

# PolicyBrief

*Issues Affecting Health Care Coverage and Access for Women with Autoimmune Diseases and Conditions*

## How Shifts in Policy Could Result in Meaningful Change

**A**utoimmune diseases and conditions, a group of more than [80 chronic and often disabling diseases](#) that develop when the immune system mistakenly attacks the body's own healthy organs, tissues, and cells, are estimated to affect between [23.5 million](#) and [50 million](#) people in the United States—and their prevalence is rising.

Women are disproportionately affected by autoimmune diseases, representing 80 percent of patients diagnosed, though gender ratios differ among individual diseases. Autoimmune diseases and conditions are a burden; they can take a significant health and financial toll on the individual affected, and they weigh heavily upon the U.S. public health care system, with treatment costs estimated to be greater than [\\$100 billion annually](#).

The burden of autoimmune diseases and conditions can be exacerbated by coverage and access policies that lead to delays in care and disease progression. Since no cure for autoimmune diseases exists, treatment centers on managing symptoms and slowing the progression and impacts of the disease. Ensuring that patients have access to effective treatments in a timely manner is essential for improving health outcomes and quality of life.

## Issue Overview

The National Pharmaceutical Council's (NPC) 2022 [The Myth of Average](#) report revealed that “a patient's coverage for a prescribed medication is likely to vary substantially based on their insurer,” with variation in the consistency, volume, and types of evidence cited by major commercial payers in their coverage policies.

The document herein explains how certain coverage and access issues can impact women with autoimmune diseases and conditions and poses recommendations about how they could be altered to improve outcomes.

### KEY MESSAGES

- For women with autoimmune diseases, receiving timely and effective treatment has critical implications for health outcomes—namely slowing the progression of the disease and preventing hospitalization, disability, or death.
- Each barrier to coverage—whether from a prior authorization, step therapy, or non-medical switching policy or using a co-pay adjustment program—can result in irreversible, adverse health outcomes for patients across the lifespan.
- Certain coverage policies, such as prior authorization, are an administrative burden for health care providers and can impede their ability to provide recommended care to patients.
- Putting commonsense guardrails around insurance policies can support patients' short-and long-term health and well-being

## Utilization Management Strategies

Utilization management (UM), sometimes called utilization review, is [defined as](#) “the evaluation of the medical necessity, appropriateness, and efficiency of the use of health care services, procedures, and facilities under the provisions of the applicable health benefits plan.” While UM tools are intended to control the costs and risks associated with prescription medicines, they can be particularly problematic for autoimmune patients.

Prior authorization (PA) and step therapy are two types of UM that can cause unnecessary burden to patients and providers.

### Prior Authorization

Prior authorization (PA) is a process used by some health insurance companies that requires the review and approval of a specific procedure, service, or drug before it is prescribed. While advertised as a cost-saving measure by insurers, PA can have far-ranging effects, resulting in administrative burden for physician practices, delays in patient care, and impacts on patients’ workplace productivity.

When it comes to physicians’ practices, a [2021 American Medical Association](#) physician survey about PA found that 88% of physicians describe the burden associated with PA as high or extremely high. Specifically, physicians and their staff spend an average of 13 hours (almost two business days) completing PA requests, and two in five physicians have staff who work exclusively on PA. This administrative burden can impact patient care and outcomes. Within the survey:

- ▶ 93% of physicians reported care delays while waiting for PA approval
- ▶ 91% of physicians reported that PA has a somewhat or significant negative impact on clinical outcomes.
- ▶ 82% of physicians report that PA can lead to treatment abandonment

A November 2021 study in [Arthritis Care & Research](#) about infused medications—many of which are biologics used to treat disease, including rheumatoid arthritis and systemic lupus erythematosus (SLE)—found that “the downstream detrimental effects of PA denials are often imposed on patients with rare diseases and

other conditions for which the treatment options are limited.” These effects can include delays in effective treatment and unnecessary glucocorticoid exposure, highlighting the damages that patients may incur as a result of PA policies.

According to a [2021 KFF issue brief](#), 99% of Medicare Advantage enrollees are in plans that require PA for certain services.

### Step Therapy

Step therapy, or “fail first,” is a policy implemented by an insurance company that requires a patient to try and “fail” a lower-cost treatment before the patient can access the treatment originally prescribed or recommended by their physician.

For autoimmune patients, the delay that can result in being able to access the medications prescribed by their doctor can lead to irreversible adverse reactions. These patients already face a [years-long battle](#) in receiving their diagnosis and subsequently finding a treatment that works, so the value of time cannot be overlooked. According to a 2018 article in [Health Affairs](#), roughly one in four coverage decisions in specialty drug and evidence coverage includes a step therapy protocol.

Beyond the delays step therapy can create for patients to accessing effective care, step therapy can also impact medication effectiveness and other health care outcomes. A 2019 [PharmacoEconomics](#) study that examined treatment outcomes of people with rheumatoid arthritis (RA) and psoriatic arthritis (PsA)—two types of immune-mediated inflammatory diseases—found that there was a 27% reduced medical adherence for PsA patients whose plans had step therapy requirements, and the likelihood of treatment effectiveness was 25% lower. RA patient plans that required step therapy had 17% lower odds of treatment effectiveness and 18% lower medication adherence. Further, RA patients with restricted access plans were three times as likely to be admitted to the hospital because of an infection and almost two times as likely to visit the emergency room during the study period. Similar to PA, more people whose plans included access restrictions filled prescriptions for glucocorticoids and nonsteroidal anti-inflammatories than those without access restrictions, potentially pointing to poorly managed disease.

## Non-Medical Switching

Non-medical switching—a cost containment strategy used by health insurance companies—occurs when insurers force patients to switch from their current medication to another drug for reasons unrelated to the patient’s health (e.g., eliminating coverage of certain medications, increasing patients’ out-of-pocket requirements).

A 2015 analysis in [Value of Health](#) found that among RA, PsA, psoriasis, ankylosing spondylitis, and Crohn’s disease patients who switched from adalimumab (ADA) to another injectable biologic “following a payer formulary change and for no apparent medical reason” incurred significantly higher all-cause medical costs and total costs during follow up. Further, a systemic review in the [Journal of Market Access & Health Policy](#) found that non-medical switching among ambulatory patients “was associated with mainly negative effects on clinical outcomes in patients with stable/well-controlled disease.”

## Co-pay Accumulators

Accumulator adjustment programs prevent any co-payment assistance for high-cost specialty drugs from



being counted toward a patient’s deductible or out-of-pocket maximum. When patients who are unaware they are enrolled in these programs learn they have to pay the full cost of their medication, it may result in them abandoning or delaying their prescription. A [2019 study](#) found that after the implementation of a co-pay accumulator adjustment program, patients with health savings accounts who are on autoimmune drugs had significantly lower monthly fill rates, higher risk of discontinuation, and lower proportion of days covered.

## Recommendations

Putting guardrails around the coverage and access challenges described above could lead to better health outcomes for women living with autoimmune and immune-mediated diseases and conditions. Policies should:

- ▶ Ensure that patients who switch insurance plans do not have to “fail” the same drug twice
- ▶ Ensure an expedited, standardized appeals process is in place so patients don’t have to wait 30 days for health plans to respond and establish an electronic PA system with the ability to provide real-time decisions in response to requests for items and services that are routinely approved
- ▶ Prevent health plans from reducing coverage for a patient’s active medication for the duration of that patient’s coverage under their chosen health plan
- ▶ Ensure transparency from insurance companies to patients as to why they may be required to go through the prior authorization process multiple times
- ▶ Develop an exception to medication step therapy protocol in certain cases, such as when a required treatment has been deemed ineffective

Legislation, including the Safe Step Act (H.R. 2163, S. 464) and the Improving Seniors’ Timely Access to Care Act of 2021 (H.R. 8487, S. 3018), have been introduced that will address some of these issues.