7/30/2023 12:00 am

Practice Management/Socioeconomic Symposium

Impact and Outcomes of Anti-VEGF Prior Authorization Requests: Insights From a Large Database Analysis

- Saira Khanna, MD
- Michael Lai, MD, PhD
- Charles Wykoff, MD, PhD, FASRS
- Sabin Dang, MD

Objective: To quantify the impact and results of the prior authorization (PA) process for intravitreal anti-vascular endothelial growth factor (anti-VEGF) pharmaceuticals on retina practices.
Purpose: The purpose of the current study was to investigate the overall approval rate for PA for aflibercept, ranibizumab and bevacizumab and the same day approval rate of PA for each of these anti-VEGF medications using a large, centralized database.
Methods: The SamaCare PA application database was queried between July 1, 2022 and December 31, 2022 for all PA requests for bevacizumab, ranibizumab, and aflibercept. The total number of approvals, denials, and the total number of same day authorization (defined as decision within 30 minutes of the request) were collected. Secondary analysis stratifying PA results based on insurance provider (Medicare Advantage, commercial insurances, or Medicaid) were also obtained.
Results: A total number of 33,178 PAs were examined. Overall, 32,397 (97.6%) of PA requests were approved. For each individual anti-VEGF agent, the denial rate was 2.32% (476/20493) for aflibercept, 2.84% (185/6508) for ranibizumab, and 1.94% (120/6177) for bevacizumab. The overall total number of same day approvals was 710 (2.14%). The mean time to approval was 2.75 days and median was 9.36 hours. When stratifying by insurance, Medicare Advantage had the lowest rate of PA rejections at 1.18% (222/18769), followed by Medicaid at 3.87% (133/3438), and finally commercial insurance at 3.95% (397/10047). Ranibizumab had the highest rate of same day approval at 4.03% (262/6508), followed by aflibercept at 1.96% (401/20493), and finally bevacizumab 0.76% (47/6177). All insurance carriers had a same day approval rate of less than 4% (range 0.32% to 3.16%).
Conclusion: Consistent with previous studies on PA, this large database analysis of PA approval rates shows that nearly all treatment requests from retina specialists are approved. But despite an eventual approval rate of greater than 97%, less than three percent are granted same day approval, resulting in delay of care for patients and potential vision loss. Furthermore, the administrative burden associated with obtaining these PAs must be acknowledged. Given the overwhelmingly positive approval rates in this large database analysis, the utility of prior authorizations for anti-VEGF intravitreal injections should be reconsidered.

IRB APPROVAL No - no IRB

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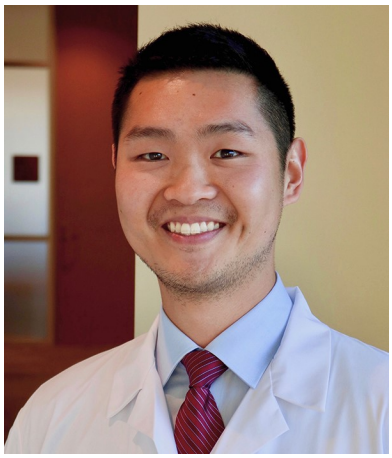
Practice Management/Socioeconomic Symposium

Accuracy of Diagnosis Codes for Patients With Concurrent Geographic Atrophy and Exudative Age-Related Macular Degeneration



- Jong Park, MD
- Xing Chen, MD
- Megan Clontz, BS
- Tedi Begaj, MD
- Margaret Runner, MD
- Jeremy Wolfe, MD, MS

Objective: Do patients with both geographic atrophy (GA) and exudative age-related macular degeneration have a diagnosis of GA documented in their electronic medical record?
Purpose: To determine the accuracy of geographic atrophy (GA) documentation in patients with concurrent exudative age-related macular degeneration (AMD).
Methods: Retrospective cross-sectional chart review of electronic medical records (EMR) for exudative AMD patients receiving intravitreal injections at a single retina practice in April 2021. Patients were selected for inclusion based on an ICD-10 diagnosis of exudative AMD affecting one or both eyes (H35.32xx) or diagnosis of both exudative AMD and GA affecting one or both eyes (H35.32xx and H35.31xx) in the EMR. The selection of these patients was independent of their treatment status. Exclusion criteria included: patients with a diagnosis of choroidal neovascularization (CNV) not in the context of AMD and diagnosis of exudative AMD in one or both eyes without evidence of GA on optical coherence tomography (OCT) analysis. OCT scans were reviewed by two trained graders to evaluate for the presence of GA. Visual acuity and documentation of GA in the examination findings and OCT interpretation were recorded.
Results: A total of 656 patients were identified with exudative AMD, of which 377 (57%) had concurrent GA by OCT. This cohort consisted of 102 males (27%), 275 females (73%). The majority of patients (82%) were Caucasian. The mean age of the cohort was 83.5 ± 9.0 years. At the April 2021 visit, 26 patients (7%) had visual acuity (VA) of 20/20. 98 patients (26%) had VA between 20/25 – 20/40. The majority of patients, 169 (45%), had VA between 20/50 – 20/200. 84 patients (22%) had VA worse than 20/200. 31 of the 377 patients (8%) had an accurate diagnosis code of GA documented. 346 of the 377 patients (92%) had evidence of GA on OCT but no diagnosis code for GA. Although GA was not coded, 257 patients (68%) had GA documented accurately in the examination findings and 202 patients (54%) had GA documented accurately in the OCT interpretation.
Conclusion: Despite the majority of patients with exudative AMD having evidence of concurrent GA on OCT, a large number of patients do not have a GA diagnosis code in the EMR. Improving coding accuracy for GA will be important for identifying patients in big data studies and aid in selecting patients for new therapies.

IRB APPROVAL Yes

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Practice Management/Socioeconomic Symposium

Organizing Disparate Data Within an EMR to Help Retina Surgeons Best Care for Patients

- Joshua Steiner, MD

Objective: Determine the utilization and effectiveness of a medical software that displays all necessary data for retinal care in an EMR system on a single screen.
Purpose: EMR systems are often compiled of multiple pages of data for any single patient, likely leading to wasted time navigating those windows. However, is it possible to display all pertinent historical data for any single patient on one screen to save time and reduce human error?
Methods: Nine retina surgeons in three practices were evaluated to determine their utilization rates for an add-on technology displaying all historical data on any single patient on one screen. The display was a spreadsheet of every visit in rows and columns with procedures, injections, plans, visions, pressures, diagnostic tests, photos, and finally, financial indicators for CPT or J code status. Each surgeon could access the add-on technology by clicking an icon within their EMR, generating a new window, on the display. The surgeons were measured for the rate by which they clicked the icon compared to the number of patients they saw (returning patients only). If a surgeon accessed the display more than once per patient, this was tallied too. The surgeons were monitored for one month. At month's end, they were surveyed on their experience.
Results: Of the nine doctors, one working in a satellite capacity and using paper summaries chose not to participate.

Practice 1: Retina only
1. Dr. A: 1,138/798 views per patient seen = 143%
2. Dr. B: 974/803 views per patient seen = 121%
3. Dr. C: 768/595 views per patient seen = 129%
4. Dr. D: 177/425 views per patient seen = 42%
5. Dr. E: 3/500 views per patient seen = 0.6%
Practice 2: Multi-Specialty
6. Dr. F: 488/views per patient seen = 280%
7. Dr. G: 289/456 views per patient seen = 63%
8. Dr. H: 205/389 views per patient seen = 53%
Practice 3: Part-time in Multi-Specialty
9. Dr. I: 72/210 views per patient seen = 34%

Surveys: 3/9 doctors, while working with a scribe, ultimately resorted to only using the single screen display when assessing and implementing patient care. 3/9 claimed that the display helped them significantly increase revenue. 100% of doctors claimed to have caught billing and medical errors. The only weakness identified was the display's inability to serve in two-way integration.
Conclusion: As evident, when offered the ability to view all patient history on a single screen, retina doctors 1) will use such a display and 2) will benefit from doing so. Ultimately, patient data can be presented successfully on a single screen to help retina surgeons implement improved patient care.

IRB APPROVAL No - no IRB

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Practice Management/Socioeconomic Symposium

Inflation-Adjusted Trends in Medicare Reimbursement for Retina Practice Expenses

- Philip Niles, MD, MBA
- Miguel Busquets, MD, FACS
- Dilraj Grewal, MD, FASRS
- Ella Leung, MD
- Ankoor Shah, MD, FASRS
- Jill Blim, MS
- Judy Kim, MD, FASRS
- Paul Hahn, MD, PhD, FASRS

Objective: To analyze the trends of the practice expense component of Medicare reimbursement over time for commonly utilized in-office retina-related current procedural terminology (CPT) codes amidst rising inflation.

Purpose: Total Medicare reimbursement consists of distinct components allocated to physician work, malpractice, and practice expense (PE). The PE component reimburses expenses including equipment, supplies, and non-physician labor costs, all of which are immediately sensitive to inflationary changes. Although decreases in inflation-adjusted total Medicare reimbursement have previously been noted, changes in PE reimbursements in a

retina practice have not been explored.

Methods: 2013-2023 data from the Center for Medicare and Medicaid website were used to analyze trends in reimbursement for the ten most frequently utilized in-office CPT codes relevant to a retina practice. The primary outcome was the percent difference between the actual 2023 PE component reimbursement compared to the PE payment amount adjusted for inflation using the Consumer Price Index. Two analyses were performed, one for a base year of 2021, to examine the effects of the recent burst in inflation, and one for a base year of 2013, to compare the effects over a longer time horizon.
Results: From 2021 to 2023, the average nominal (unadjusted for inflation) change for the PE component of the 10 most frequent retina codes was -0.5%. After adjusting for inflation, there was a mean 2-year reduction of 14.3% in the average payment amount, or 7.2% per year. For the 2013 to 2023 period, the average nominal percent change for the same codes was -0.5%. After adjusting for inflation, there was a mean reduction of 29.7% in the average payment amount, or 3.0% per year.
Conclusion: Reimbursement for retina practice expenses has not matched the pace of inflation, resulting in an overall decrease in adjusted reimbursement. This discrepancy has become particularly impactful with the recent rise in inflation. Not adjusting reimbursements for inflation will likely continue to negatively impact retina practices.

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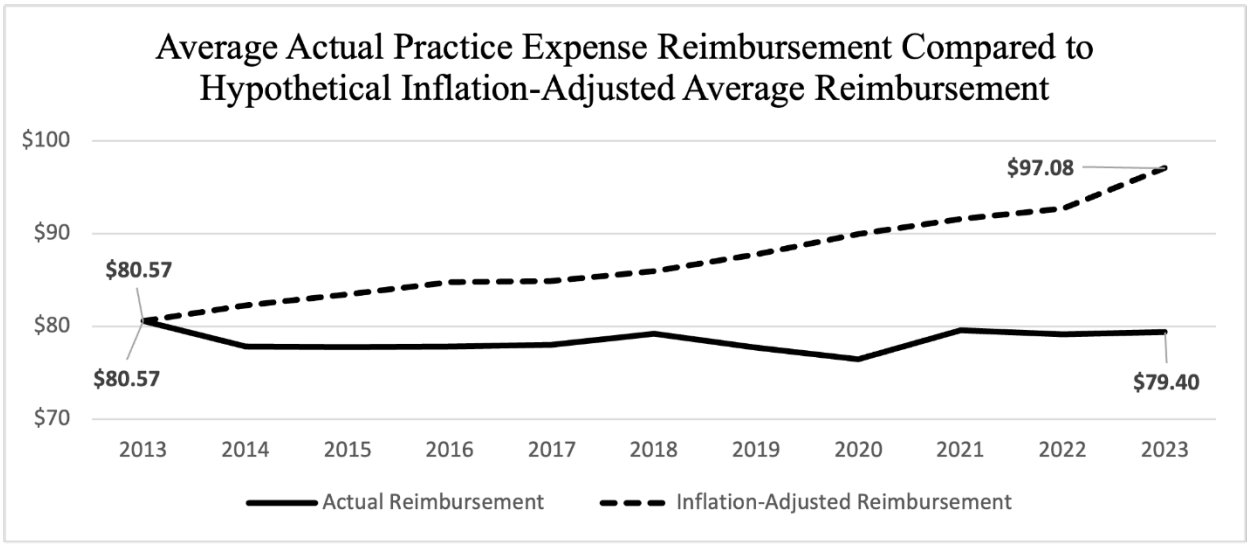
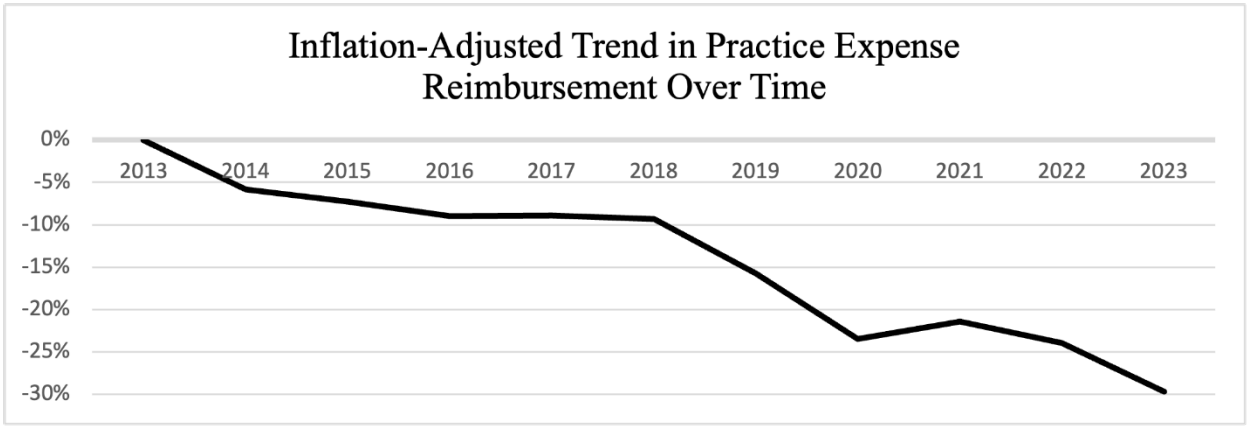


Actual reimbursement compared to average inflation-adjusted reimbursement



Ratio of actual reimbursement compared to inflation-adjusted reimbursement

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Practice Management/Socioeconomic Symposium

Bevacizumab-First vs Real-World Cost Outcomes for Diabetic Macular Edema: 2-Year Cost Analysis Modeled on DRCR Protocol AC Results

- Dilraj Grewal, MD, FASRS
- Ella Leung, MD
- Miguel Busquets, MD, FACS
- Philip Niles, MD, MBA
- Ankoor Shah, MD, FASRS
- Jill Blim, MS
- Judy Kim, MD, FASRS
- Paul Hahn, MD, PhD, FASRS

Objective: Can DRCR Retina Network Protocol AC findings be directly applied to the real-world setting and support cost savings of step therapy with bevacizumab first for treatment of diabetic macular edema (DME)?

Purpose: DRCR Retina Network Protocol AC involved a frequent treatment and follow-up protocol, and these results should only be applicable to real-world therapy if the same protocol frequency is replicated. We compare the modeled cost of Protocol AC bevacizumab first-arm to actual real-world cost over a 2-year period in a similar DME population.
Methods: Published data from the DRCR Protocol AC bevacizumab-first arm (n=128 eyes) were used to model 2-year treatment cost. Real-world costs were modeled from Vestrum Health (Naperville, IL) utilization and outcomes data from a 2016-2018 cohort (n=1062) of treatment-naïve eyes with DME that were treated with anti-VEGF monotherapy (2016 was selected as the index year to post-date potential practice pattern shifts from Protocol T and precede effects from recent increases in step therapy mandates). Real-world data were matched to the visual acuity (VA) inclusion criteria for Protocol AC (Snellen VA 20/50-20/320 at baseline). A secondary cost analysis was performed for those eyes with 2-year vision gain ≥14 letters (n=289, to exceed the VA outcomes in Protocol AC). Per eye costs of the injection procedure, medication, office visit, fundus photography, and OCT imaging were modeled based on 2022 Medicare reimbursement data (non-facility setting, national payment amount) and the December 2022 Medicare Part B Drug and Biological Average Sales Price.
Results: In Protocol AC, the modeled 2-year DME treatment cost in the bevacizumab-first arm was $18,896 with a mean of 16.1 injections over 22.5 visits, and 70% of eyes being switched to aflibercept by year 2. Modeled cost for the Protocol AC aflibercept-only arm (n=132 eyes) was $31,909 with a mean of 14.6 injections over 22.0 visits. Real-world 2-year cost from 2016-2018 was $11,308 (mean of 8.6 injections over 13.8 visits, medication distribution 42% bevacizumab, 45% aflibercept and 13% ranibizumab, mean VA gain 4.7 letters). In a cohort including only those with VA gain ≥14 letters over 2 years, the real-world 2-year mean VA gain was 22.7 letters (vs Protocol AC bevacizumab-first of 14.0 letter gain) and the 2-year cost was $15,362 (mean of 12.1 injections over 16.7 visits, medication distribution 41% bevacizumab, 47% aflibercept and 13% ranibizumab).

Conclusion: Real-world 2-year DME treatment costs were 40.2% lower than Protocol AC bevacizumab-first costs, in which 70% of eyes were switched to aflibercept by year 2. Even among those with real-world VA gain ≥14 letters, costs were 18.7% lower. Accounting for reimbursement bundling (eg: of exam with injection and of photos with OCT) had a marginal influence on these modeled effects. Application of Protocol AC findings into real-world utilization, as with step therapy mandates, should only be considered if the same intensive protocol is followed. These data suggest that real world costs are significantly lower, even in the better VA outcome group.

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Practice Management/Socioeconomic Symposium

Economic Benefit of Higher Durability Anti-VEGF Agents in the Treatment of Neovascular Macular Degeneration

- Sabin Dang, MD
- Mahir Bansal
- Saira Khanna, MD
- Alia Durrani, MD

Objective: To model the economic impacts of high durability anti-VEGF agents in the use of neovascular age related macular degeneration (nAMD)
Purpose: The purpose of this study was to model and understand the economic costs associated with the release of longer acting anti-VEGF agents. Previous published work has reported the direct cost benefits of these medications. We aim to add to these models by calculating the indirect costs due to loss of economic productivity from missed work by patients and their caregivers to the US economy.
Methods: A model was created in Microsoft Excel including variables for direct and indirect costs. Direct costs were defined as cost of ranibizumab, cost of faricimab, average number of injections needed per patient with nAMD for both agents, and average administration cost. Indirect costs were also calculated, with percentage of patients requiring a driver to receive treatment, the time spent commuting to and from the appointment, the total time spent within the office, the percentage of nAMD patients who currently work, national median wage, national wage multiple, and unemployment rates.
Results: Ranibizumab had an increased cost of $7,535.32 per patient relative to faricimab for the first year of treatment. The average impact of lost productivity to the US economy due to missed work per injection measured $116.82 (95% CI $95.46 - $138.18), resulting in a savings of $700.92 in economic productivity per patient, an additional 9.3% above the cost savings from the direct costs alone. The switch to faricimab from ranibimzuab would result in a total US economic savings of $8,236.24 per patient for the first year of treatment.
Conclusion: This study demonstrates that there is significant cost savings to switching patients to higher durability anti-VEGF agents. Our study adds to prior work in this area by further modeling the economic impact due to lost work by patients and their caregivers.

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Practice Management/Socioeconomic Symposium

Biosimilar Paradox: How Biosimilar Use Will Increase Patient and Healthcare Costs

- Ravi Parikh, MD
- Scott Friedman, MD
- Prithvi Mruthyunjaya, MD, MHS
- Casey Zhang

Objective: To determine the impact of biosimilars on patient and payor costs.
Purpose: Anti-vascular endothelial growth factor (anti-VEGF) medications for intraocular use are a major and increasing cost, and biosimilars may be a means of reducing the high cost of many biologic medications. However, a bevacizumab biosimilar, which is currently pending FDA approval (bevacizumab-vikg), may paradoxically increase the cost burden of intravitreal anti-VEGF, as “off-label” compounded drug may no longer be allowed per the Drug Quality and Security Act (DQSA). We aim to investigate the potential impact of biosimilars on the health system and patient costs in the US.

Methods: Average sales price (ASP) of ranibizumab, aflibercept, and bevacizumab are calculated from Medicare allowable payments. ASPs of biosimilars are calculated from wholesale acquisition costs from a representative distributor. The cost of an intraocular bevacizumab formulation is modeled at $500 and $900/1.25mg dose, increased from $84.91/1.25mgdose with current off-label use. Medicare data from October 2022, previously published market share data from 2019 to determine anti_VEGF usage.

Results: If an intraocular bevacizumab biosimilar were to be priced at $500, costs to Medicare would increase by $457 million from $3.01 billion to $3.47 billion (an increase of 15.2%). Patient responsibility would increase by $117 million from $768 million to $884 million. Similarly, if intraocular bevacizumab were priced at $900, Medicare costs would increase by $897 million to $3.91 billion (an increase of 29.8%), and patient responsibility would increase by $229 million to $997 million. Theoretically, use of ranibizumab and aflibercept biosimilars may offset the increased cost of bevacizumab. However, were the price of bevacizumab to increase to $500, switching all patients currently on ranibizumab or aflibercept to respective biosimilars would only compensate for 28.8% of the increased cost. For ranibizumab and aflibercept use to compensate for the cost of a bevacizumab biosimilar priced at $500, current prices of ranibizumab and aflibercept would have to decrease by an aggregate of 15.7%. to $616.80, $1027.97,and $1436.88/injection for ranibizumab 0.3 mg, 0.5 mg, and aflibercept, respectively.

Conclusion: Use of an FDA-approved bevacizumab biosimilar for ophthalmic use could significantly increase costs to the healthcare system and patients, raising concerns for access. This increase in cost would not be offset by ranibizumab and aflibercept biosimilar use at current prices. These data support the need for an exemption of section 503A of the FD&C Act and continued use of compounded or repackaged off-label bevacizumab.

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