct costs change	Specialty Agree/ Disagree	(If Disagree) Specialty Comment
47538	Supply item replaces another item; see preamble SD152	$130.00	Disagree	ACR - A Dowd catheter is designed and FDA approved for use in the prostatic URETHRA by retrograde placement through the penile urethra. It is not designed for use in an antegrade URETERAL dilation procedure. The replacement is inappropriate. SIR - CMS is replacing supply item “catheter, balloon, PTA” (SD152) with supply item “catheter, balloon ureteral (Dowd)” (SD150) on an interim final basis. They believe that the use of this balloon catheter, which is specifically designed for catheter and image guidance procedures, would be more typical than the use of a PTA balloon catheter. A Dowd catheter is designed and FDA approved for use in the prostatic URETHRA by retrograde placement through the penile urethra. It is not designed for use in an antegrade URETERAL dilation procedure. The replacement is inappropriate. SIR requests that SD152 be reinstated for CPT Codes 47538, 47539, 47540, 47542 and 47544.
	Supply item replaced by another item; see preamble SD150	($487.00)	Disagree	See above comments.
	Refined equipment time to conform to established policies for PACS Wo	($0.07)	Agree	
	Refined equipment time to conform to established policies for equipmen	($0.02)	Agree	
	Refined equipment time to conform to established policies for equipmen	$0.00	Agree	
	Refined equipment time to conform to changes in clinical labor time	($15.76)	Agree	
	Refined equipment time to conform to established policies for equipmen	($0.04)	Agree	
	Refined equipment time to conform to established policies for equipmen	($0.02)	Agree	
	Refined equipment time to conform to established policies for non-highl	($0.04)	Agree	
	Refined equipment time to conform to established policies for non-highl	($1.05)	Agree	
	Refined time to standard for this clinical labor task	($1.23)	Agree	
	Duplicative; supply is included in conscious sedation pack SA044	($1.60)	Agree	
	Duplicative; supply is included in conscious sedation pack conscious sed	($4.67)	Agree	
47539	Supply item replaces another item; see preamble SD152	$130.00	Disagree	ACR - A Dowd catheter is designed and FDA approved for use in the prostatic URETHRA by retrograde placement through the penile urethra. It is not designed for use in an antegrade URETERAL dilation procedure. The replacement is inappropriate. SIR - CMS is replacing supply item “catheter, balloon, PTA” (SD152) with supply item “catheter, balloon ureteral (Dowd)” (SD150) on an interim final basis. They believe that the use of this balloon catheter, which is specifically designed for catheter and image guidance procedures, would be more typical than the use of a PTA balloon catheter. A Dowd catheter is designed and FDA approved for use in the prostatic URETHRA by retrograde placement through the penile urethra. It is not designed for use in an antegrade URETERAL dilation procedure. The replacement is inappropriate. SIR requests that SD152 be reinstated for CPT Codes 47538, 47539, 47540, 47542 and 47544.
	Supply item replaced by another item; see preamble SD150	($487.00)	Disagree	See above comments.
	Refined equipment time to conform to established policies for PACS Wo	($0.07)	Agree	
	Refined equipment time to conform to established policies for equipmen	($0.02)	Agree	
	Refined equipment time to conform to established policies for equipmen	$0.00	Agree	

HCPCS code	Comment	Direct costs change	Specialty Agree/ Disagree	(If Disagree) Specialty Comment
47540	Refined equipment time to conform to changes in clinical labor time	($15.76)	Agree	
	Refined equipment time to conform to established policies for equipmen	($0.04)	Agree	
	Refined equipment time to conform to established policies for equipmen	($0.02)	Agree	
	Refined equipment time to conform to established policies for non-highl	($0.04)	Agree	
	Refined equipment time to conform to established policies for non-highl	($1.05)	Agree	
	Refined time to standard for this clinical labor task	($1.23)	Agree	
	Duplicative; supply is included in conscious sedation pack conscious sed	($1.60)	Agree	
	Duplicative; supply is included in conscious sedation pack conscious sed	($4.67)	Agree	
	Supply item replaces another item; see preamble SD152	$130.00	Disagree	ACR - A Dowd catheter is designed and FDA approved for use in the prostatic URETHRA by retrograde placement through the penile urethra. It is not designed for use in an antegrade URETERAL dilation procedure. The replacement is inappropriate. SIR - CMS is replacing supply item “catheter, balloon, PTA” (SD152) with supply item “catheter, balloon ureteral (Dowd)” (SD150) on an interim final basis. They believe that the use of this balloon catheter, which is specifically designed for catheter and image guidance procedures, would be more typical than the use of a PTA balloon catheter. A Dowd catheter is designed and FDA approved for use in the prostatic URETHRA by retrograde placement through the penile urethra. It is not designed for use in an antegrade URETERAL dilation procedure. The replacement is inappropriate. SIR requests that SD152 be reinstated for CPT Codes 47538, 47539, 47540, 47542 and 47544.
	Supply item replaced by another item; see preamble SD150	($487.00)	Disagree	See above comments.
47541	Refined equipment time to conform to established policies for PACS Wo	($0.07)	Agree	
	Refined equipment time to conform to established policies for equipmen	($0.02)	Agree	
	Refined equipment time to conform to established policies for equipmen	$0.00	Agree	
	Refined equipment time to conform to changes in clinical labor time	($15.76)	Agree	
	Refined equipment time to conform to established policies for equipmen	($0.04)	Agree	
	Refined equipment time to conform to established policies for equipmen	($0.02)	Agree	
	Refined equipment time to conform to established policies for non-highl	($0.04)	Agree	
	Refined equipment time to conform to established policies for non-highl	($1.05)	Agree	
	Refined time to standard for this clinical labor task	($1.23)	Agree	
	Duplicative; supply is included in conscious sedation pack conscious sed	($1.60)	Agree	
	Duplicative; supply is included in conscious sedation pack conscious sed	($4.67)	Agree	

HCPCS code	Comment	Direct costs change	Specialty Agree/ Disagree	(If Disagree) Specialty Comment
47542	Supply item replaces another item; see preamble SD152	$65.00	Disagree	ACR - A Dowd catheter is designed and FDA approved for use in the prostatic URETHRA by retrograde placement through the penile urethra. It is not designed for use in an antegrade URETERAL dilation procedure. The replacement is inappropriate. SIR - CMS is replacing supply item “catheter, balloon, PTA” (SD152) with supply item “catheter, balloon ureteral (Dowd)” (SD150) on an interim final basis. They believe that the use of this balloon catheter, which is specifically designed for catheter and image guidance procedures, would be more typical than the use of a PTA balloon catheter. A Dowd catheter is designed and FDA approved for use in the prostatic URETHRA by retrograde placement through the penile urethra. It is not designed for use in an antegrade URETERAL dilation procedure. The replacement is inappropriate. SIR requests that SD152 be reinstated for CPT Codes 47538, 47539, 47540, 47542 and 47544.
	Supply item replaced by another item; see preamble SD150	($243.50)	Disagree	See above comments.
47544	Supply item replaces another item; see preamble SD152	$65.00	Disagree	ACR - A Dowd catheter is designed and FDA approved for use in the prostatic URETHRA by retrograde placement through the penile urethra. It is not designed for use in an antegrade URETERAL dilation procedure. The replacement is inappropriate. SIR - CMS is replacing supply item “catheter, balloon, PTA” (SD152) with supply item “catheter, balloon ureteral (Dowd)” (SD150) on an interim final basis. They believe that the use of this balloon catheter, which is specifically designed for catheter and image guidance procedures, would be more typical than the use of a PTA balloon catheter. A Dowd catheter is designed and FDA approved for use in the prostatic URETHRA by retrograde placement through the penile urethra. It is not designed for use in an antegrade URETERAL dilation procedure. The replacement is inappropriate. SIR requests that SD152 be reinstated for CPT Codes 47538, 47539, 47540, 47542 and 47544.
	Supply item replaced by another item; see preamble SD150	($243.50)	Disagree	See above comments.
49185	Refined equipment time to conform to established policies for equipmen	$0.08	Agree	
	Refined equipment time to conform to established policies for equipmen	$0.02	Agree	
	Refined equipment time to conform to established policies for equipmen	$0.33	Agree	
	Clinical labor task redundant with clinical labor task Assist physician in	($11.10)	Disagree	This is a separate staff person / staff type and appropriate to include
	Aligned supply quantities with changes to number of clinical labor staff	($1.68)	Agree	
	Refined equipment time to conform to established policies for moderate	$0.00	Agree	
	Equipment item replaced by another item EL014	($241.71)	Disagree	See comment below.

HCPCS code	Comment	Direct costs change	Specialty Agree/ Disagree	(If Disagree) Specialty Comment
50606	Equipment item replaces another item EL011	$65.48	Disagree	An R/F device is incapable of 3-axis rotational imaging. An R/F room (fixed imaging plane) is not conducive to performance of these procedures because it cannot image the target surgical field in multiple obliquities except by moving the patient (rolling from side to side). However, rolling the patient is impractical and dangerous while the patient is sedated. While performing these procedures, the patient must not physically move to avoid physical injury from the needles and other tools used during the procedure. Sterility is also a major concern in an R/F room where the fixed imaging chain is not amenable to standard surgical sterile preparation. Additionally, an R/F room would create unacceptable radiation exposure to the physicians, their staff, and their patients, which would be contrary to ALARA principles of minimized patient radiation dose.
	Refined equipment time to conform to established policies for moderate	($0.01)	Agree	
	Refined equipment time to conform to established policies for moderate	($0.01)	Agree	
	Refined equipment time to conform to established policies for non-highl	$0.01	Agree	
50705	Refined equipment time to conform to established policies for moderate	$0.00	Agree	
	Equipment item replaced by another item EL014	($320.54)	Disagree	See comment below.
	Equipment item replaces another item EL011	$86.37	Disagree	An R/F device is incapable of 3-axis rotational imaging. An R/F room (fixed imaging plane) is not conducive to performance of these procedures because it cannot image the target surgical field in multiple obliquities except by moving the patient (rolling from side to side). However, rolling the patient is impractical and dangerous while the patient is sedated. While performing these procedures, the patient must not physically move to avoid physical injury from the needles and other tools used during the procedure. Sterility is also a major concern in an R/F room where the fixed imaging chain is not amenable to standard surgical sterile preparation. Additionally, an R/F room would create unacceptable radiation exposure to the physicians, their staff, and their patients, which would be contrary to ALARA principles of minimized patient radiation dose.
	Refined equipment time to conform to established policies for moderate	($0.01)	Agree	
	Refined equipment time to conform to established policies for moderate	($0.01)	Agree	
	Refined equipment time to conform to established policies for non-highl	$0.01	Agree	
	Refined equipment time to conform to established policies for moderate	$0.00	Agree	
	Equipment item replaced by another item EL014	($320.54)	Disagree	See comment below.

HCPCS code	Comment	Direct costs change	Specialty Agree/ Disagree	(If Disagree) Specialty Comment
50706	Equipment item replaces another item El011	$86.37	Disagree	An R/F device is incapable of 3-axis rotational imaging. An R/F room (fixed imaging plane) is not conducive to performance of these procedures because it cannot image the target surgical field in multiple obliquities except by moving the patient (rolling from side to side). However, rolling the patient is impractical and dangerous while the patient is sedated. While performing these procedures, the patient must not physically move to avoid physical injury from the needles and other tools used during the procedure. Sterility is also a major concern in an R/F room where the fixed imaging chain is not amenable to standard surgical sterile preparation. Additionally, an R/F room would create unacceptable radiation exposure to the physicians, their staff, and their patients, which would be contrary to ALARA principles of minimized patient radiation dose.
	Refined equipment time to conform to established policies for moderate	($0.01)	Agree	
	Refined equipment time to conform to established policies for moderate	($0.01)	Agree	
	Refined equipment time to conform to established policies for non-highl	$0.01	Agree	
	Supply item replaces another item; see preamble SD152	$166.00	Disagree	ACR - SD019 is a retrograde, transurethrally placed, double-J ureteral stent in which a dilation balloon is integrated at the cranial end (end inserted first from a retrograde approach). There are two problems with this proposed catheter input. First, the balloon would be at the ureteral-vessicle junction when placed antegrade via a percutaneous nephrostomy negating the ability to treat the most common lesion, a UPJ syricture. Second the system is meant to be endoscopically retrieved. This input is not appropriate for a percutaneous procedure and should be used with a retrograde endoscopic procedure. SIR - For CPT code 50706, CMS is replacing the RUC-recommended supply item “catheter, balloon, PTA” (SD152) with a “catheter, balloon, ureteral-GI (strictures)” (SD019) in the nonfacility setting. We believe that the latter balloon catheter, which is specifically designed for ureteral procedures, would be more typically used for these procedures than a PTA balloon catheter.
	Supply item replaced by another item; see preamble SD019	($243.50)	Disagree	See comments above.
65779	Refined equipment time to conform to established policies for surgical in	($0.01)	Agree	
	Aligned discharge day management clinical labor time with the discharg	($2.28)	Agree	
66170	Refined equipment time to conform to office visit duration	($0.86)	Agree	
	Refined clinical labor to align with number of post-operative visits	$10.26	Agree	
	Refined clinical labor to align with number of post-operative visits	($13.68)	Agree	
	Refined supply quantity to align with number of post-operative visits	$1.19	Agree	
	Refined supply quantity to align with number of post-operative visits	($2.00)	Agree	
67110	Refined equipment time to conform to established policies for surgical in	($0.02)	Agree	
67113	This input is not applicable in the non-facility setting	($11.98)	Agree	

HCPCS code	Comment	Direct costs change	Specialty Agree/ Disagree	(If Disagree) Specialty Comment
67228	Aligned discharge day management clinical labor time with the discharg	($2.28)	Agree	
73523	Refined equipment time to conform to changes in clinical labor time	($0.07)	Disagree	See comment below.
	Refined equipment time to conform to changes in clinical labor time	($1.45)	Disagree	See comment below.
	Refined clinical labor time to conform with identical labor activity in oth	($1.23)	Disagree	This study involves greater than 5 views which is comparable to the crosswalk codes we presented including 72114 and 72052
78264	See preamble text Non-standard equipment time formula	($0.84)	Agree	
	Refined equipment time to conform to established policies for PACS Wo	$0.35	Agree	
	Refined time to standard for this clinical labor task	($1.23)	Agree	
78265	See preamble text Non-standard equipment time formula	($0.84)	Agree	
	Refined equipment time to conform to established policies for PACS Wo	$0.37	Agree	
	Refined time to standard for this clinical labor task	($1.23)	Agree	
78266	See preamble text Non-standard equipment time formula	($0.84)	Agree	
	Refined equipment time to conform to established policies for PACS Wo	$0.24	Agree	
	Refined time to standard for this clinical labor task	($1.23)	Agree	
88104	See preamble text	($0.09)	Disagree	The solvent recycling system costs are direct expenses as they are based on the amount of recycled solvent allocated to each specimen. Solvents were allocated to specific specimens based on batch size. The time allocated to the solvent recycling system was based on the amount of time necessary for the system to recycle the amount of solvent used for each specimen. The amount of solvent listed in supplies is based on the amount of solvent that is added in addition to that from the solvent recycling system as the system does not reclaim 100% of solvent. If the solvent recycling system is eliminated the amount of solvent required for each specimen would increase substantially.
	Indirect Practice Expense input and/or not individually allocable to a par	($0.33)	Disagree	The clinical labor tasks and time for EPA hazardous solvent recycling are direct expenses as they are based on the amount of recycled solvent allocated to each specimen. Solvents were allocated to specific specimens based on batch size. The time allocated to the solvent recycling system was based on the amount of time necessary for the system to recycle the amount of solvent used for each specimen. The amount of solvent listed in supplies is based on the amount of solvent that is added in addition to that from the solvent recycling system as the system does does not reclaim 100% of solvent. If the solvent recycling system is eliminated the amount of solvent required for each specimen would increase substantially.
	Indirect Practice Expense input and/or not individually allocable to a par	($0.18)	Disagree	Clinical labor activities such as ordering, restocking, and distributing specimen containers and or slides with requisition forms are direct costs, with the time determined based on the time required for a single specimen with consideration of batch size. For example, if it took a technician 60 minutes to perform this task for 60 specimens (the typical batch size in this example), then each specimen would be allocated 1 minute for this activity.

HCPCS code	Comment	Direct costs change	Specialty Agree/ Disagree	(If Disagree) Specialty Comment
	Refined clinical labor time to conform with identical labor activity in oth	$0.18	Agree	
88106	See preamble text	($0.09)	Disagree	The solvent recycling system costs are direct expenses as they are based on the amount of
	Indirect Practice Expense input and/or not individually allocable to a par	($0.33)	Disagree	The clinical labor tasks and time for EPA hazardous solvent recycling are direct expenses as
	Indirect Practice Expense input and/or not individually allocable to a par	($0.18)	Disagree	Clinical labor activities such as ordering, restocking, and distributing specimen containers
	Refined clinical labor time to conform with identical labor activity in oth	$0.18	Agree	
88108	See preamble text	($0.09)	Disagree	The solvent recycling system costs are direct expenses as they are based on the amount of
	Indirect Practice Expense input and/or not individually allocable to a par	($0.33)	Disagree	The clinical labor tasks and time for EPA hazardous solvent recycling are direct expenses as
	Indirect Practice Expense input and/or not individually allocable to a par	($0.18)	Disagree	Clinical labor activities such as ordering, restocking, and distributing specimen containers
	Refined clinical labor time to conform with identical labor activity in oth	$0.18	Agree	
	See preamble text	$0.15	Disagree	CMS has not accounted for the batch size that was specified at the RUC meeting. For codes
	See preamble text	$2.13	Disagree	CMS has not accounted for the batch size that was specified at the RUC meeting. For codes
	See preamble text	$1.18	Disagree	CMS has not accounted for the batch size that was specified at the RUC meeting. For codes
88112	See preamble text	($0.09)	Disagree	The solvent recycling system costs are direct expenses as they are based on the amount of
	Indirect Practice Expense input and/or not individually allocable to a par	($0.33)	Disagree	The clinical labor tasks and time for EPA hazardous solvent recycling are direct expenses as
	Indirect Practice Expense input and/or not individually allocable to a par	($0.18)	Disagree	Clinical labor activities such as ordering, restocking, and distributing specimen containers
	Refined clinical labor time to conform with identical labor activity in oth	$0.18	Agree	
	See preamble text	$0.15	Disagree	CMS has not accounted for the batch size that was specified at the RUC meeting. For codes
	See preamble text	$2.13	Disagree	CMS has not accounted for the batch size that was specified at the RUC meeting. For codes
	See preamble text	$1.18	Disagree	CMS has not accounted for the batch size that was specified at the RUC meeting. For codes
88160	See preamble text	($0.09)	Disagree	The solvent recycling system costs are direct expenses as they are based on the amount of
	Indirect Practice Expense input and/or not individually allocable to a par	($0.33)	Disagree	The clinical labor tasks and time for EPA hazardous solvent recycling are direct expenses as
	Indirect Practice Expense input and/or not individually allocable to a par	($0.18)	Disagree	Clinical labor activities such as ordering, restocking, and distributing specimen containers
	Refined clinical labor time to conform with identical labor activity in oth	$0.18	Agree	
88161	See preamble text	($0.09)	Disagree	The solvent recycling system costs are direct expenses as they are based on the amount of
	Indirect Practice Expense input and/or not individually allocable to a par	($0.33)	Disagree	The clinical labor tasks and time for EPA hazardous solvent recycling are direct expenses as
	Indirect Practice Expense input and/or not individually allocable to a par	($0.18)	Disagree	Clinical labor activities such as ordering, restocking, and distributing specimen containers
	Refined clinical labor time to conform with identical labor activity in oth	$0.18	Agree	
88162	See preamble text	($0.09)	Disagree	The solvent recycling system costs are direct expenses as they are based on the amount of
	Indirect Practice Expense input and/or not individually allocable to a par	($0.33)	Disagree	The clinical labor tasks and time for EPA hazardous solvent recycling are direct expenses as
	Indirect Practice Expense input and/or not individually allocable to a par	($0.18)	Disagree	Clinical labor activities such as ordering, restocking, and distributing specimen containers
	Refined clinical labor time to conform with identical labor activity in oth	$0.18	Agree	