

Prior Authorization and Utilization Management Concepts in Managed Care Pharmacy

SUMMARY

Formularies that include prior authorization and utilization management are widely used by managed care organizations (MCOs), including health plans and pharmacy benefit management companies. Utilization management criteria are essential to optimizing patient outcomes and reducing waste, error, unnecessary drug use, and cost. The Academy of Managed Care Pharmacy (AMCP) Professional Practice Committee has developed the following 9 specific concepts for effective prior authorization practices by MCOs: (1) patient safety and appropriate medication use, (2) clinical decision making, (3) evidence-based review criteria, (4) automated decision support, (5) transparency and advanced notice, (6) emergency access, (7) provider collaboration, (8) need for timeliness and avoiding disruptions in therapy, and (9) cost-effectiveness and value. AMCP supports these concepts to allow for further collaboration between prescribers and payers in order to ensure that patients receive appropriate and timely access to drugs, devices, and other therapeutic agents.

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Formularies that include prior authorization and utilization management are widely used by managed care organizations (MCOs), including health plans and pharmacy benefit management companies. Utilization management criteria are essential to optimizing patient outcomes and reducing waste, error, unnecessary drug use, and cost. The safety and clinical appropriateness of medication therapy selection for a covered population is the primary goal of formularies. A thorough review of clinical evidence is the cornerstone of managed care formulary decisions.^{1,2} For individuals who require medications and treatments not included on formularies, prescribers and health plans can work together through exceptions and appeals processes to provide appropriate access to therapy. Health plans, employers, and government-sponsored health care programs focus on optimizing patient outcomes through the use of medications that have established evidence of efficacy and safety, while providing the highest value. Prior authorization (PA) is a utilization management tool that enables plans to implement patient-focused goals of safe and appropriate medication use. Also known as coverage determinations in the Medicare Part D program, PA coverage criteria are centered on patients' clinical needs and therapeutic rationale.

The Academy of Managed Care Pharmacy (AMCP) Professional Practice Committee has developed the following 9 specific concepts for effective PA practices by MCOs. AMCP supports these concepts to allow for further collaboration between prescribers and payers in order to ensure that patients

receive appropriate and timely access to drugs, devices, and other therapeutic agents. Additionally, these concepts are timely, given recent attention and proposed reforms to PA.³

Concept 1: Patient Safety and Appropriate Medication Use

Using clinically sound, evidence-based principles, PA guides safe and appropriate medication therapy for patients. MCOs work with prescribers to ensure that treatment goals are met, while considering the health plan benefit design and all statutory and regulatory requirements. For example, PA can be used to support careful patient selection and manage ongoing medication use for medications with a high potential for misuse or abuse, or those with unknown long-term safety or durability of effect.

Concept 2: Clinical Decision Making

PA guidelines are designed by MCOs to efficiently improve the use of clinically appropriate, affordable medications and therapies. This is especially useful for classes of medications that include multiple agents of varying effectiveness, for which PAs are an additional way to encourage the use of appropriate formulary alternatives. MCOs should regularly confirm that agents on the formulary provide appropriate care across the membership of a plan and that the plan's coverage requirements align with standards of relevant accreditation bodies and quality organizations.

Concept 3: Evidence-Based Review Criteria

Medication utilization management criteria based on an evaluation of clinical trials, peer-reviewed literature, and consensus guidelines are a common part of PA programs. These criteria are developed by a pharmacy and therapeutics (P&T) committee that includes health care providers (e.g., pharmacists, nurses, and physicians) and administrators, quality-improvement managers, and others involved with the medication use process.⁴ The P&T committee reviews the safety and efficacy evidence of a medication in comparison with therapeutic alternatives to render a clinical determination for drug formulary placement.^{4,5} Furthermore, the P&T committee considers subgroups or special populations of patients for whom the evidence indicates a drug may have differing effectiveness or adverse effect incidence. The P&T committee evaluates all pertinent, accessible medication trial data when making formulary decisions. While cost is an evaluated component, it is used as a comparator when the alternative is therapeutically equivalent or shown to produce similar results. In order of priority, formulary decisions are derived first from safety and efficacy, followed by cost considerations.^{4,5}

The intent of a formulary and utilization management is to encourage the use of medically appropriate and cost-effective drug-related products that meet the needs of patient populations.⁴ Formularies and utilization management criteria should be updated regularly to keep pace with changes in clinical practice, clinical guidelines, new drugs, evolving health plan designs, and the reality that patients may change health plan coverage.^{4,5}

Concept 4: Automated Decision Support

Provider burden and/or dissatisfaction with approval processes has been documented in the literature.^{6,7} Health information technology solutions should be used to reduce paperwork and waste, standardize data and processes for utilization management, and improve the patient and clinician experience.⁸ For example, adoption of electronic PA (ePA) allows for secure, electronic transmission of patient information to complete a PA review, thus, decreasing the administrative burden for prescribers and MCOs and improving the turnaround time for the benefit of patients.⁹⁻¹¹ According to a national ePA technology vendor, providers who use electronic solutions spend an average of 2.5 fewer hours on PA per week.¹² Best practice guidelines or state regulations should be followed as the industry continues to develop uniform, national industry standards for the electronic exchange of health information. An effective ePA process includes automation at the point of care, point of sale, or any point where a PA originates. To support the decision-making process for patients and providers, the patient's financial responsibility, as well as any potential less costly therapeutic alternatives, should be displayed at the point of care.

Concept 5: Transparency and Advanced Notice

MCOs should provide advanced notice of formulary changes to the provider and patient. Advanced notice is vital to avoid disruptions in care.

MCOs should make current formulary and utilization management requirements available and transparent in a manner that is easily accessible and understandable to patients. Members and providers should be able to easily identify a particular formulary and any changes made, as well as search for drug-utilizing tools such as medication search tools and formulary guides. Details of utilization management criteria should be presented, including required documentation that supports the request for authorization or a formulary exception, the volume of requests, and the approval and denial rates.

Concept 6: Emergency Access

In emergency situations, access to medication therapy without impediments is imperative. This includes situations in which care is sought outside of standard business hours. PA criteria are not applied to medications used in inpatient or emergency care settings. Utilization management tools should not cause delay of care or have an effect on medical treatment during emergency care situations. MCOs should avoid broad or

inflexible PA requirements for drug therapies commonly used as part of emergency care.

Concept 7: Provider Collaboration

MCOs should collaborate and communicate clearly with providers throughout the PA process. Utilization reviews should provide detailed explanations for PA denials, including an indication of any missing information. The PA process should support health plan transparency and multidisciplinary collaboration to obtain the best outcomes for the member/patient and the best value for the health care system. Additionally, PA criteria should be subject to continuous improvement, revisions, and, where necessary, removal. This requires dynamic discussion and partnership with providers to ensure that patients are receiving appropriate care without unnecessary hurdles. All PA denials should include the clinical rationale for each determination (e.g., national medical specialty society guidelines and peer-reviewed clinical literature), provide the plan's covered alternative treatment, and detail the appeal process.

In cases where different providers are not aware of all the medications or treatments a patient is receiving, the MCO may act as the care coordinator when reviewing medication regimens or PAs. Ensuring that all providers are aware of the medications being prescribed to a patient can lead to discontinuation of duplicate medications or modifications that optimize the medication regimen. MCOs need to continue bridging any gaps in medication coordination between providers.

MCOs should monitor utilization of medications across the medical and pharmacy benefit, including those administered in a physician's office or outpatient treatment facility. Coverage of medical and pharmacy benefit drugs, devices, or therapies should be coordinated to enable more cost-effective therapy selection and streamlined medication management.

Concept 8: Need for Timeliness and Avoiding Disruptions in Therapy

MCOs should allow for timely PA approval for medically necessary exceptions and for timely handling of denial appeals. When requesting nonurgent care, PAs should be reviewed and acted upon promptly and within statutory and regulatory timelines and accreditation standards. When a provider and the MCO do not agree on the utilization management criteria used for approval of a therapy or a coverage decision for a member, a provider should have access to a peer-to-peer clinical discussion to resolve the matter.

Patients newly enrolled in plans who are stabilized on therapy should be allowed sufficient time for therapy continuation during the PA review process, sometimes referred to as a grandfathering or transition period. Transitional coverage promotes coordinated care and prevents unnecessary therapy changes or gaps in care.

Concept 9: Cost-Effectiveness and Value

As MCOs and providers enter into risk-based arrangements, use of PA as a tool to ensure delivery of affordable, high-quality, patient-centered care must evolve to facilitate shared decision making. When there is shared risk involved in contracts between providers and payers, PA can be a tool to ensure alignment of providers around evidence-based care. The evolution of PA should be a partnership between payers, providers, and administrators of health care contracts to include alignment of incentives, clinical approach, and operational capabilities. As noted in the American Medical Association Reform Principles,³ collaboration among stakeholders is necessary to achieve cost-effective and value-based care.^{13,14}

Conclusions

MCOs should focus on ensuring access to appropriate, evidence-based, and cost-effective medications for their members. These concepts provide a framework to ensure that PA and utilization management are timely, transparent, and collaborative, which is ultimately synonymous with patient-centered care. MCOs have the responsibility and opportunity to incorporate clinical and technology advancements into these processes with a constant goal of improving health outcomes and cost-effectiveness.

AUTHOR CORRESPONDENCE: Tricia Lee Wilkins, PharmD, MS, PhD, Director of Pharmacy Affairs, Academy of Managed Care Pharmacy, 675 N. Washington St., Alexandria, VA 22314. Tel.: 703.684.2641; E-mail: tlwilkins@amcp.org.

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