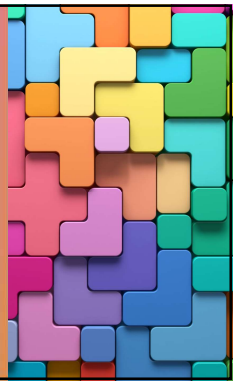
Fundamentals of the Drug Approval Process



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Financial Disclosure

- Ashley Nahrwold, COA is the Revenue Cycle Director for The Retina Institute in St. Louis. She acknowledges no financial interest in the subject matter of this presentation.

COURSE OBJECTIVES

- Optimize practice workflows for the drug approval process
- Identify reimbursement concerns prior to injection
- Reduce injectable drug denials
- Reduce patient out of pocket costs
- Promote collaboration amongst Clinic, Front Desk, and Revenue Cycle teams

Prior Authorization - Is it enough?

Example 1:

Drug Name	Drug Code	Authorization Status
Injection, aflibercept, 1 mg	J0178	Approved

The authorization provided is not a guarantee of payment to the provider. Payment is based on the patient's benefit plan and eligibility when the services are received.

Example 2:

Aetna Medicare Gold Advantage (HMO) got your request to review the following drug(s). We are pleased to tell you that we approved the following drug(s).

LUCENTIS Soln Pref Syr 0.5MG/0.05ML

If this drug will be given in your provider's office, please check to see if your provider is in-network. Coverage for out-of-network services may be limited if you are enrolled in an HMO plan. If you are enrolled in a PPO plan, your out-of-pocket costs may be higher if you receive services out-of-network.

DRUG APPROVAL PROCESS

A strong drug approval process needs to expand across multiple departments and functions within your practice and account for all variables that could prevent or delay receiving full reimbursement for every drug injected.

These variables are the fundamentals of the drug approval process.

Fundamentals

Practice	Payer	Patient	Pharma
Payer Contracts	Payer Coverage Policies	Insurance Eligibility	FDA Approved "On Label" Diagnoses
Credentialing and Billing - Group vs. Individual MD	Prior Authorization Requirements	Plan Specific Drug Benefit Coverage	Dosing frequency
Drug Acquisition, Cost and Margins	Step Therapy Requirements	Specialty Pharmacy Requirements	Copay Assistance Options
Inventory Management	Specialty Pharmacy Requirements	Out of Pocket Cost	CPT Billing Code
Communication	PCP Referral Requirements	Severity of Disease / Urgency to Treat	New Indications

Injection Status

The goal of the drug approval process should be to take all these fundamentals and guarantee that each billable drug will be reimbursed in full prior to the injection occurring in the clinic.

The method of communicating the drug approved back to the physician is called the Injection Status.

Getting Started

- Assign a project leader or task force
- Gather data
- Develop practice protocols
- Reach out to industry reimbursement specialists for help

PAYER CONTRACTS

- Do you have a copy of all your payer contracts?
- Are they outdated? Have they been renegotiated in the past 1 year, 2 years, 5 years?
- What is the fee schedule? Are you being reimbursed appropriately for drugs?
- How is the language within the contract related to new drug reimbursement? Reimbursement for billing a new drug with a miscellaneous J code or Q code for biosimilar drugs may be problematic with older contracts.
- If you are in a group practice, are your contracts under the group Tax ID or does each physician have a separate contract? If so, do the physician contracts vary in regard to this information?
- No payer contract could mean your practice is out of network with that payer.

CREDENTIALING & BILLING

- Payer credentialing is the process that links the individual providers with the payer contract
- Payer contracting, credentialing, obtaining prior authorization and billing should be synchronized to use the same provider identifiers (NPI and Tax ID)
- Payer contracts with individual physicians and/or credentialing of individual physicians with no group practice linkage means prior authorizations will be linked to that individual physician and not to the group
- Physician not credentialed or linked to the group practice could leave the individual provider in an out of network status with that payer
- This method will allow coverage for drug authorizations under the group practice in the event the patient needs to be treated by another physician within the same practice
- Best practice is to credential the group NPI and tax ID to the payer contract then link all the individual providers to the group

Drug Cost & Inventory

Determine which drugs you will stock in inventory versus which drugs will be ordered as needed or approved

Compare your drug cost to your Medicare allowed amount each quarter

Sample Medicare Drug Fee Schedule Cost Comparison

Code	Units Billed	Medicare Allowed Amount (Current Quarter - Q2)	80% Reimbursed By Medicare (when primary)	Medicare 2% Sequestration Adjusted from Payment	Reimbursement Received From Medicare (when primary)	20% Patient Responsibility if no Secondary Insurance or Patient Assistance	WAC	Drug Cost	Cost Discount Amount	Cost Discount Percentage	Margin per Drug (From Expected Reimbursement Excluding Rebates)
J9035	1	$71.35	$57.08	$1.14	$55.94	$14.27	$27.00	$27.00	$0.00	0%	$43.21
J0179	6	$1,889.13	$1,511.30	$30.23	$1,481.08	$377.83	$1,850.00	$1,807.73	$42.27	2%	$51.17
J0178	2	$1,787.10	$1,429.68	$28.59	$1,401.09	$357.42	$1,850.00	$1,592.85	$257.15	14%	$165.66
J2778	5	$1,238.27	$990.61	$19.81	$970.80	$247.65	$1,950.00	$1,109.55	$840.45	43%	$108.90
J2778	3	$742.96	$594.37	$11.89	$582.48	$148.59	$1,150.00	$665.73	$484.27	42%	$65.34
J2777	60	$2,245.32	$1,796.26	$35.93	$1,760.33	$449.06	$2,190.00	$2,124.30	$65.70	3%	$85.09

COMMUNICATION

1. Return to clinic plans should indicate which drug has been selected to treat the patient
2. Determine how drug requested will be communicated to the staff obtaining prior authorization
3. Consider drug specific appointment scheduling events to identify, report and generate tasks for upcoming planned injections
4. Determine how staff will communicate back to the clinic when a drug is approved – Injection Status
5. Develop protocols for how often drug approvals are re-verified to ensure reimbursement continues for the duration of treatment

PAYERS

- Insurance payers can vary based on geography and market
  Medicare jurisdictions vary by state and policies are not universal
- Payers often have multiple products and plan types that may have varying authorization and coverage policies (Commercial, Medicare Advantage, Medicaid)
- Obtain a list of payers seen at your practice
- Create guides for each payer product and each payer driven fundamental
- Payer policies change from time to time
  Develop a system for identifying changes and keeping your guides current

PATIENTS

- Insurance eligibility verification confirms if a patient's insurance plan is active
- Most automated electronic eligibility returns the patient's status as of the date eligibility was ran, not by a future appointment date
- Most employer sponsored plans will be active until the end of the calendar month even if the plan is terminated
- State Medicaid and Managed Medicaid plans are renewed monthly based on patient's eligibility. Some states will change the patient's Managed Medicaid plan throughout the year
- Many patients do not know what insurance plan they have, their covered benefits or their cost share (copay, deductible and coinsurance)
- Develop a practice protocol for who will be responsible for insurance eligibility verification, when the verification will occur and when it will be rechecked on each patient

TRADITIONAL MEDICARE

- Patients with traditional Medicare Part B only (no secondary payer) will have a 20% coinsurance for all services including drug.
- For branded anti-VEGF drugs, this can be around $200-500 out of pocket per injection.
- For patients receiving monthly bilateral treatment and relying on a Good Days grant to cover their out-of-pocket cost, there may not be enough funds to cover them for a full year.

MEDICARE ADVANTAGE PLANS

- Medicare eligible patients that have elected to have a Part C replacement policy (Medicare Advantage Plan) usually have a lower out of pocket cost.
- These patients will retain their original Medicare card.
- Insurance eligibility will still run active under the Traditional Medicare ID number even though the patient will now be covered under an advantage plan.
- Most Medicare Advantage Plans require prior authorization for branded anti-VEGF drugs.
- Some Medicare Advantage Plans require step therapy or double step therapy.

PHARMA

- FDA approved diagnoses are not universal across all branded anti-VEGF drugs
- Traditional Medicare will cover all FDA approved diagnoses
- Commercial payers may develop their own coverage policies that may not be inclusive of all FDA approved diagnoses
- If an established drug receives FDA approval for a new indication, verify payers update their coverage policies to include the indication
- Create a guide of Copay Assistance options available by payer type, drug and diagnosis. Include eligibility criteria.

NEW DRUGS

- New drugs to market will be billed using a miscellaneous J-code until a permanent CPT is established (typically two quarters).
- Payers usually release coverage policies closely following FDA approval. This does not mean reimbursement will cover the cost of drug.
- Reimbursement for miscellaneous J-code under commercial payers is directly tied to your contract language.
- Prior authorization is usually required for the drug even with miscellaneous J-code.
- Once the permanent CPT code is established, make sure to update your prior authorizations with the payer.

COMBINING THE DATA

Combine all fundamental data gathered for the practice, payers, and pharma to create a master Insurance Drug Coverage Guide that will be utilized in clinic to select a covered drug at decision to treat.

This does not approve a same day injection. Best practice is to have the patient return for injection unless clinically urgent. The Insurance Drug Coverage Guide is a tool to avoid requesting a drug that will not be approved. Example: Request for branded drug for a payer that has strict step therapy requirements.

Drug Approval Workflow

This workflow is based upon all patients being checked in with correct and verified insurance attached to their chart. This workflow also assumes PCP Referrals are on file for required plans.

1. Patient is seen in clinic and needs anti-VEGF injections.
2. Physician should utilize the Insurance Drug Coverage Guide to determine which drug choice is appropriate for the patient's diagnosis and primary insurance payer.
3. Chart notes are typically required to be sent with prior authorization requests. The exam impression should clearly state the diagnosis and medical need for injection treatment. The return to clinic plan should specify the drug selected by the physician.
4. Patient should sign the corresponding authorization form to run a detailed insurance benefit investigation through the drug company's provided service.
5. Check out staff should schedule the patient's return appointment using the appropriate drug specific appointment event.

Drug Approval Workflow

Prior to next visit (injection visit):

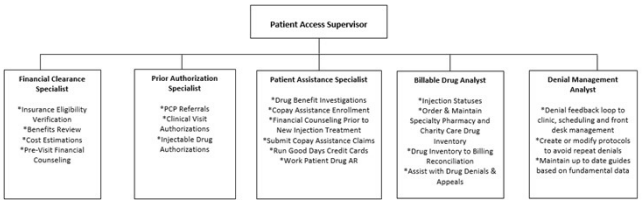
6. Obtain prior authorization from the patient's insurance for the drug requested.
7. Run the benefits investigation through the drug company portal.
8. Enroll the patient in copay assistance if applicable and eligible.
9. Complete Financial Counseling with the patient for out-of-pocket cost. Prepare the patient to pay at check in of the injection visit.
10. Three business days prior to the return visit, re-verify the patient's insurance to confirm it is still active.
11. Two business days prior to the return visit, confirm patient's payer/diagnosis/drug combination clears all check points and provide the appropriate Injection Status for this appointment.

Who Provides the Injection Status

- Staff members responsible for each function within the drug approval process may vary from practice to practice
- Determine the workflow that works best for your practice
- In my practice, this work is completed within the Revenue Cycle Department
- Our Revenue Cycle Department is divided between the Patient Access Team and the Billing Team
- Number of FTEs needed will vary by provider count, patient volume, and automated technology

The Patient Access Team

Sample Organizational Chart



FINANCIAL CLEARANCE FUNCTIONS

- Insurance eligibility verification – primary and secondary insurance verified 3 business days prior to appointment for every patient before every visit
- Confirm practice and provider are in network with patient's insurance plan
- Benefit review – complete once annually for all plans and update as needed
- Cost estimations – complete as needed based on patient's insurance plan benefits and planned services
- Pre-visit financial counseling – complete each visit when patient's out of pocket cost exceeds their office visit copay. Prepare patient to pay at check in for planned services

PRIOR AUTHORIZATION FUNCTIONS

PCP referrals & visit authorizations – review payer specific report of appointments scheduled the previous day and obtain referral or authorization prior to each visit based on payer requirements

Injectable drug authorizations – review report of appointments scheduled the previous day for drug specific events and obtain authorization for drug requested.

Note: CPT 67028 for administration may also need prior authorization.

PATIENT ASSISTANCE PRE-VISIT FUNCTIONS

Drug benefit investigations - review report of upcoming appointments scheduled for drug specific events and review the detailed benefit investigation returned from the drug company.

Copay assistance enrollment – the benefit investigation results will include the patient's drug benefits (if deductible applies and percent cost share of coinsurance). Enroll patients as needed based on their individual scenario.

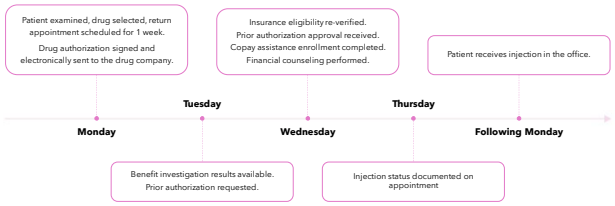
INJECTION STATUS GRANTED

"Based on the knowledge of the fundamentals, the Patient Access Team believes if this drug is injected the practice will be reimbursed 100%."

2 business days prior to appointment, the Billable Drug Analyst reviews a report of appointments scheduled for drug specific events and assigns an Injection Status based on the confirmation of data gathered by the team. The Injection Status is attached to the appointment in a field that will be communicated to the clinic on the day of service.

Example Injection Status: IVE OD for AMD H35.3211

FIRST INJECTION APPROVAL TIME



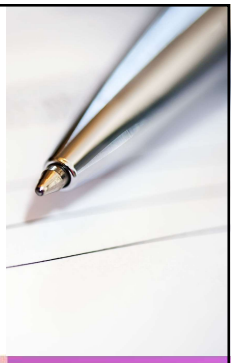
SAME DAY INJECTIONS

- There will be times where the patient clinically cannot return in 1 week for injection and will need to be treated same day.
- We call this a Verbal Injection Status.
- During certain scenarios patients will be approved for a one time buy and bill drug based on the knowledge we have of that payer's fundamentals.

SUBSEQUENT INJECTIONS

Functions that should be repeated every visit for appointments scheduled with drug specific events:

- Review report of expiring prior authorizations and/or remaining visits/units
- Insurance eligibility verification for primary and secondary payers
- Review patient's accounts receivable / confirm reimbursement for previous injections
- Copay assistance grant balance
- Confirm no change with drug / diagnosis code combination compared to prior authorization approval
- Injection Status approved and attached to appointment for subsequent injection visit



MANAGING CHANGES

If any of the following elements change, the drug approval process should be restarted:

- Payer fundamentals – coverage policy, prior authorization requirements, step therapy requirements
- Patient's insurance payer or plan benefits
- Patient's eligibility or need for copay assistance
- Drug change requested by physician
- Diagnosis change – slight changes in diagnosis or disease stage may require a new or amended prior authorization

OPTIMIZING THE WORKFLOW

- Keep data organized
- Maintain current guides for the fundamentals
- Provide clear protocols and guidelines to staff
- Review denials, identify reimbursement problems and adjust protocols accordingly
- Leverage technology for automation
- Be creative to implement new workflow or utilize existing technology in new ways
- Ongoing staff training

THANK YOU