Should All Drugs Be Treated Equally When It Comes to Utilization Management?

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Executive Summary

Prescription drug utilization management programs such as step therapy and prior authorization are important clinical tools to help ensure that patients receive medications that are safe and effective for their condition, limit off-label use of drugs, promote adherence to guidelines when they are available, and reduce costs. However, the use of step therapy and prior authorization can present a significant barrier to care for patients. This paper looks at the potential for unintended consequences of programs such as these.

Key findings include:

- Early treatment is vital in both multiple sclerosis and rheumatoid arthritis to prevent disease progression and disability, and prior authorization and step therapy can delay access to important treatment options for patients.
- Plan sponsors indicate that member dissatisfaction, delayed treatment for patients, and physician complaints and dissatisfaction are the top challenges of prior authorization and step therapy programs for multiple sclerosis and rheumatoid arthritis.
- Plan sponsors should consider whether their utilization management programs are aligned with their goals.

Introduction

Prior authorization is an administrative requirement a physician must obtain from the insurer to ensure the cost of a prescribed drug will be reimbursed. Prior authorization may require physician documentation that the patient has the FDA-approved indication and, in some cases, meets even narrower requirements. When used appropriately, prior authorization is an important clinical tool that helps ensure patients receive medications that are safe and effective for their condition, limits off-label use of drugs, and promotes adherence to available guidelines. However, prior authorization may present a barrier to care for patients.

Often used in conjunction with prior authorization, step therapy can help control costs and improve patient safety by requiring the use of one or more first-line therapies, or "steps," for a given condition. The patient will only move to a higher-line therapeutic alternative if they do not respond or if they experience adverse drug effects.[1] This approach was initially used for traditional oral solids used to treat common chronic conditions such as hypertension, gastroesophageal reflux disease (GERD), and high cholesterol, and the strategy gained popularity as pharmacy benefit managers (PBMs) touted cost savings.[2] In some cases, step-therapy policies seemed to meet their intended objectives, such as when multiple agents within a therapeutic class were perceived as clinically similar, with the only differentiator being cost. In these instances, patients were asked to first try a generic before being prescribed a brand name drug in the same class.

Today, prior authorization and step therapy programs have extended beyond their original use. They are now commonly used for both traditional and specialty drugs, addressing complex diseases such as cancer, multiple sclerosis, and rheumatoid arthritis. The extension of prior authorization and step therapy in the treatment of serious, specialty-drug treated conditions has led groups like the Community Oncology Alliance (COA) to formally oppose the use of "first fail" step therapy for patients with cancer and other serious diseases because it puts the health of patients in jeopardy by delaying treatment with the physician-preferred, first-therapy choice.[3]

This work aims to provide insights into current step therapy and prior authorization programs for members using medications to treat multiple sclerosis and rheumatoid arthritis. We also highlight the findings of a national survey on attitudes toward the cost, clinical value, and overall outcomes of prior authorization and step therapy programs.

Why focus on specialty drugs?

Specialty drugs present one of the most significant concerns for plan sponsors. Not only are specialty drugs expensive and growing rapidly as a share of total drug spend, but patients who use them typically require complex clinical management. Today, advances in drug therapy allow many patients with conditions treated by specialty drugs to live decades longer than in the past. Recent research from the Pharmacy Benefit Management Institute (PBMI) showed that in 2018, 95 percent of self-insured

employers used prior authorization and 86 percent used step therapy for specialty medications covered under the pharmacy benefit.[4]

Prior authorization and step therapy can have unintended consequences. Even a decade ago, research on step therapy programs for antihypertensives showed that there were unintended consequences created by step therapy, including reduced adherence, medication discontinuation, increased hospital admissions, and emergency visits. Also, after a short-term decline in spending, these approaches may ultimately result in higher total health costs.[5] Given the complex and progressive nature of many diseases treated with specialty drugs, these unintended consequences may be even graver, particularly in the area of patient disease progression and disability. We examine two specific conditions to illustrate this potential.

Specialty Conditions of Focus: Multiple Sclerosis and Rheumatoid Arthritis

The impact of prior authorization and step therapy on two specific conditions are the focus of this research: multiple sclerosis and rheumatoid arthritis.

Multiple sclerosis is a chronic inflammatory and degenerative disease of the central nervous system, most often affecting the brain, the optic nerve, and the spinal cord.[6,7] Multiple sclerosis is estimated to affect approximately one million people in the United States, and women are 2.8 times more likely to be diagnosed with this condition than men.[8,9] Treatment for multiple sclerosis focuses on preserving neurological function by slowing disease progression and avoiding relapses primarily through the use of disease-modifying therapy (DMTs).[10] DMTs work by reducing the frequency and severity of acute flares and prevent the development of new brain lesions, slowing down the development of disability. Newer DMTs have shown more effective at reducing measurable disease progression,[11] and real-world studies of patients receiving early intensive treatment with DMTs showed reduced five-year disability compared to similar patients using first-line, moderate efficacy DMTs and only escalating to second- and third-line drugs as symptoms intensified.[12] Early treatment is particularly important in multiple sclerosis. According to Dr. Jonathan Calkwood, Director of the Schapiro Center for Multiple Sclerosis at the Minneapolis Clinic of Neurology, delays in treatment result in people with multiple sclerosis having more significant disabilities including accelerated brain volume loss, or as he put it “Time equals brain.” [13,14]

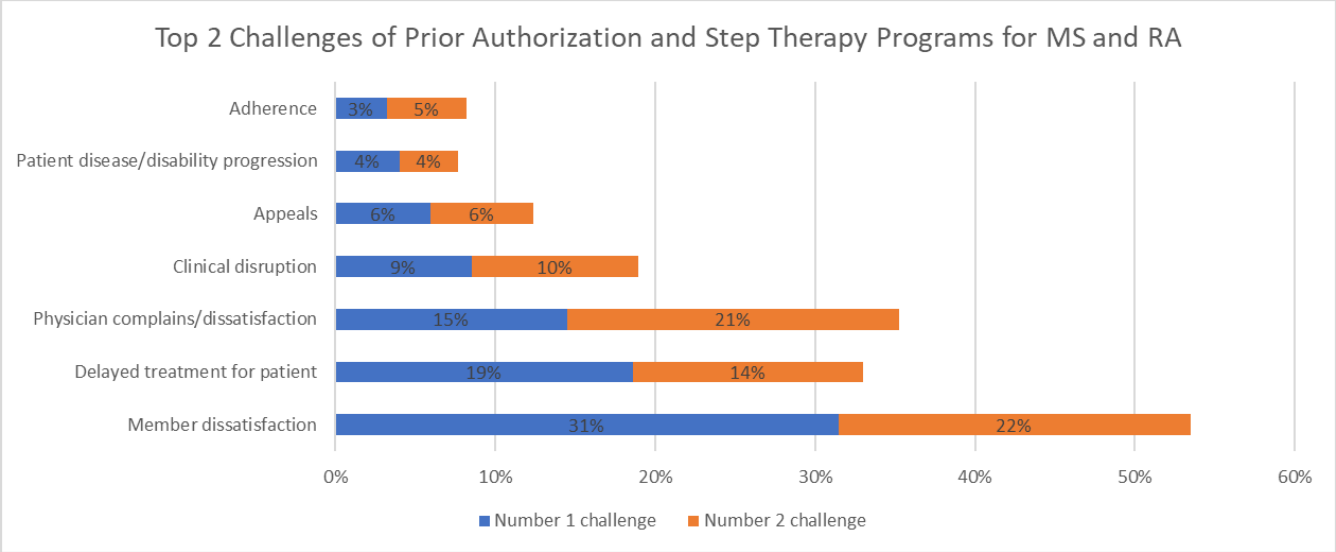
Rheumatoid arthritis is a chronic systemic autoimmune disorder in which the body's immune system attacks the joints.[15] It is the most common form of inflammatory arthritis. Rheumatoid arthritis is estimated to affect approximately 1.5 million people in the United States, and women are three times more likely to be diagnosed with this condition than men.[15] Rheumatoid arthritis costs include drug costs (primarily disease-modifying anti-rheumatic drugs, more commonly known as DMARDs such as methotrexate, analgesics, and biologics) and medical costs, including office visits and surgery to replace or repair damaged joints, improve mobility, and reduce pain. Treatment focuses on reducing inflammation, managing pain, and reducing disability. Advances in biologic therapies for rheumatoid arthritis have transformed the treatment paradigm, allowing patients to live healthier lives by slowing disease progression.

Methods

A national survey of drug benefit decision-makers was fielded in late 2018. The survey was designed to collect information on current utilization management strategies used for specialty medications, payer attitudes on the cost, clinical value, and overall outcomes of prior authorization and step therapy programs; and future strategies being considered. Descriptive and inferential statistical analyses were conducted using the Statistical Package for Social Sciences (SPSS), version 25 (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.) and the analysis tool embedded in the online survey platform (Qualtrics, Provo, UT).

Results

Of the 344 plan sponsor respondents, prior authorization is used by 88 percent and 86 percent of plan sponsors respectively for multiple sclerosis and rheumatoid arthritis. Prior authorization was generally seen as successful, with 37 percent of respondents indicating prior authorization was their most successful strategy to manage multiple sclerosis drugs, followed by step therapy where 22 percent noted this as most successful. This does not mean that prior authorization and step therapy programs do not have challenges recognized by plan sponsors. The top two challenges noted by plan sponsors with their multiple sclerosis and rheumatoid arthritis prior authorization and step therapy programs were member dissatisfaction (53 percent), followed by physician complaints/dissatisfaction (35 percent), and delayed treatment for the patient (33 percent).



Additionally, we looked at examples of prior authorization and step therapy requirements that plan sponsors had in place. For most plans, prior authorization and step therapy were used in conjunction with each other for multiple sclerosis and rheumatoid arthritis. Core components of prior authorization programs include lab results, proof of previous therapy tried, diagnosis code, duration of disease, physician specialty, and patient age. However, the criteria differed, with some plans being very restrictive, and others allowing more flexibility. An example of a plan with a restrictive prior authorization and step therapy criteria required the following conditions be met before authorization for drugs on a less advantageous formulary placement:

- Diagnosis confirmed through MRI, and
- One of the following:
    - Two disabling relapses within 12 months, or
    - Secondary progression with an observable increase in disability over six months, or
    - Loss of ability to walk for a period longer than six months, and
- Trial and failure of at least two other DMTs, and
- Results from required lab tests (CDC, liver enzymes, tuberculosis test, pregnancy test)

Restrictive prior authorization criteria like this require demonstration of disabling relapses or disease progression to occur before a patient is allowed access to medications their physician feels will be more effective for them.

Case Study: Questioning UM for Multiple Sclerosis: An Employer Putting it into Practice

One large employer group, that includes multiple sclerosis in their top three spend categories across both medical and pharmacy benefits, has taken a second look at their formulary and utilization management strategies for this category of specialty drugs.

Like most employers, they had preferred therapies for multiple sclerosis on their formulary. However, in addition to preferred therapy requirements, the employer group had in place prior authorization criteria from their PBM, that required trial and failure of preferred therapies and ONE of the following in addition to a diagnosis of relapsing/remitting multiple sclerosis:

- Two disabling relapses within 12 months
- Secondary progression with an observable increase in disability over six months
- Loss of ability to walk for a period longer than six months

After attending a drug benefit conference and listening to a session in which a neurologist and multiple sclerosis patient discussed the importance of access and timing for the right therapies, the employer took a second look at the prior authorization criteria for their members with multiple sclerosis prescribed specialty medications. They had learned that in the treatment of multiple sclerosis, time is very important. As the neurologist said, "time equals brain," and they recognized that any delays in optimal treatment could contribute to brain volume loss for their members.[14] As a result, they had the following questions for their pharmacy benefit consultant:

- Is there value in our current process?
- Are the prior authorization criteria currently in place consistent with evidence-based guidelines for the treatment of multiple sclerosis?
- Are criteria requiring trial and failure of previous multiple sclerosis therapies clinically warranted?
- Is the execution of the prior authorization process contributing to delays in treatment for our members?
- Are there medical consequences to delays in treatment for our members?

Together with their consultant, they revised the prior authorization criteria to remove any requirement of worsening disease. They felt strongly that members should have timely access to multiple sclerosis treatments to give them the best chance for optimal treatment outcomes. Ultimately, they realized that there was no evidence of long-term financial gain by delaying treatments, and restrictive prior authorization criteria risked increasing disease, and disability progression for members.

Discussion and Conclusions

PBMs and other insurers tout the value of prior authorization and step therapy for specialty drugs. However, an analysis of pilot demonstration data from Employers Health, a coalition of more than 300 private and public members, found minimal economic value to pharmacy-based step-therapy programs for specialty drugs used to treat rheumatoid arthritis and multiple sclerosis unless negotiated rebates for enrollment were substantial.[16]

A key takeaway is that time matters, and current prior authorization and step therapy policies are stealing time in several ways.

For patients, delays in receiving physician-preferred personalized treatment can result in permanent damage to brains and joints. Delays mean fewer years between disease onset and significant disability.

Patients also lose time just trying to get the treatment they need. Patients living with diseases such as multiple sclerosis and rheumatoid arthritis often spend countless hours battling insurance requirements, following up with physicians, and trying to find ways to afford the treatments they need to stay as healthy as possible. Step therapy may require them to try and fail a treatment that is preferred by the insurance plan — typically a payer-preferred drug their doctor doesn't think is right — before their benefit plan will cover the doctor-preferred drug. This can create lengthy delays, as a patient may need to try and fail multiple steps. According to a survey conducted in 2016 by the Arthritis Foundation, more than half of all patients reported having to try two or more different drugs prior to getting the one their doctor originally ordered.[17] This can mean months, or even a year, of time lost if those other drugs fail to treat their condition optimally.

Additionally, patients may lose time dealing with side effects from failed steps, which may result in lost work or school days, as well as time spent on additional healthcare utilization, such as hospital stays or additional physician office visits. Patients with rheumatoid arthritis who experience delayed or failed treatment may require surgery to repair permanent joint damage caused by unnecessary disease progression. Patients with multiple sclerosis may lose time to being unable to care for themselves and their families. Patients may also have to repeat the process if they have a change in insurance status, such as from a job change or employer-provided coverage, or when an employer switches PBM vendors.

Depending on the benefit plan, patients may have to stop a treatment that is currently working and switch to whatever agent is the first step in their new plan until they demonstrate they have failed again. Being prescribed traditional versus specialty medications for rheumatoid arthritis has also been associated with higher healthcare utilization (number of medication, number of office visits, and spending on emergency department visits).[18] Additionally, a review of the literature found no evidence that step therapy and prior authorization are associated with long-term cost savings for either condition.

Prior authorization and step therapy create challenges for physicians and their staff, as well, taking time away from direct patient care, adding costs to the delivery of care and requiring additional staff to process. In a December 2017 study from the American Medical Association (AMA), 86 percent of physicians reported that prior authorizations had increased in the prior five years,[19] and more than 90 percent of physicians reported that prior authorization had a negative effect on patient clinical outcomes, either by delaying care or causing patients to abandon treatment. The same survey found that physicians and their staff spend an average of 14.6 hours per week to complete prior authorization requirements, including 34 percent of physicians with staff to work exclusively on prior authorization. The AMA study also showed that prior authorization requirements could delay treatment, with 64 percent of physicians reporting their practices wait at least one business day for insurers to decide on a prior authorization and 30 percent reporting an average wait of at least three days.[19]

The question is: if the goal of prior authorization and step therapy is to ensure appropriate use, shouldn't physician-preferred medications be considered appropriate? Are we wasting not only time and money — but also affecting patients' health?

When considering policies around prior authorization and step therapy, plan sponsors should discuss these points with their pharmacy benefit consultant:

- Is there value to prior authorization for all specialty conditions?
- Are there conditions that should be treated differently?
- Are the criteria consistent with evidence-based guidelines?

- How are step edits and prior authorization designed? Are criteria requiring trial and failure of first line/earlier step therapies clinically warranted?
- Does the execution of the prior authorization contribute to delays in treatment?
- Are there medical consequences to delays in treatment?
- Could there be unintended medical costs associated with these utilization management techniques?

Disclosure

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