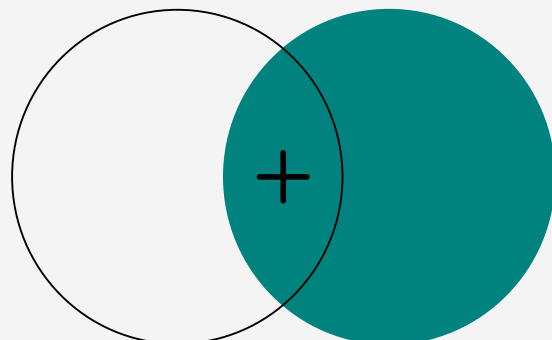


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Successfully Navigating Prior Authorization

**A Guide for
Life Sciences
Companies**



Executive Summary

As healthcare costs increase and specialty medications proliferate, health plans and other payers increasingly use cost-containment tools to control access through drug utilization management. Unfortunately, some tools, specifically prior authorization, create administrative hurdles that may keep patients from adhering to the therapy their healthcare providers prescribe.

To improve patient access and value, pharmaceutical commercialization teams should consider augmenting their utilization management strategy by forming partnerships with companies that deploy a technology-driven prior authorization approach that assists providers, patients, and pharmacies in navigating the prior authorization process and improves patient outcomes.

This guide describes the current landscape and outlook of drug utilization management, including how prior authorization hurdles impact vital stakeholders in the pharmaceutical industry. Discover how life sciences companies can reframe their approaches to prior authorization through digital solutions that boost patient access.

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Prescription Drug Utilization Management 101

What is drug utilization management?

Drug utilization management (UM) refers to the comprehensive review and oversight of the use of prescription medications. A multidisciplinary Pharmacy and Therapeutics (P&T) Committee determines which medications are on the formulary by evaluating a drug's efficacy, real-world clinical performance, and cost. Health plans often add drug UM requirements to optimize patient outcomes and reduce waste, errors, unnecessary medication use, and costs, particularly for higher-cost specialty drugs.¹

Current managed care strategies include:

01. Prior Authorization (PA)

Prescriber must get approval for coverage from the health plan before dispensing the therapy, usually a specialty or specialty lite medication, to a patient.

02. Step Therapy

Also known as step edits, this policy requires that a lower-cost drug in the same therapeutic class must be prescribed and fail before allowing coverage of more expensive options.

03. Quantity Limits

A limitation on the total quantity of a prescription drug that can be dispensed at one time and within a specified time interval.

04. Mandatory Generic Substitution

Streamline the process for approving coverage and provide differentiated dispense programs based on payer behavior.

05. Formulary Tiering

Drugs on the formulary are assigned to tiers that correlate with their cost, reimbursement coverage, and member cost-sharing amount. Lower-tier drugs are more cost-effective for the health plan and require less out-of-pocket costs from patients.

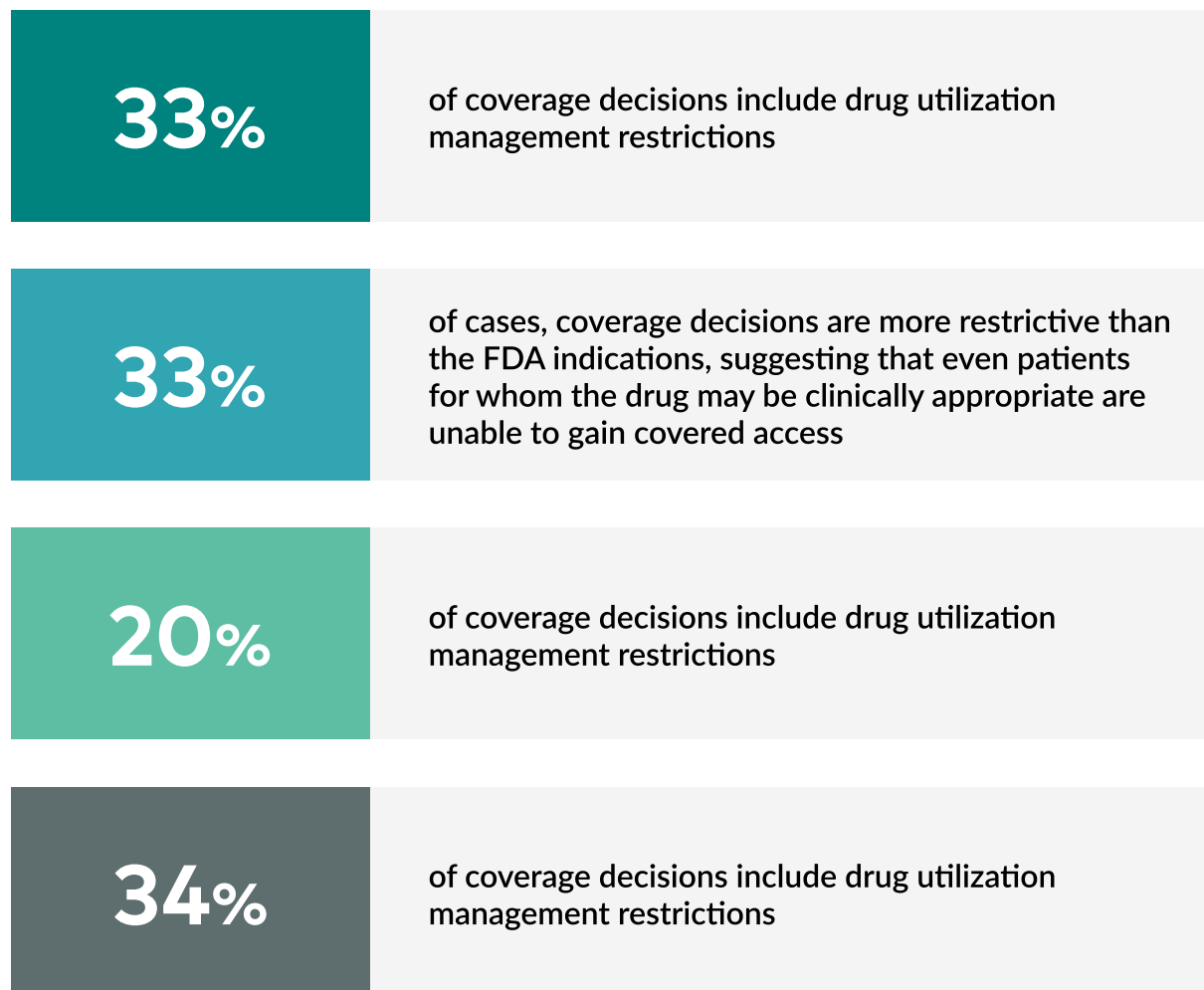
06. Formulary Design

Closed formularies often limit the number of products in each drug class, strongly favor generic equivalents over brands, and rarely reimburse non-formulary therapies. Open formularies reimburse both formulary and non-formulary drugs; however, they may use additional utilization tools to encourage on-formulary prescriptions.

How Do Payers Approach Drug Utilization Management?

A 2018 study evaluated insurance coverage and reimbursement for specialty medications by the largest commercial health plans in the United States. While it revealed significant variabilities in prescription drug coverage across payers, overall, the strictest drug utilization requirements applied to drugs that were self-administered, recently approved, or had at least one therapy alternative available. The drug indications subject to the most UM tools fell into the specialty therapeutic category and were: rheumatoid arthritis, psoriatic arthritis, multiple sclerosis, and plaque psoriasis.²

How payers are applying drug utilization requirements:



Inconsistencies across health plan coverage decisions suggest that a person's plan may substantially influence their access to specialty drugs. ~ Health Affairs (2018)

What's The Outlook For Drug Utilization Management?

Growth will be driven by adoption of newly launched innovative products, which are expected to occur at higher levels than in past years with an average of 50-55 new medicines launching per year over the next five years, including those in oncology or with specialty or orphan status. ~ AARP Policy Institute (2022)

More than 94% of health insurance marketplace plans report they use UM to control prescription drug costs and access. From 2016 to 2020, the percentage of brands subject to UM increased in several therapeutic areas.⁴

Emerging cost-containment strategies include clinical pathways and guidelines, exclusion lists, value-based contracts, and second specialty tiering. Payers are also starting to leverage data from EHRs, advanced analytics, and AI to identify treatment patterns and gain more insight into outcomes vs. costs.⁵

With the continued increase in costs – driven chiefly by specialty pharmaceuticals – it is safe to say these cost-containment approaches are not going away anytime soon. The most recent specialty medication spending increase has been driven by prescription growth in the HIV, autoimmune, and oncology drug classes. New therapies in oncology, immunology, and neurology are forecast to contribute to drug spending growth through 2026.⁶

What's The Outlook For Drug Utilization Management?

Consider the following trends and forecasts:

98%	Of medical practices reported that PA requirements stayed the same or increased in 2021-22 ⁸
4% - 6%	The expected rise in overall prescription drug spending in 2022 ⁹
55%	Specialty medicines account for 55% of overall medication spending in the U.S., up from 28% in 2011 ⁶
32%	Proportion of total healthcare spending from pharmacy costs ¹⁰
2x	Pharmacy expenditures are expected to more than double between 2022-27 ¹⁰

Another driving force in the outlook for drug UM is pharmacy benefit management organizations (PBMs), which act as an intermediary between payers, manufacturers, and pharmacies.

PBMs anticipate using price negotiations and UM tools to reduce spending by consumers and plan sponsors by more than \$1 trillion through 2029.¹⁰

PA creates a significant economic burden

A recent study found healthcare industry stakeholders incur annual costs of \$93.3 billion navigating drug UM.¹¹

- Patients spend \$35.8 billion a year in cost sharing
- Providers spend \$26.7 billion annually interacting with payers, primarily on PA requests
- Drugmakers spend \$24.8 billion annually to support patient access
- Drugmakers spent \$13-15 billion in direct financial support in 2018
- Payers spend \$6 billion each year to administer drug PAs

The Impact Of Utilization Management On The Healthcare System

The hidden cost of medication nonadherence

Poor medication adherence is linked to a 17% higher risk of hospitalization and is estimated to cause 125,000 avoidable deaths and \$100 billion in preventable healthcare costs each year.¹² In fact, medication adherence is linked to a 21% reduction in long-term mortality¹³, and the American Medical Association (AMA) advises physicians to “consider medication nonadherence first as a reason a patient's condition is not under control.”¹⁴

Drug UM can create barriers to patient access, greatly increasing the risk of the following types of medication nonadherence:

01. Prescription Abandonment

An estimated 20% of prescriptions are never filled.¹¹ When patients are in the dark about their prescription status, they are more likely to forget to pick it up or decide not to because of cost concerns.

02. Treatment Delays

Also known as step edits, this policy requires that a lower-cost drug in the same therapeutic class must be prescribed and fail before allowing coverage of more expensive options.

03. Quantity Limits

Step therapy and PA requirements during treatment can disrupt the continuation of needed treatment – 88% of physicians report that PA interferes with continuity of care.¹⁵

Patients are paying a high price as they struggle to understand and navigate their health insurance coverage requirements.

In a recent PhRMA report, 1 in 5 consumer respondents said they spent two or more hours on phone calls and administrative tasks with their insurance company over the previous three months to access prescribed medications. Another study revealed that 4 in 10 people with insurance coverage could not anticipate what they would have to pay for their medications.¹⁶

The Impact Of Utilization Management On The Healthcare System

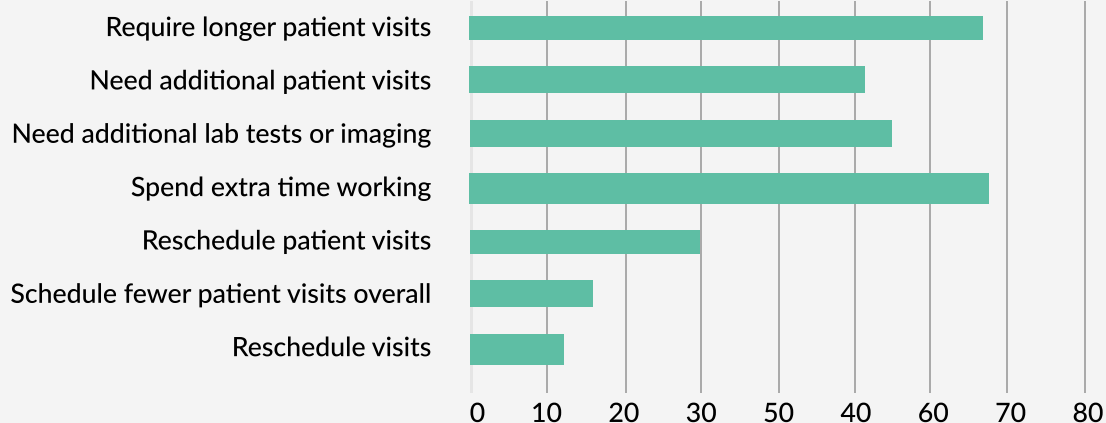
A burden on healthcare providers

Healthcare providers face time-consuming processes to comply with UM requirements, particularly PAs, which are burdensome, cause frustration, and divert resources away from direct patient care. In fact, 88% of HCPs describe the burden associated with PAs as “high” or “extremely high.”¹⁷

A recent national survey of physicians’ perceptions on drug UM revealed the following findings:¹⁸

- 01.** 80% refrain from prescribing certain medications over half the time because of UM
- 02.** 1 out of 2 physicians report that UM policies rarely or never align with clinical evidence
- 03.** 1 out of every 5 prescriptions are impacted with PAs and formulary restrictions, the most common forms of UM encountered

Impact of Drug Utilization Management of HCPs



Source: PLOS ONE¹⁸

Percentage of providers

34%

Medical practices reported that PA requirements stayed the same or increased in 2021-2288

Why Life Science Companies Need A PA Strategy

A burden on healthcare providers

When it comes to drug UM, pharmaceutical brands must understand therapeutic dynamics if they want to effectively optimize market access of their brands across the lifecycle.

Many pharma companies make considerable investments in rebate programs, value-based contracting, and patient hubs for their specialty therapies. It is critical for brand teams not to overlook the potentially high-impact – and cost-effective – strategy of assisting prescribers in navigating the administrative burden of PAs. Burdensome PA processes reduce patient access and proper treatment adherence, negatively impacting health outcomes and the bottom line.

A 2016 study found that medication nonadherence costs the pharma industry an estimated \$250 billion in potential annual revenue, a 33% increase from 2012.²⁰



It's critical for brand teams to not overlook the high impact – and cost-effective – strategy of assisting prescribers in navigating the administrative burden of PAs, which leads to increased drug adherence and more favorable patient outcomes.” ~Patrick Leary, Chief Commercial Officer, Phil Inc.



Rethinking the PA approach

While some retail pharmacies assist with the PA process, most leave it up to the prescriber or patient. Typically, pharmacists and pharmacy techs manually process PA requests, which is time consuming and delays therapy initiation. This is generally consistent across specialty pharmacies as well.

Many pharmacies and healthcare systems have recently adopted electronic PA (ePA) systems. Access to an electronic solution does not necessarily have the desired impact as it still leaves a significant process for patients and HCPs to navigate, including completing required forms, albeit in a digital format.

In the face of overwhelming evidence, pharmaceutical commercialization teams should look closely at the toll PAs have (or potentially have) on their brands. Partnering with an integrated ePA solution with proven outcomes provides HCPs and pharmacies with a digitally-enabled approach to streamlining PA workflows and communications and improving patient access while maximizing brand ROI.

Why Life Science Companies Need A PA Strategy

Finding the right access solution for your brand

When evaluating access solutions, brand teams should be looking for one that:

- 01.** Has a proven track record of assisting prescribers in successfully navigating the PA process and facilitating accurate PA submissions
- 02.** Delivers a modern HCP and patient experience, tailored to the needs of HCPs and patients
- 03.** Offers a frictionless, integrated ePA process
- 04.** Allows for scalability across the brand's lifecycle
- 05.** Provides real-time visibility across the patient prescription journey with insights on patient, HCP, and payer behavior to facilitate patient access and adherence

How Phil can help

PhilRx is patient access platform that helps life sciences and pharmaceutical companies optimize their brand value by facilitating patient access to therapy. To maximize PA success our platform assists HCPs by prepopulating required forms to enable “1-click” submissions.

85% PA Submission Rate

The screenshot shows a web interface for PhilRx. At the top left is the PhilRx logo and at the top right is the text "Smarter Prescriptions https://md.phil.us/". The main heading is "A prior authorization is ready for submission". Below this, it says "Date of request: 12/09/2020, 15:00 PST" and "Please login to CoverMyMeds to submit the PA before the form expires." There is a table with two columns: "Patient Name: Amy Rodriguez" and "Prescription". The "Patient Name" column contains "DOB: 03/25/1980", "Provider Name: BETH AARHUS", and "NPI: 1508832221". The "Prescription" column contains "CINFLXOZICE 100MG TAB ER", "24H QTY: 38", "Refills: 6", and "CoverMyMeds Key: 735325". Below the table is a "Message from Phil Team:" section with the text: "Hello! Our mutual patient's prescription Cinfloxize requires a PA. We've completed the PA and it is ready for submission. Please log in to your CoverMyMeds account and press the orange 'Submit to Plan' button using the key: 735325. We will be notified of the decision."

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