The Who, What, When, Why, and How of Prior Authorization

WHO: Most individuals in the United States do not independently pay for medical or pharmacy services without the use of a third-party payer. Third-party payers include both private insurance and government-funded health plans. The focus of the health plan(s) is the delivery of services. The focus of third-party payers, and pharmacy benefit managers, is payment for those services. *(Kahn & Bousvaros, 2022)*

WHAT & WHEN: Prior authorization (PA) is a process determined by third-party payers (insurance plans) to help control cost by requiring the assessment of eligibility of their covered members for the approval of certain healthcare services **before** they are initiated. This method was established to ensure that appropriate and cost-effective testing, treatments, prescription drugs, and durable medical equipment are medically necessary and eligible for insurance coverage. Healthcare providers must often obtain a prior authorization **before** a service is delivered to the patient to qualify for payment, except for in the case of an emergency. Without prior authorization, an insurance company may deny payment for those services, leaving the patient/family responsible for full payment of charges. Prior authorization is sometimes referred to as prior approval, preauthorization, predetermination, or precertification. *(HealthCare.gov (n.d.))*

WHY: Medical advancements, screening lab tests, medical management, and therapeutic treatment options have increased significantly over the past two decades. With those advancements, the cost of medical services has increased exponentially. *(Kahn & Bousvaros, 2022)*

Newer medications used to treat inflammatory bowel disease, such as biologics and small molecule medications, are very effective treatments but cost significantly more than older and often less effective medications. Given the cost, biologics and small molecule medications are highly regulated by third-party payers. This has resulted in implementation of utilization management mechanisms, such as prior authorization, formulary restrictions, and step therapy. *(Kahn & Bousvaros, 2022; Constant et al., 2022)*

HOW: After completing a comprehensive evaluation of the patient, healthcare providers and patients determine the best therapy plan. This could include additional testing or initiation of therapy through shared decision making with the patient and/or family.

Once a therapy plan has been determined, the healthcare provider must often submit a PA to seek approval before the insurance company will provide the insurance benefits to the insured patient. In the case of medication therapy, this step should occur before sending the prescription to the pharmacy and prior to initiation of therapy. If the prescription is sent to the pharmacy before the request for PA, the pharmacy will often communicate with the insurance plan specialist and notify the patient and/or provider that prior authorization is needed.

At this step in the process, denials can occur, necessitating an appeal with a letter of medical necessity or peer-to-peer review. Depending on the patient's clinical status and need for the prescribed therapy, a rapid appeal process is often imperative to avoid unintended consequences in patient care and well-being.

Denials: The most common reasons for PA medication denials in pediatrics are:

- **Non-formulary medication**
- **Missing, incomplete or inaccurate information** provided with the original prescription.
- **Off-label use** in children. The drug is not FDA approved for use in children or the dose is not approved in children.
- **Step-therapy (fail first) algorithm.** Some insurance companies follow a step-therapy algorithm forcing providers to prescribe older, less expensive, less effective therapy first before approving the provider's original treatment option.
- **Non-medical switches.** Some insurance companies require non-medical switches such as denying the site of care for infusions (i.e., changing to non-hospital-based infusion center).

This process can result in delaying optimal patient care in a timely manner, increase healthcare utilization, and impact outcomes. *(Constant et al., 2023; Shah et al., 2022; Kahn & Bousvaros, 2022)*.

If a denial occurs, the provider usually has two options for appeal:

- **Writing a letter of medical necessity (LOMN)**
    - A letter of medical necessity should outline the patient-specific condition, why you are choosing the medication, prior treatments and response, consequences if the patient doesn't get the requested medication, and supportive medical literature references.

- **Completion of a peer-to-peer review**
    - A peer-to-peer review is a telephone communication between the medical provider and an insurance company reviewer. The reviewer may be a pharmacist or a physician but often is not be a specialist in pediatric gastroenterology. **It is important to inform the peer reviewer that the conversation will be documented in the medical record and should include the name and qualifications of the reviewer and the reviewer's employer (insurance company, pharmacy benefit manager, or third-party reviewer).** This will be pertinent if negative patient outcomes occur because of a denial or delay in therapy.

KFF reported in 2023 that patients in ACA plans appeal less than 1% of their claims denials; that 17% of all claims are denied, and; 41% of denied claims are overturned on appeal.

After this, the denial can be overturned or upheld.

If overturned, the planned care can be implemented. In the case of medications, the prescription can be written, filled, and administered to the patient. Tests and procedures can be scheduled. Sites of services can be maintained.

If the denial is upheld, the patient/family has a right to take the next step for appeal *(HealthCare.gov (n.d.)*, which can include:

- Filing a formal grievance with the insurance company for an internal appeal.
    - https://www.healthcare.gov/appeal-insurance-company-decision/internal-appeals

- Filing a letter of grievance with the State Insurance Commissioner (external appeal)
    - https://www.healthcare.gov/appeal-insurance-company-decision/external-review/

This process can take weeks to months to complete, further impacting patient care, illness severity, and outcome.

Tips and tools for getting prior authorization:

- Persistence generally pays off!
- Integration of a specialty pharmacist, pharmacist technician, or specialty department insurance specialist is key as they have expert knowledge on the approval process, how to navi-

gate the complex system, and awareness of payer requirements. They can curate supporting documentation to help expedite the PA or appeal and update references routinely.

- Develop templated letters so that only patient-specific documentation needs to be included with each request. Several already templated letters are available:
    - Crohn's & Colitis Foundation Appeal Letters: https://www.crohnscolitisfoundation.org/science-and-professionals/program-materials/appeal-letters
    - NASPGHAN Advocacy Letters for Children: https://members.naspghan.org/NASPGHANMembers/NASPGHANMembers/Practice/Advocacy_Letters_.aspx
- Periodically review the literature to assure the supporting documentation is the most up-to-date information.
- Patients can help by reaching out to their employers or by working with a case manager who will advocate for them.

Acknowledgement:

Developed by Amy Donegan, MS, CPNP-PC. September 2024. Contributions by Teri Jackson, MSN, APRN, and Whitney Gray, CRNP. Reviewed by the Crohn's & Colitis Foundation's Nurse & Advanced Practice Committee.

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