Prior Authorization and the Formulary Exception Process—Examples From the Real World

Managed care organizations (MCOs) are constantly faced with the challenge of balancing cost savings generated by prior authorization (PA) programs and formulary decisions with member disruption, physician disruption, employer group concerns, and the administrative costs of running the program itself, while complying with all pertinent legal and regulatory requirements. The goals of these programs are fairly straightforward—to encourage and provide coverage for the best quality care at the lowest overall price. In this issue of *JMCP*, the Professional Practice Committee of the Academy of Managed Care Pharmacy describes prior authorization as applied to pharmacy benefits management and the formulary exception process.[1]

The tools MCOs have available to attain the same or better clinical or service outcomes at lower cost comprise more than PA and formulary management. Other tools include quantity limits, step-care protocols, copay tiers, coinsurance, deductibles, provider network access, concurrent and retrospective drug utilization review (DUR) programs, physician profiling, case management, disease state management, and various strategies that promote the effective use of generic drugs. Each of these programs alone can have an impact, but maximum value is realized when careful coordination of all these programs is woven together to create a comprehensive management plan that benefits the members, providers, employer groups, and the health plan.

Examination of the medical literature reveals articles that illustrate the clear cost benefit of these aforementioned programs, while other articles question their effectiveness and value.[2-11] MCOs implement these utilization management principles for one primary reason—they work. Unlike in academia, the focus of many MCOs is not to publish but to provide value to employer groups and individual members while generating a financial return on investment for the MCO. Thus, much of the cost-savings data associated with managed care interventions are not available in the published literature. An increased interest is now emerging in the managed care community to publish the benefits of these programs so that others may take advantage of successful programs or avoid investing in interventions that are found to be ineffective or inefficient.

MCOs are searching for new and innovative ways to continue these management programs while keeping the administrative costs to a minimum. Many MCOs' efforts have turned to automation of PA and nonformulary criteria when feasible. The automation process for pharmacy benefits involves the application of coverage criteria as the pharmacy claim is submitted electronically (online) by the pharmacy provider at the point of service. Automation is particularly efficient when used for programs where the diagnosis can be inferred by surrogate drug markers or in situations where other medications need to be used first. Beta-blockers are not a good surrogate marker for identifying members with congestive heart failure because of the numerous other potential indications for their use, ranging from hypertension to migraine headache prophylaxis, but insulin is a good surrogate marker for a diagnosis of diabetes because of its very low potential for off-label use.

Two common classes of medications that present good opportunities for automating approval criteria include the cyclooxygenase 2 (COX-2) inhibitors and the leukotriene receptor antagonists (LRAs). Given the recent attention to the COX-2 inhibitors, including the market withdrawal of Vioxx on September 30, 2004, and Bextra on April 7, 2005, drug use management of this class becomes more important for patient safety reasons.[12] Although there is no evidence to show that the COX-2 inhibitors are more clinically effective than nonsteroidal anti-inflammatory drugs (NSAIDs), they may be safer in patients who are at a high risk for developing a gastrointestinal (GI) bleed.[12-17] Many MCOs provide coverage for the COX-2 inhibitors when the member is at higher risk of a GI bleed, e.g., older than 65 years, receiving concomitant therapy with an anticoagulant, or having previously tried generic prescription NSAIDs.

Automation is particularly useful in this situation because the requisite information is readily available in the drug claims processing system. The date of birth is required for all pharmacy claims, permitting instant identification of persons potentially at greater risk for a GI adverse event because of advanced age. The claims processing system can be programmed to recognize a list of NSAIDs and anticoagulants and determine if there are previous or concurrent pharmacy claims for those medications within a predetermined time frame. If there are claims for those targeted medications in the member's profile, the system will automatically allow payment for the COX-2 inhibitor pharmacy claim, requiring no paperwork or other intervention.

The standard request process—via paper or phone call—would remain necessary for those members with other medical conditions (e.g., previous ulcer) that would normally be eligible for coverage but the relevant information is not captured in the pharmacy claims data. Still, the use of pharmacy claims history significantly reduces the administrative burden (hassle factor) associated with PAs for pharmacists, members, and prescribers.

Similarly, the LRA class of drugs presents a great opportunity for criteria automation. If the MCO's drug benefit plan covers LRAs for asthma or allergic rhinitis, surrogate drug markers can be used to identify those members in each category. If the MCO's criteria allow for coverage of the LRAs as a first- or second-line option for the treatment of asthma, the computer system can screen prior pharmacy claims for medications such as albuterol or inhaled corticosteroids. Since it is unlikely that these products are being used to treat a condition other than asthma, the system can be programmed to automatically

approve coverage and pay an electronic claim for an LRA when there are concurrent or prior pharmacy claims for these products.[18]

Published data suggest that LRAs are equal to or less effective than nasal steroids or oral antihistamines when used to treat allergic rhinitis.[19-22] If the MCO covers the LRA as a second- or third-line treatment for allergic rhinitis, the system can be programmed to scan for prior claims for oral antihistamines or intranasal corticosteroids. Despite the differences in indications and the use of various alternatives that may be required first, the automatic approval process that evaluates previous claims remains the same. The authorization occurs without any intervention from the pharmacist, physician, or MCO as long as the necessary member information is in the pharmacy claims database.

The benefits and implications of automation are significant, and many MCOs continue to look for opportunities to add more of these programs while transitioning existing manual PAs to an automated platform. The most prominent advantage of automation of approval criteria is that it allows for continued management of high-cost, highly utilized medications at the point of service and eliminates the unnecessary rejection of claims, which results in decreased member disruption and dissatisfaction with the benefits. All automatic approvals are invisible to the member, physician, and dispensing pharmacist. Automation decreases the time involved by the dispensing pharmacist and the physician because it removes paperwork and phone calls from the appeals process, thus allowing pharmacists and physicians more time to take care of patients. Automation also decreases the administrative burden on MCOs, permitting reallocation of resources to effectively manage other medications and disease states.

It is important to remember that the goal is to focus resources and management strategies on the areas where the most impact can be obtained with the least amount of hassle and incursion on providers of care. Automation allows the MCO to continue to effectively manage a variety of medications and conditions but with less time and effort for all parties involved. The ultimate goal of any PA, nonformulary, quantity limit, and other pharmacy benefit management tool is to promote appropriate utilization while keeping prescription drug benefits affordable.

It is important to be selective in the choice of programs to automate. The potential benefits of automation in PA criteria, nonformulary criteria, step-care, and other pharmacy benefit management strategies are only partially realized because there are limitations. For example, new members to a health plan have no administrative claims history from which to apply prior-use criteria. Furthermore, existing members may experience significant changes in their pharmacy benefits. Members may change group enrollment, potentially removing the claims history in some claims processing systems if the primary member number changes as a result of a change in group enrollment. A manual process remains necessary for these situations.

Pharmacy Benefits Management and the Medicare Modernization Act

The Medicare Modernization Act provides a new set of challenges for physicians, pharmacists, and MCOs. The Centers for Medicare and Medicaid Services (CMS) states that heath plans may implement various utilization management techniques (PA, quantity limits, etc.) and various formulary designs, which represent the cornerstone of any pharmacy benefits management program.[23] CMS recognizes that these management techniques exist and provide for good clinical and financial management of the pharmacy benefit. The criteria that are used to evaluate the exception requests must be supported by evidence-based literature and sound clinical rationale.

CMS supports multiple formulary benefit designs as long as the base requirements for the formulary are met. For example, a compliant formulary will have at least 2 drugs per therapeutic category and class (when applicable), and the prescription drug plan (PDP) or Medicare Advantage Prescription Drug Plan (MA-PD) will have an established formulary coverage exceptions process to allow for a "medical necessity" review for nonformulary medications. "Medically necessary" is a somewhat ambiguous term that must be clearly defined by the plan's policies for individual exception requests. The plan must be careful in its policy writing because those policies must address as many different clinical scenarios as possible.

The Medicare rule for exception requests has many implications for PDPs and the physician community. The PDPs' criteria for copayment tier exceptions must take into consideration whether there is a therapeutically equivalent drug covered on the formulary and also must consider the number of drugs on the formulary that are in the same category as the requested drug.

The requirements placed on physician requests are also outlined. A physician may request a copayment tier coverage exception by providing a supporting statement to the plan. This statement will need to explain why the formulary alternatives would not be as effective as the requested product and/or that the formulary products would result in an adverse event for the member. It is difficult to predict with certainty what the outcomes of any therapy will be in advance. Plans will have to be as specific as possible in their coverage exceptions criteria in order to clarify this grey area. The exceptions review process must remain consistent to ensure that the pharmacy benefit is administered uniformly to all members, while providing flexibility to accommodate providers and members in unique clinical situations. Plans and providers will be challenged to meet CMS's regulatory requirements while continuing to do what is best for the individual member without incurring avoidable costs.