Prior Authorization In Today's Dynamic Healthcare Marketplace

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Forward

The growth of biologics and specialty drugs continues to increase at warp speed. The pipeline is full of great promise, but most of these products will be for higher cost orphan diseases and oncology. There is no relief in sight for employers—as for all plan sponsors—that serve as the primary commercial market purchasers of all healthcare costs (56%) in the U.S. today.

With limited opportunities to reduce costs, employers are looking at the supply chain. Leading employers recognize they need to know the cost of a drug at its point of service, not just a price that has no direct relevance to a claim cost. In fact, it's anticipated approximately 30–40% of an employer's total drug spend comes from pharmacy benefit managers (PBMs). Similarly, drug-related medical spend has grown significantly in the past few years. How is this possible?

PBMs are mostly unregulated, and most healthcare stakeholders are uncertain how they really function, what deals they cut, how they generate income and what services or value they provide. Finding value in medical claim spending and where the money for all drug related claims is buried in the contracts (e.g., rebates, spread, claw backs and mandating distribution in-house, etc.) is very difficult as they are not reflected in the contract's administrative expenses. For plan sponsors, such as employers, medical and drug benefit contracting is an important area to focus on as it relates to managing total cost of care.

While benefit managers also make money through the services that they offer, such as utilization management (UM), typically it can be disruptive or counterproductive to delivering improved outcomes. This inefficient use of UM includes prior authorization (PA). This white paper will help you better understand what is going on behind the curtain for PAs in both the medical and pharmacy benefit, including when they are needed (or not) and how they can align more effectively with other utilization management strategies.

When a patient (member of the plan) receives clinically appropriate medications that address safety concerns and when plan sponsors advocate for lower cost alternatives while ensuring there are no delays in getting the treatment, everyone wins. And that should be everyone's goal.

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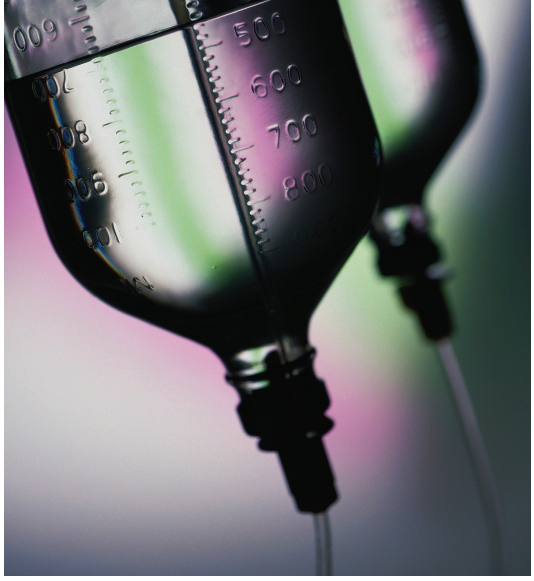
Larson co-leads the National Employer Initiative on Specialty Drugs, an employer-driven, multi-year research project that serves as a roadmap to support employers by providing knowledge, access to the latest research and best practices, as well as no-cost resources.



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Introduction

Specialty drugs are administered to less than 1–2% of the U.S. population, yet account for 38% of U.S. prescription drug costs.[1] U.S. specialty drug costs are expected to account for 50% of all prescription drug costs by 2020.[2]

The robust specialty pipeline is one of the major drivers of this growth. New drugs typically increase utilization and high prices at launch are common, particularly for innovative products offering more effective treatments.[3] Two additional drivers of increased specialty drug costs are FDA approvals for new indications for existing drugs and periodic pricing increases.

Prior authorization (PA) is a requirement that a physician obtain approval from the patient's health insurance plan or designated entity to ensure financial coverage for a prescribed medication.

Table 1
New Drugs Approved By Year[4]

Year	New drug approvals
2017 (Jan–Jun)	26
2016	22
2015	45
2014	41
2005–2013 (average per year)	25

Specialty drugs can be covered either under a payer's pharmacy or medical benefit or both, depending on a plan design. To address rapidly rising specialty drug costs, managed care organizations (MCOs) such as health plans, third party administrators, pharmacy benefit managers (PBMs) and specialty pharmacies frequently deploy various drug utilization and clinical management strategies to control drug utilization and costs.

One of the most commonly used drug utilization management tools for MCOs is prior authorization (PA). It is often cited as an essential managed care tool to ensure that drug benefits are administered in accordance with policy design and that medication therapy is safe, effective for the condition, and provides the greatest value.[5]

Drug prior authorization programs have been in existence for many years and have evolved over time. Most commonly deployed MCO PA strategies for specialty medications still incite active debate between plan sponsors (i.e., employers), physician providers and patients as to the ability of these programs to increase safety and decrease costs.

The objective of this white paper is to identify the pros and cons of commonly used prior authorization programs, with an emphasis on drugs billed through the medical benefit and the subsequent implications to MCOs, plan sponsors, physicians and patient stakeholders.

This white paper will also explore new approaches to prior authorization and the use of alternative metrics to identify measurable value for delivering effective drug utilization and cost controls.

What is Prior Authorization?

PA is a requirement that a patient's physician obtain approval from the health insurance plan or designated entity to ensure financial coverage for a prescribed medication. In its purest form, PA is primarily focused on monitoring for safety and efficacy concerns for prescribed medications.

Over the past decade, PAs have evolved to more of a strategic or tactical approach for minimizing drug costs. Under today's approach to PA, benefits are only paid if the medical care has been pre-approved by the MCO. This is especially true for high-cost specialty medications.

PA Objective	Examples	Notes
Identifying efficacy concerns	► *FDA approved indications* ► *Off-label indication*	► *Is the medication being prescribed by FDA-approved indications? If not, are there nationally recognized evidence-based references that support its use for a prescribed medication?*
Identifying safety concerns	► *Dosing* ► *Drug interactions* ► *Contraindications*	► *Is the prescribed dose by FDA-approved dosing schedules?* ► *Does the medication have the potential for drug interactions that could cause patient harm?* ► *Does the drug have any additional identified characteristics that can cause patient harm?*

Table 2

Most Common Types of MCO Utilization Management Strategies

Utilization management tool	Description
Prior authorization	▶ Ensure drug benefits are administered as designed, with an emphasis on ensuring clinical appropriateness and safety by payer coverage rules. ▶ Prior authorizations can also trigger other utilization management tools such as step therapy, quantity limits or formulary management. ▶ Key factors used in determining prior authorization requirements include a drug's price, significant clinical risks and disease complexity.
Step therapy	▶ A form of utilization management in which a lower cost but equivalent drug must be used initially. Drugs subject to step therapy are usually referred to as "preferred drugs." ▶ Preferred drugs are usually determined by a formal Pharmacy and Therapeutics Committee that focuses on fully assessing a drug's clinical efficacy, safety and cost. ▶ Depending on an MCOs coverage policy, step therapy exceptions can be made either through a formal request or as part of an appeals process.
Quantity limits	▶ Applying drug quantity limits, typically a month (30-day) supply, serves to minimize drug waste. This is easier to apply to pharmacy benefit drugs since this follows traditional dispensing of an oral tablet, capsule or liquid formulation supported by well-established operational processes. Quantity limits, particularly for pharmacy benefit drugs, can also identify potential fraud, waste, and abuse. ▶ Certain MCOs mandate a 15-day quantity or multiple 14– to 15–day limit for high-cost specialty medications (e.g., oral oncology drugs) with the stated goal of ensuring patients can tolerate therapy before any longer-term refills are provided. ▶ Quantity limits for medical benefit drugs are more complex. Injectable or infused drugs are often based on patient-specific weight or body surface area (BSA) calculations. Unlike pharmacy benefit drugs, it is also challenging to identify medical benefits' fraud, waste, and abuse since claims are nonspecific HCPCS versus NDCs.

Prior Authorization in Today's Market

Beyond validating drug efficacy and safety concerns, MCO administered PAs can achieve cost savings through a variety of ways, as identified in Table 2.

PAs can be required for any specialty medication, regardless of the pharmacy or medical benefit drug design, as well as by the payer or the plan sponsor-defined plan design. It can be administered by pharmacy benefit managers (PBMs), specialty pharmacies, health plans' internal pharmacy or medical management teams, and other external vendors or by a combination of different entities. (See Table 3)

PAs administered for specialty drugs under the pharmacy benefit—typically oral tablet, capsule or liquid and self-injectable formulations—are usually easier to manage. This is largely due to the well-defined industry standards and workflow processes identified in Table 4.

"Studies have shown that prior authorization is the biggest 'pain point' among providers," says Pam Jodock, senior director of healthcare business solutions at HIMSS. "The issue is not automation; it's the business processes to which automation would be applied." [6]

J. Frieden, *MedPage Today*

Up to 50% of specialty drug costs occur with injectable or intravenous medications under the medical benefit.[7] PA for these specialty drugs are more problematic for payers to employ. A key medical benefit drug management concern is the lack of clear and verifiable utilization and meaningful cost data. There are a number of differences when compared to pharmacy benefit drug management. (See Table 4)

PA Implications for Payers, Providers and Patients

Prescribers and patients often cite significant administrative burdens and delays in prior authorization approvals. One study estimated $23 to $31 billion of associated annual costs attributed to managed care prior authorizations.[8] Beyond these administrative costs is the very real potential for delays in patient care. Physician specialists (e.g., oncologists, hematologists, rheumatologists) also encounter frustration when communicating with MCO staff who are not board-certified physician specialists and who often lack knowledge of disease complexity or the latest proven scientific advances.

MCOs also encounter heavy administrative costs for PAs. A cross section of MCO pharmacy and medical directors cited the cost for drug PAs ranging from $20.00 to more than $50.00 per drug.[9] Medical benefit PAs, particularly for cancer, are at the higher end of the scale, reflecting disease complexity and the more prevalent use of drugs for off-label indications. In addition, medical benefit management drugs frequently include multiple high-cost specialty drugs in specific combinations, and thereby incur multiple PA events. This further adds to administrative costs and a greater likelihood of delaying patient care.

Specialty drug costs continue to rise at double-digit annual trends, with an increasing number of drugs exceeding six figure sums per year of treatment. Against this backdrop, PAs will continue to be the primary tool for managing escalating drug costs. A recent payer survey noted that PA is “the single most impactful clinical utilization management tool.”[9]

Prior authorizations are not just a frustrating impediment to providing patients with quality care. To physicians, they represent hundreds of millions of hours of lost productivity and billions of dollars in revenues with little benefit to patients.

The December 25, 2016 issue of *Medical Economics*, in an article entitled "Top 10 Challenges Facing Physicians in 2017," identified the time and energy required for prior authorizations as the second challenge facing doctors today. The first was identified as payment reform for physician services.[10]

The market's current approach to managing prior authorizations is extremely fragmented, with health plans' internal pharmacy, medical and utilization management teams playing a role. Additionally, payers also frequently utilize external vendors, such as PBMs and specialty pharmacies, to manage PAs.

Market surveys indicate that stakeholders are receptive to products and services that will relieve administrative burdens from internal pharmacy, medical, PA and utilization management teams.[11]

It would be overly simplistic to believe the solution is to eliminate PAs. The specialty pipeline, along with double-digit annual trends, will undoubtedly reserve a place for a PA mechanism. The challenge, therefore, is to utilize PAs that effectively balance the demands of MCOs and plan sponsors to manage limited financial resources against the demands of providing patients with the most clinically and cost-effective drug therapy. A higher value PA solution should also minimize the administrative burdens on providers and benefit patients with faster times to initiate prescribed drug therapy.

"There is not a lot of economic analysis for substitution effects such as when drugs are denied, what was substituted, and the measurement of direct costs and indirect costs such as emergency room and in-patient hospitalization."

AMI Primary Market Research on File

Measuring PA Value or Program Effectiveness

To evaluate the effectiveness of a PA program, it is necessary to adopt metrics that accurately measure its clinical and financial impact.

Various industry-accepted metrics such as per member per month (PMPM), per member per year (PMPY), per patient per month or year (PPPM, PPPY) are the most frequently used parameters to measure drug spend, trend and the overall effectiveness of utilization management approaches.

The value of these metrics, however, may be limited. They do not represent true drug costs as that is diluted amongst the total member population rather than the afflicted patient cohort. Payers are beginning to consider per utilizer per month (PUPM) metrics. This measure accurately depicts the true drug costs for a specific patient cohort afflicted with the disease.

Another gap for traditional PAs under the medical benefit is the inherent challenge of linking prior authorization clinical data to claims. This makes it difficult to validate whether the provider followed the PA directives or determine if clinical and cost optimization is occurring. The ability to link relevant clinical data and financial claims data would provide a necessary step in establishing a program's efficacy.

Current MCO Utilization Management Strategies

Specialty, as well as non-specialty drugs, can be administered through a managed care organization's pharmacy or medical benefit plan design or both. Although there are some exceptions (e.g., transdermal patches), pharmacy benefit drugs are traditionally oral formulations, while medical benefit drugs are typically injectable or infused formulations. Specialty drugs, such as erythropoietin stimulating agents, that can be self-administered in a home or ambulatory clinic setting, are examples of drugs that can be administered under a payer's pharmacy or medical benefit or both.

To control the escalating costs and utilization of specialty drugs, MCOs frequently deploy prior authorization and other utilization management strategies identified in Table 2. While the strategies and implementation can vary by the type of MCO (i.e., health plan, PBM, specialty pharmacy), these management approaches have broad implications for payers, plan sponsors, providers, patients and drug manufacturers. Prior authorization has historically been cited as one of the most prevalent forms of clinical utilization management, with the stated goal of ensuring that a patient is receiving clinically appropriate medications, addressing outstanding safety concerns and advocating lower cost alternatives.

The stated goals of PA are consistent across MCOs. However, its application varies widely, and often, different PA criteria create confusion and frustration for physicians and patients. Prior authorization has evolved to be a catch-all term which can mean different things to different stakeholders, and depending on the stakeholder's perspective, a program of great value or a waste of resources.

Medical associations have proposed prior authorization standardization[12] and transparency since physician practices usually contract with

multiple payers such as commercial health plans, medical service organizations, and federal and state Medicare and Medicaid programs. Any process that allows providers and patients a uniform workflow would be beneficial.

As noted, the costs to administer a prior authorization ranges from $20.00 to $50.00 for each drug prior authorization.[9] Included in this cost are handling denials or appeals by the prescriber. Medical benefit PAs are frequently recognized as being more expensive than pharmacy benefit PAs due to disease complexities—such as cancer with its high prevalence of off-label utilization and multiple drug protocols—which make automation difficult. According to the National Committee for Quality Assurance (NCQA), as well as many state regulations that require Medical Director involvement, this lack of automation drives up labor costs.[13]

"I would like to see a single entity hande PAs for both oral and injectable drugs, which would reduce office workload and allow my patients to receive treatment faster."

Medical Oncologist, quoted in AMI Primary Research

Administration (Management) of Prior Authorizations

Clinical utilization management responsibilities are largely dependent on if a drug is administered through an MCO's medical or pharmacy benefit plan design and if it can be managed by single or multiple entities, as shown in Table 3.

In a perfect world, a patient would have a disease that can be treated with a single drug. A single entity would manage the process, and all PAs would follow a uniform workflow to allow a physician office to reduce administrative burdens. The reality is something quite different.

There is a fragmented approach to managing medical PAs in today's market. Payers have either developed an internal infrastructure or contracted with an external vendor, such as a PBM or specialty pharmacy, to manage PAs. PBMs and specialty pharmacies frequently build the cost of PA management into drug dispensing. Since drug dispensing produces revenues, PBMs and specialty pharmacies can be viewed as being incentivized to approve PAs for drugs they dispense.[14]

While there are some exceptions, most medical benefit drugs are physician buy-and-bill. Drug dispensing and administration revenues reside with the physician office, providing little financial incentive for PBMs and specialty pharmacies to support medical benefit PAs. Most medical benefit drug PAs are managed by the payer's internal medical management or pharmacy teams. The average PA turnaround for notification differs for urgent requests (1–2 days) versus non-urgent requests (7–14 days). Different payers have different methodologies and requirements for inputting clinical information for adjudication. Denials and any subsequent appeals further prolong ultimate approvals or coverage refusal.[9]

The issue of timely PA processing and reporting is especially pronounced for medical benefit prior authorizations. PA decisions are rarely linked to submitted claims, creating a blind spot in validating whether PA decisions are followed. Medical benefit drug claims rely heavily on HCPCS codes. These could include non-descript miscellaneous, encounter or other "revenue" codes—creating a major barrier for validating the actual drug used, diagnosis or even drug quantity administered. Also, unlike pharmacy benefit drug claims, medical benefit claims payment can be days, weeks or months after the claim submission. This creates reporting challenges, such as capturing actual drug costs by disease state pharmacy teams.[9]

Table 3
Utilization Management and Team Responsibility

Benefit design	Drug formulation	Party or parties responsible for management
Pharmacy benefit	Oral solid or liquid	▶ Health plan pharmacy team ▶ Pharmacy benefit manager ▶ Specialty pharmacy ▶ Retail or chain pharmacy
Medical benefit	Injectable or infused	▶ Health plan utilization management, prior authorization, pharmacy or medical team To a lesser degree ▶ Pharmacy benefit manager ▶ Specialty pharmacy

Medical Benefit Drug Prior Authorizations

While Table 4 highlights some key differences between medical and pharmacy benefit drug prior authorizations, key challenges include:

- The format of medical benefit claims increase reliance on the use of less descriptive HCPCS codes that do not identify a specific drug manufacturer, commercially available package sizes or a specific quantity of drug administered.
- There is an inability to view integrated clinical and financial information because medical benefit drug claims payment can be days, weeks, months or even a year after claims submission.
- Medical benefit PAs are often isolated from pharmacy benefit PAs creating duplicative workflows and data reporting issues.

Table 4
Challenges and Implications on Controlling Specialty Medical Versus Pharmacy Benefit Drug Costs

Challenges	Medical Benefit	Pharmacy Benefit
Wasteage	► Patients do not use all of drug in commercial package sizes. ► Reimbursement is based on percentage of markup, such as ASP; may encourage use of more expensive medications. ► Use of mandatory specialty (white bagging) incurs waste since mailed medications are patient specific and paid by payers even in situations in which the patient has not received medications(s). Provider costs also increase due to maintaining separated drug inventories and increased paperwork.	► Lower opportunity for waste if patients are given quantities based on daily requirements, and limited to short days' supply (e.g., 14 days) versus 90-day mail order quantities. ► Drug delivery is coordinated with patient and provider.
Special handling	► Most medications are injectable or intravenous liquid or lyophilized formulations, so there are greater requirements for refrigeration, avoiding high temperatures, and minimizing breakage of glass vials and syringes.	► With some exceptions, most pharmacy benefit drugs do not require refrigeration or other unique delivery methods. White bag drugs could have temperature and fragility issues.
Claim integration	► Site of service and data fragmentation (PBMs, physicians, payers) create significant barriers to integration across benefit utilization and costs.	► Site of service and data fragmentation (PBMs, physicians, payers) create significant barriers to integrating across benefit utilization and costs.
Prior authorizations	► Inconsistently applied and typically single rather than multi-drug focused, creating administrative burdens and possible treatment delays. ► Not all specialty drugs require prior authorization, preventing determination of clinical and cost optimization. Especially evident in cancer drug therapy. ► Pathway vendors (e.g., Oncology) may utilize proprietary rule sets that create a lack of transparency issues across stakeholders. Pathway vendors may also vary between payers, placing burdens on providers to vary treatments per patients' health insurance policies. Lack of uniformity increases cost.	► More extensive utilization management tools, such as formulary, dose and quantity are available. But coverage confusion or proprietary rules create same transparency issues. ► Single drug focused. Multiple drug therapy requires multiple PA submissions.

Continued on page 12

Table 4 – Continued from page 11

Challenges and Implications on Controlling Specialty Medical Versus Pharmacy Benefit Drug Costs

Challenges	Medical Benefit	Pharmacy Benefit
Adherence and abandonment	► Adherence is presumed to be high since the patient usually needs to be treated under clinical supervision in a physician office or clinic, but not proven. ► Abandonment is low since injectable or infused drugs are only prepared when the patient is physically in a physician office, clinic or ambulatory infusion center. ► Obtaining data on both cost and quality or outcomes is limited.	► Adherence and abandonment are a well-recognized challenge in both retail and mail-based pharmacy settings. ► Does not address lack of patient engagement to seek or continue treatment. ► Obtaining data on both cost and quality or outcomes very limited.
Identification of providers not optimizing evidence-based and cost-effective care	► Inconsistently applied prior authorizations make identification very difficult. ► Cross benefit (medical and pharmacy) drug utilization data is very difficult to capture pre-service and impedes identification of optimal and cost-effective drug use.	► Well-established processes, such as prior authorizations for drugs processed through the pharmacy benefit, allow for effective prospective utilization management.
Patient drug education	► The key challenge is ensuring consistent patient education across varied and multiple sites of service (physician office versus outpatient clinic). ► While preserving the physician and patient relationship, a physician office or clinic site is typically viewed as an optimal opportunity to educate patients face-to-face, but good data is lacking.	► Drug education usually handled by telephone. While operationally efficient, the debate on face–to-face versus remote continues. ► Current drug therapy management removes an element of personalized human interaction, especially when a new drug therapy is started.

Characteristics of an ideal medical benefit drug PA management solution would include:

- Coordinating drug PAs through a single entity—or at maximum, two entities—regardless of medical or pharmacy benefit design, drug formulation or site of service. Ideally, this would be an organization that is not reliant on drug dispensing revenues, removing any potential channel conflicts and providing better positioning to support site of service optimization.
- Reducing provider and payer administrative burdens through technology and PA work flows that augment provider clinical and operational workflows to reduce processing delays.
- Obtaining greater physician adoption through the use of actively practicing board-certified physician specialists or subspecialists supporting peer-to-peer interventions. Given the increasing complexities for medical benefit drugs, such as cancer and auto-immune diseases (i.e., rheumatoid arthritis, Crohn's Disease, psoriasis), this would go a long way in reducing provider frustration when dealing with typical non-board-certified MCO personnel.
- Capturing and reporting all PA interventions that identify associated clinical and financial impacts to clarify PA return on investment.

Conclusion

Despite its current shortcomings, medical benefit drug prior authorizations, if appropriately modified, can be a valuable tool in managing the clinical and cost-effectiveness of high-cost specialty medications for payers, health systems and providers.

There is strong market interest in such an approach, based on payers surveyed in Spring 2017 by Access Market Intelligence. Primary research indicated that there are a number of benefits to be gained from a successful medical benefit drug management program, including:

- Relieve administrative burdens from the internal payer and provider teams.
- Obtain greater physician support.
- Document drug savings from all PA associated activities.
- Customize programs to meet unique organizational needs.
- Integrate with pharmacy benefit PA management.
- Manage all PAs regardless of benefit design through a single entity.
- Integrate clinical and financial outcomes through near real-time access to data.[9]

Improving medical benefit PA system and processes represents an opportunity to promote operational efficiency and optimal clinical outcomes, while improving PA return-on-investment.

Specialty medications hold considerable promise for a range of diseases and conditions. Payers and providers that commit to optimizing their PA processes and systems will be taking the steps necessary to ensure that a wide range of patients can benefit from current and future life-changing, as well as life-saving, medications. Successful specialty pharmaceutical programs are attainable. Now is the time to explore promising new approaches and solutions.

Steps to Success

- Adopt a unique technology platform.
- Develop a collaborative rather than an adversarial approach with providers.
- Validate clinical decision-making with actively practicing board-certified physician specialists and subspecialists.
- Ensure transparent and actionable reporting that can be used as a tool to identify optimal clinical and financial practices for network providers to deliver a meaningful, measurable and sustainable return on investment.

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For a glossary and definition of terms, see:
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