A Toolkit for Pharmacy—Managing Prior Authorizations Operations

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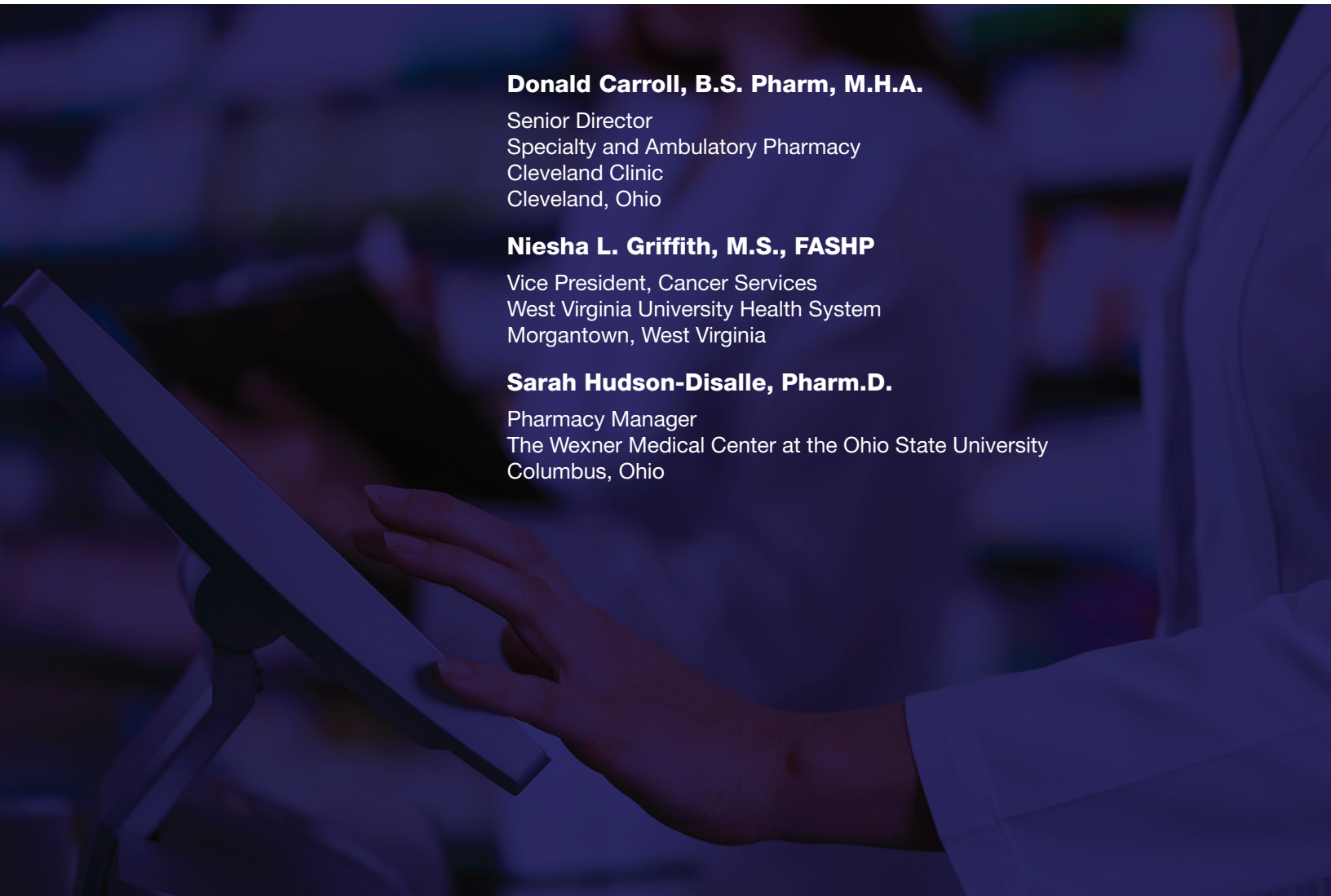

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A Toolkit for Pharmacy—Managing Prior Authorizations Operations

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Target Audience

This continuing pharmacy education series was planned to meet the needs of pharmacy technicians in a variety of settings, and it would be particularly beneficial for pharmacy technicians, supervisors, and educators who are interested in prior authorization management.

Executive Summary

Prior authorization is a process used by payers, such as insurance companies, to determine if they will cover the cost of a prescribed medication. If prior authorization is requested and not approved, the patient will not be reimbursed for the cost of the drug. The process is intended to control healthcare costs. Qualified pharmacy staff contributes to the approval process by initiating paperwork, collecting data, tracking requests, and communicating with insurance companies.

Learning Objectives

- Describe the steps necessary to implement or improve a prior authorization program.
- Apply strategies for training technical and clinical staff to perform or support prior authorizations.
- Develop processes for overcoming a denial or rejection.

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Care providers must help maintain financial viability for their organizations while providing quality patient care. One method for controlling costs is the drug prior authorization process.

Definitions of terms used when referring to prior authorizations:

Prior Auth/Precert—asking for permission for on-label use or any other time the payer policy requires permission. It does not guarantee coverage or reimbursement.

Predetermination (PreD)—process used with commercial payers to gain approval for off-label use prior to the patient receiving treatment. It does not guarantee coverage or reimbursement.

Medication Reimbursement and Patient Support Services for Oncology at The James Cancer Hospital at The Ohio State University

The Medication Assistance Program at Ohio State was established approximately 15 years ago to serve uninsured patients. The budget for charity and take home medications was increasing at an alarming rate, primarily due to expensive IV oncology agents, supportive care agents, and oral oncolytics. The program needed dedicated staff to work with a wide variety of complex manufacturer assistance forms that required clinical information and physician signatures. The work requires someone with the ability to multi-task on a daily basis and exceptional communications skills, as they interact with patients from all walks of life and various health care professionals. Their work is time-intensive and complex. With changes in national healthcare coverage leaving fewer people uninsured, the program now primarily serves underinsured patients.

The current scope includes the use of manufacturer assistance programs, disease based grants and foundations, and hospital charity funds to provide support for:

- Inpatient replacement (IV meds)
- Outpatient replacement (IV meds)
- Off label support (IV meds—oncology and specialty meds)
- Take home medications (free drug for indigent, copay cards for underinsured)
- Copay assistance for IV infused agents

Staff members also assist patients with enrollment in Medicare Part D drug benefit, social security, and low-income subsidy programs.

Staff consists of financial counselors and social workers. Social workers, especially those with healthcare experience, initially appeared to be best suited to lead the program due to their experience with insurance plans and payers and with accessing other patient support programs. The first position dedicated to medication assistance was justified based on charity dollars and write offs for medications, with a return on investment (ROI) goal of 1. The actual return exceeded the goal ROI by ten times. It is a highly successful program in terms of patient satisfaction, physician satisfaction, and dollars of medications accessed/cost avoidance.

The program is currently run by the pharmacy for several reasons. Pharmacists help connect Medication Assistance Coordinators with the patient care team and help with accessing clinical information. Coordinating the program through the pharmacy ensures that the receipt and handling of medications adheres to all laws and regulations. It also ensures pharmacist verification of medications and counseling of patients when necessary.

Growth of Services

Services have expanded to include off-label use approvals, high dollar medication approvals, denials, and prior authorizations.

Off Label Use Approval

After the Medication Assistance Program was established, the team began to work with the Finance Department to develop off-label approval policies and reimbursement processes. They established a formal policy and process because many of the newer, expensive oncology agents were being studied for multiple indications outside of their FDA-approved labeling. They observed an increase in off-label use at all practice sites and were concerned about the financial impact. The policy provided for a structured peer review and approval with requirements for providing supportive evidence. A pre-determination is performed for all of these requests with commercial payers (this process does not apply to government payers) consisting of a clinical packet containing medical records, labs, scans, literature, compendia listings, past therapies and letters of medical necessity for consideration by a clinical reviewer at the insurance company prior to infusion.

Originally, Nurse Reimbursement Specialists working in the Finance Department received education on how to effectively process and seek approval for an off-label indication. With the increasing complexity and number of off label requests, these resources have since expanded and moved to the pharmacy cost center. This change occurred to ensure training and ongoing education, as well as connection and collaboration with the clinical team, especially with the oncology pharmacists.

High Dollar Medication Approval

Because payer prior authorization policies are often delayed following the release of new high cost medications, it was decided that all payers would be contacted in advance to ensure payment. The process is applied to all medications with an annual cost of treatment of $50,000 or greater. The high dollar approval process is very similar to a routine prior authorization process but with additional steps including enrollment in pharmaceutical manufacturer program benefits investigation programs.

Initially the program began in the Revenue Cycle department with a Nurse Reimbursement Specialist performing the High Dollar Approval process. Due to lack of resources in this department and the increased demand for these medication requests, much like the off-label work described here, these positions were also moved to the pharmacy department. Reimbursement Specialists in the Pharmacy Department are provided with the list of medications and instructions on how to access, complete and submit the forms to the manufacturers. Pharmacists alert them when a targeted medication is ordered. Reimbursement Specialists contact the payer for a prior authorization and contact the manufacturer to perform the benefits verification. In some cases, it may be necessary to supply additional information during this process, much like an off label predetermination. If a denial is received during this front-end process, the team is notified as well as the Medication Assistance Program Coordinator to seek assistance from the pharmaceutical manufacturer.

Denials

The oncology-trained nurse performing the off label and high dollar approvals also began to review the medication denials. She found that in addition to the issues already identified (missed approvals, lack of information) denials were being written off because they “timed out,” or missed the deadline to be reconsidered. The finance staff reported that they were unable to address the number of denials in their work queue in a timely fashion. In response, a more in depth investigation was performed. The findings identified write offs in excess of $2 million dollars that could have been avoided.

Having an oncology-trained nurse in the Reimbursement Specialist role had already proven to be beneficial. She developed relationships with the oncology pharmacists and was able to efficiently and effectively get questions answered and approvals completed. It was clear that the Reimbursement Specialists role were under-resourced in its ability to complete the denials requests. As a result, two full time equivalent (FTE) positions were approved for the pharmacy department in addition to the existing staff of three FTE already working authorizations, to take over all medication approvals and denials, with the

assumption that those preparing the approvals were in the best position to efficiently respond to the denials.

Prior Authorizations

In the process of working on the denials, it was discovered that some of the routine prior authorization approvals for on label use were also being denied. Due to the complex nature of the drugs and diseases in oncology, more clinical information was being requested, similar to that required for off label use.

The Pharmacy Department assumed responsibility for these prior authorizations. Pharmacy committed to developing a productivity model for the added financial work in the department, allowing for an increase in the staff as the workload increased. Pharmacy also developed a new IT workflow to assist with identification and follow-up of all off label, high dollar, and routine prior authorizations.

Pharmacy-Managed Prior Authorization: Oncology and Outpatient Infusion

Qualifications for the Reimbursement Specialist Role in the oncology and outpatient infusion pharmacy included a clinical background, ideally with experience in oncology, and a fundamental understanding of payer terminology and requirements. Other important qualities included:

- Self-sufficiency and the ability to multitask
- Independence and motivation
- Strong prioritization and organizational skills
- A strong understanding of the disease implications, use of various treatment modalities, and expected outcomes

The Reimbursement Specialist performs all types of approvals (predeterminations, high dollar, prior authorization) and prepares appeal letters for denials. The specialist must have familiarity with payer polices and requirements. The specialist must be able to gather all pertinent clinical information from the Electronic Medical Record (EMR) (treatment plan, diagnostic studies, and so forth) and gather all supporting evidence (literature, compendia, coverage decisions).

Responsibilities include:

- Communicate with the clinical staff as well as the payers. Communicate the status of requests to stakeholders.
- Identify trends in denials
- Identify gaps in coverage policies and assist with preparation of reconsideration packets.
- Hold payers accountable for their contractual obligations.
- Educate clinical staff on policies and requirements for authorization
- Work with medical information management to ensure proper ICD-10 and CPT coding are performed on patient claims

The first step in the prior authorization process is to determine medication eligibility with the insurance payer. This requires review of payer-specific documents such as clinical policies and requirement of authorization. The authorization should be obtained in electronic format so it is available if needed later in the event of a denial. The Reimbursement Specialist must be up to date on the prior authorization guidelines and requirements of major payers, keeping track of medications the payer considers medically necessary vs. experimental or unproven and requirements for payment. It is important to review clinical policy bulletins and newsletters monthly and quarterly.

One or more of the Specialists should be assigned to attend managed care quarterly meetings in person to hear updates, elevate issues, and build relationships. It is vital to build relationships with case managers at third party administrators (TPAs) used by major payers. It is also important to develop relationships with the pharmaceutical account reimbursement representatives to leverage the ability to impact payer policies and practices. The department should work with IT to develop an effective and efficient form of notification to ensure identification, such as a work queue or other trigger to indicate that a patient is scheduled to receive a medication on the prior authorization list.

A Prior Authorization Work Queue was set up by the Pharmacy Department at The James Caner Hospital. In this plan, a referral is created when a treatment plan is assigned to a patient, starting the authorization process for the patient's treatment. Reimbursement Specialists are automatically notified of the following changes:

- Medication added to the treatment plan
- Dose changes >11percent
- Insurance changes

The status of authorization for every order in the queue is visible to all participating caregivers, including the prescriber, infusion pharmacist, infusion nurse, and people working on the claim.

Common reasons for prior authorization denials include:

- Lack of pre-certification or authorization
- Medical necessity not established
- Experimental and investigational
- Requires additional information
- Non-covered service or medication on the plan benefit
- Out of network provider
- Timely filing of claims
- Multiple diagnoses coding for disease states and metastases- payer does not apply correct codes to medications
- Error in number of units billed to payer

Case Example 1:

- The pharmacy received a request for pembrolizumab 2 mg/kg every three weeks for metastatic melanoma to lymph nodes (no prior pembrolizumab, no BRAF testing done)
- Diagnosis code C77.9
- Insurance: Caresource
- Cost of therapy: $155,567 per year
- Level of evidence
- FDA approved—ipilimumab trial no longer required, BRAF testing not required
- NCCN supported level 1
- Payer has clinical policy for pembrolizumab use

The case appeared to be straightforward but the claim was denied. After investigation, it was discovered that the clinical policy was outdated with BRAF testing and prior ipilimumab therapy required. A peer-to-peer telephone conversation between the oncologist and the medical staff at Caresource was requested. The peer-to-peer conference was scheduled but the payer never called during the times provided and the appeal expired. The payer pharmacy director was contacted by the Pharmacy Reimbursement Manager to request reconsideration due to the outdated policy. The denial was overturned and the patient was treated with minimal delay.

Case Example 2:

- The pharmacy received a request for a combination of carfilzomib, dexamethasone, and cyclophosphamide for progressed multiple myeloma
- Diagnosis code: C90.0
- Insurance: United Healthcare
- Cost of therapy: $110,636
- Level of evidence: Combination not supported by NCCN

Carfilzomib and dexamethasone in combination are NCCN approved (Level 2A) and the cyclophosphamide is oral and reimbursed through the pharmacy benefit, therefore it was thought that the case would be approved without issue. However, the case was denied. The denial stated

that the level of evidence did not warrant the use of the oral cyclophosphamide (medical and pharmacy benefit for this payer are combined). A peer-to-peer discussion was held with the prescriber and the payer Medical Director. As a result of this conversation, the prescribing physician changed the regimen of carfilzomib and dexamethasone to follow the ENDEAVOR trial (higher dose carfilzomib with dexamethasone but no cyclophosphamide). After the change, authorization for the original regimen was granted for one year of therapy.

A Tool Kit for Pharmacy—Managed Prior Authorizations: Specialty Pharmacy

The Cleveland Clinic Specialty Pharmacy opened in September 2014. Approximately 95 percent to 100 percent of medications filled through the specialty pharmacy require prior authorization.

The Cleveland Clinic is dedicated to value-based care, or outcomes over cost. The Cleveland Clinic value propositions include:

- Most efficient process for providers and caregivers
- Concierge onboarding—prior authorization is undertaken
- Epic EMR charting
- Data warehouse development

The program is growing and now fills approximately 3,000 prescriptions per month.

Specialty pharmacy personnel are divided into teams designed to concentrate a group of people around a therapeutic area (e.g., cancer, multiple sclerosis, hepatitis C). Resources are available to coordinate all aspects of medication care including prior authorizations. Teams are structured to include:

- Basic care structure:
  - Pharmacist (1)
  - Technicians (2–3)
  - Nurse (shared)
- Support team:
  - Reimbursement
  - Delivery
  - Purchasing
  - Material handlers

Technicians perform the initial prior authorization for all therapies. In the event of an appeal, the pharmacist or nurse becomes involved. Pharmacists have been able to represent the clinic during peer-to-peer conferences, allowing physicians to focus their time elsewhere. Most medication regimens require a new prior authorization approval every 12 months. The Hepatitis C team is especially busy because patients typically require a new prior authorization following lab results every six weeks rather than annually. The care team is responsible for contacting the patient to ensure that the lab tests are conducted and reported.

There are a number of benefits in taking responsibility for prior authorization tasks from providers.

- Matches task with economic incentive
- Creates a centralized skill set in specialty pharmacy
- Matches organizational strategy for top of license
- Status exists in Epic EMR
- Fax machines disappear

Process Overview

The prior authorization process for a specialty pharmaceutical at Ohio State includes the following steps:

1. Adjudicate prescription
2. Identify the need for prior authorization
3. Complete and approve prior authorization
4. Service determination
5. Pharmacy fill

Training and Competency

Basic training and competency requirements for the prior authorization teams include:

- Familiarity with drug lists and rule sets by the payer
- Epic EMR navigation
- Knowledge of basic therapeutics
- Understand indications for use
- Knowledge of insurance requirements
- Use of home grown tools: Example—a Hepatitis C prior authorization training guide for technicians was created for the specialty pharmacy at the Cleveland Clinic

Barriers

The providers' role in the prior authorization process is to document thoroughly and participate in peer reviews as needed. Insurance companies institute some barriers that make it problematic for a hospital specialty pharmacy to take over all prior authorization tasks.

Aetna requires that a doctor contact them regarding prior approvals.[1] This makes it difficult for the pharmacy to be responsible for the peer-to-peer meetings required during the approval process.

Anthem policy states that specialty medications may not be covered if they are obtained from a pharmacy other than Accredo. The plan allows for the members to get the first two fills of the specialty medication at a participating retail pharmacy, but then the prior authorization work must be handed over to the national pharmacy.[2] After the Cleveland Clinic provides all of the necessary information for approval, another pharmacy takes over filling the patient's prescription.

Reflective Question 1.

Which of the following is true about prior authorization process?

A. Requires focused training

B. Only a doctor can complete

C. Therapy can start while a prior authorization is pending

D. Delays in approval are always in the best interest of the patient

Reflective Question 2.

Successfully completing a prior authorization means you can service the patient.

A. True

B. False

Instituting a prior authorization team

Key considerations when instituting a prior authorization team include:

- Define the prior authorization process and develop training tools
- Centralize the prior authorization process
- Operationalize workflow to avoid controversial denials

Summary

The prior authorization process must be closely monitored to ensure that patients receive the care they need and patients and pharmacies receive proper reimbursement. Large hospitals may require a dedicated team to successfully navigate the prior authorization process. Pharmacy technicians are an active and valuable part of that team. They may initiate paperwork, collect data, track requests, and communicate with insurance companies.

Activity Assessment

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1. **Which of the following is true regarding Prior Authorization/Precertification?**
   a. It guarantees coverage or reimbursement.
   b. It asks permission for on-label use.
   c. It asks permission for off-label use.
   d. It is submitted to the manufacturer.

2. **The Medication Assistance program at Ohio State was implemented to serve which of the following?**
   a. Uninsured patients.
   b. Outpatients only.
   c. Insured patients.
   d. Patients with no copay.

3. **The Medication Assistance program at Ohio State is involved in all of the following areas except:**
   a. Denials.
   b. High dollar medication approvals.
   c. Prior authorizations.
   d. Medication pricing.

4. **At Ohio State, a Prior Authorization Work Queue referral is triggered when:**
   a. A patient is admitted.
   b. A patient is discharged.
   c. A patient's insurance changes.
   d. A dose changes less than 10%.

5. **Which of the following is the first step in the prior authorization process?**
   a. Contact the prescriber.
   b. Gather clinical information.
   c. Determine medication eligibility.
   d. Determine medication cost.

6. **Which of the following is true regarding the prior authorization process?**
   a. Requires focused training.
   b. Only a doctor can complete.
   c. Therapy can start while a prior authorization is pending.
   d. Delays in approval are always in the best interest of the patient.

7. **Successfully completing a prior authorization means you can service the patient.**
   a. True.
   b. False.

8. **Which of the following is most likely to result in denial of a prior authorization request?**
   a. Filling a prescription order from an in-network provider.
   b. Filling a prescription order for an oncology product.
   c. Filling a prescription order for an expensive medication covered on the plan benefit.
   d. Filling a prescription order for an experimental or investigational drug.

9. **Which of the following is a benefit of centralizing responsibility for prior authorizations in the Pharmacy Department?**
   a. It creates a centralized skill set in the pharmacy.
   b. It ensures that all drug product revenues go to the pharmacy.
   c. It makes fewer clinical demands on the nurses administering drugs.
   d. It allows pharmacy technicians to provide clinical information directly to patients.

10. **Which of the following is not a qualification for the role of Reimbursement Specialist?**
    a. The ability to multitask.
    b. A background in clinical research.
    c. An understanding of payer terminology.
    d. An understanding of treatment modalities.

References:

1. 2016 Aetna Pharmacy Drug Guide. Four Tier Open Aetna Value Plus Small Group Plan. Available at: https://fm.formularynavigator.com/MemberPages/pdf/2016AetnaFourTierOpenSmallGroupPlanCTMDWV_7024_Full_0.pdf.
2. Anthem Blue Cross Specialty Pharmacy Program. Prescription Drug Benefit Changes. Available at: www.anthem.com/wps/portal/ca/provider?content_path=provider/f0/s0/t0/pw_a134685.htm&label=Anthem%20Blue%20Cross%20Specialty%20Pharmacy%20Program#P12_1359.

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Answers to Reflective Questions— 1. A; 2. B