The Academy of Managed Care Pharmacy's
Concepts in Managed Care Pharmacy

Prior Authorization

What is Prior Authorization and Why is it an Essential Managed Care Tool?

Health plans, employers and government-sponsored health care programs are focusing their attention on optimizing patient outcomes through the use of medications that have established evidence of efficacy and safety, while providing the highest value. Implementation of a well-designed, evidence-based prior authorization program optimizes patient outcomes by ensuring that patients receive the most appropriate medications while reducing waste, error and unnecessary prescription drug use and cost. Prior authorization (PA) is an essential tool that is used to ensure that drug benefits are administered as designed and that plan members receive the medication therapy that is safe, effective for their condition, and provides the greatest value. Prior authorization requires the prescriber to receive pre-approval for prescribing a particular drug in order for that medication to qualify for coverage under the terms of the pharmacy benefit plan.[1] Drugs that require prior authorization will not be approved for payment until the conditions for approval of the drug are met and the prior authorization is entered into the system. Prior authorization procedures and requirements for coverage are based on clinical need and therapeutic rationale. The process gives the prescriber the opportunity to justify the therapeutic basis for the prescribed medication.[2] Administration of a prior authorization process must take into consideration the desired outcome for the patient, the design of the drug benefit, the value to the plan sponsor, and all statutory and regulatory requirements. Prior authorization may also be referred to as "coverage determination," as under Medicare Part D.

Guidelines and administrative policies for prior authorization are developed by pharmacists and other qualified health professionals Each managed care organization develops guidelines and coverage criteria that are most appropriate for their specific patient population and makes its own decisions about how they are implemented and used. Well-designed prior authorization programs consider the workflow impact on health care system users and minimize inconvenience for patients and providers.

Requiring prior authorization in a drug benefit can effectively help avoid inappropriate drug use and promote the use of evidence-based drug therapy. Such efficient and effective use of health care resources can minimize overall medical costs, improve health plan member access to more affordable care and provide an improved quality of life.[3]

Examples of How Prior Authorization is Utilized within a Prescription Drug Benefit

Prior Authorization Addresses the Need for Additional Clinical Patient Information:

The prior authorization process can address the need to obtain additional clinical patient information. For example, online adjudication of prescription claims by prescription benefit management companies (PBMs) and health plans has resulted in an efficient process for administering the drug benefit, however necessary and pertinent information required for drug coverage decisions is not always available via the online adjudication system. For example, a patient's clinical diagnosis, weight and height information, laboratory results, over-the-counter medication use, and non-drug therapy are examples of information that is not transmitted during the claims adjudication process. The prior authorization process can be used to obtain this additional information. This information is then evaluated against established plan coverage guidelines to determine if coverage is appropriate.

An example of a situation in which more information would be needed in order to make sound, cost effective, clinical decisions would be for medications that are approved to treat more than one condition. For example, Botox is used to treat muscular disorders, but can also be used for cosmetic purposes (e.g., eliminate wrinkles). If the plan does not cover cosmetic products or procedures, the prior authorization program would ensure that Botox is covered only when it used for appropriate medical indications

A Tool to Promote Appropriate Drug Use and to Prevent Misuse:

Prior authorization can be used for medications that have a high potential for misuse or inappropriate use. For some categories, health plans may limit the coverage of drugs to FDA-approved uses and require a prior authorization for off-label indications. An example of an off-label use could be a physician prescribing a powerful opiate that has only been approved by the FDA to treat break-through cancer pain, in a patient that has chronic back pain. In this case there is insufficient clinical evidence supporting the use of the medication for non-cancer purposes and prescribing such a medication could pose a serious safety risk for the patient. Prior authorization would be used to limit coverage in this situation to those patients where safety and appropriate use has been documented.

A prior authorization request for an off-label indication requires documentation from the prescriber to confirm the use for which the product was prescribed. The plan may require the prescriber to present evidence supporting the unapproved use or assign a pharmacist to conduct a medical literature review to search for evidence for that indication. A pharmacist would then evaluate the documentation to determine whether use of the prescribed drug for the indication provided is justifiable.

In addition, prescribing access to select medications may be limited to specific physician specialists. Prior authorization guidelines may stipulate that only certain medical specialists may prescribe a given medication. This type of prior authorization requirement is appropriate for specialized medications that require a high level of expertise in prescribing and monitoring treatment. The prior authorization process will ensure that coverage for these select medications

will be granted when medically necessary and prescribed by the appropriate specialist (e.g. limiting the prescribing of chemotherapy medications to oncologists.)

Administration of Step Therapy:

Another prior authorization approach is step therapy. A step therapy approach to care requires the use of a clinically recognized first-line drug before approval of a more complex and often more expensive medication where the safety, effectiveness and value has not been well established, before a second-line drug is authorized. Step therapy requirements ensure that an established and cost-effective therapy is utilized prior to progressing to other therapies. If the required therapeutic benefit is not achieved by use of the first-line drug, the prescriber may request use of a second-line medication.

For example, a step therapy approach may be used for non-steroidal anti-inflammatory drugs (NSAIDs), a drug class that is used to treat conditions such as arthritis pain and inflammation. Traditional NSAIDs are available in generic forms and offer an established option for treating pain and inflammation, but they can sometimes result in stomach irritation and side effects. A newer, more expensive branded NSAID also treats pain and inflammation, but may be a better option for patients who have experienced a gastrointestinal side effect with a traditional NSAID or who already have a gastrointestinal condition. An NSAID step therapy rule requires that a patient try a traditional, generic NSAID or provide documentation of a gastrointestinal condition prior to receiving approval to fill a prescription for the newer, more expensive branded product.

The step therapy approach may utilize automated adjudication logic that reviews a patient's past prescription claims history to qualify a patient for coverage at the point-of-sale without requiring the prescriber to complete the administrative prior authorization review process. If patients have the first-line drug in their claims history, they may automatically qualify for coverage of a second-line therapy without triggering a review for coverage. In addition, this type of logic may use other available patient data (e.g., age, gender, concomitant medications, diagnosis, and physician specialty) to qualify patients for coverage without the need for a prior authorization review. Utilization of this logic allows plans to manage the benefit without requiring unnecessary member or prescriber disruption. While this sophisticated "look-back logic" is often used for step therapy rules, it can be used for other types of prior authorization rules as well.

Administration of Quantity Management Rules:

The prior authorization process can be used to administer quantity management rules, including rules based on duration of therapy, quantity over a period of time and maximum daily dose edits. A plan may limit drug benefit coverage to quantities that are consistent with FDA-approved durations or dosing. There may be instances, however, where these limits should be overridden in the best interest of patient care. For example, proton pump inhibitors are effective in treating peptic ulcer disease. Most ulcers are healed within an eight-week duration of therapy; therefore, plans may limit the duration of treatment to minimize side effects and reduce inappropriate long-term use. Certain conditions, such as erosive esophagitis, however, may require chronic

administration of proton pump inhibitors. By employing the prior authorization process, plans can extend the duration of the therapy limit for patients who meet established parameters.

Exception Process for Closed Formulary Benefits:

The formulary is a key component of health care management and is a tool used to ensure that the medications available for use in a prescription drug program have been demonstrated to be safe, effective and affordable while maintaining or improving the quality of patient care.[4] Formulary administration generally falls into one of two categories - open or closed. Under an open formulary pharmacy benefit, the health plan or payer provides coverage at the point-of-sale for all medications covered under the prescription benefit, even those not listed on the formulary.

Under a closed formulary pharmacy benefit, the health plan or payer provides coverage at the point-of-sale only for those drugs listed on the formulary. The prior authorization process can be used by prescribers and patients to request coverage for drugs that are not included on a plan's formulary. As no formulary can account for every unique patient need or therapeutic eventuality, formulary systems frequently employ prior authorizations. . This process provides a mechanism to provide coverage on a case-by-case basis for medications otherwise not eligible for coverage.

For example, to protect against cardiovascular disease, a patient may need significant reductions in LDL (bad) cholesterol levels that may not be achievable with a health plan's formulary drug and therefore a coverage exception for a high-potency non-formulary medication would be requested using the plan's exception process provided certain circumstances are met to ensure patient safety and appropriate utilization.

Conclusion

The Academy of Managed Care Pharmacy (AMCP) recognizes the role of prior authorization in the provision of quality, cost-effective prescription drug benefits. The fundamental goal of prior authorization is to promote the appropriate use of medications. Pharmacists in all practice settings must develop specific guidelines to ensure that the prior authorization process is administered in the most efficient manner possible, is fully compliant with statutory and regulatory requirements, and provides members, prescribers and pharmacists with an evidence-based, rational process to promote appropriate drug use.

The Academy of Managed Care Pharmacy's mission is to empower its members to serve society by using sound medication management principles and strategies to achieve positive patient outcomes. AMCP has more than 4,800 members nationally who provide comprehensive coverage and services to the more than 200 million Americans served by managed care. More news and information about AMCP can be obtained on their website, at www.amcp.org.

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[1] Neil MacKinnon and Ritu Kumar. "Prior Authorization Programs: A Critical Review of the Literature." *Journal of Managed Care Pharmacy* 7 (July/August 2001): 297.

[2] Robert Navarro, Michael Dillon and James Grzegorczyk, "Role of Drug Formularies in Managed Care Organizations," in *Managed Care Pharmacy Practice*, ed. Robert Navarro, p. 249.

[3] Academy of Managed Care Pharmacy. *Concepts in Managed Care Pharmacy Series -- Formulary Management.* 2009. http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=9298 (accessed March 28, 2012).
[4] Academy of Managed Care Pharmacy. *Concepts in Managed Care Pharmacy Series -- Formulary Management.* 2009.