

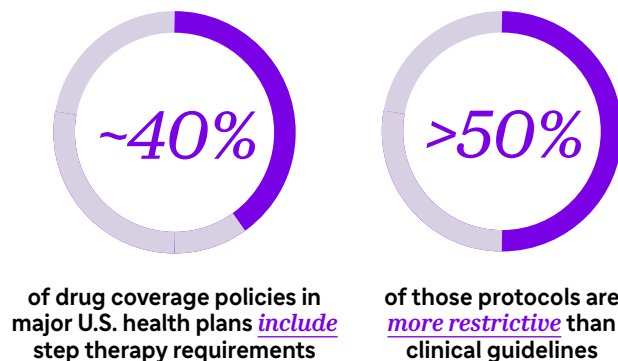
Step Therapy: *How “Fail First” Can Fail Patients*

Starting on a new treatment should be simple: follow the plan a doctor recommends. In practice, patients are often required to try other therapies first, delaying access to the prescribed option.

Step therapy, often called “fail first” therapy, is a practice used by health insurers and pharmacy benefit managers (PBMs) that requires patients to try one or more “preferred” lower-cost medications before access is granted for the treatment originally prescribed by their doctor.

In some cases, step therapy has a clear clinical role, such as generic-first step therapy programs intended to promote the use of clinically equivalent medicines at a lower cost.

However, the use of step therapy has expanded significantly in recent years. In some instances, this expansion is tied to financial incentives, including rebates for PBMs, and can increase patient costs. As a result, this has raised concerns that utilization management policies are *overriding evidence-based treatment decisions and individualized patient care*.



While patients and physicians can request an exception or file an appeal regarding a step therapy requirement – and are often successful – only a small fraction of patients ever appeal.

A Guide to Access Barriers: Key Terms You Need to Know

Utilization management (UM):

Tools used by health insurers and pharmacy benefit managers to evaluate the medical necessity, appropriateness, and efficiency of healthcare services, procedures, and medication.

Prior authorization:

A class of UM requirements in which insured patients must obtain payer approval before being able to access the healthcare service or medication.

[Read more here.](#)

Step therapy:

A requirement applied by insurers or PBMs that mandates an insured patient to try a preferred, lower-cost medicine before a patient can access the treatment initially prescribed by their physician.

Specialty medicine:

Highly complex and often requiring special handling, these therapies are not available at traditional retail pharmacies and must instead be dispensed through specialty pharmacies. [Read more here.](#)

The People Impacted *by Step Therapy*

Behind every step therapy protocol is a person. Every day that person spends waiting for a decision or appeal can mean additional discomfort or uncertainty that may have been avoidable.

While these policies are often designed to manage costs, the experience can feel very different on the patient side. **But to someone’s parents, partners, family, and friends, the delay feels cruel and indefensible, often negatively impacting areas of their lives outside of care, such as missed school/work days and mental health challenges.**

For...



Adults and Children Living with Chronic, Progressive, Rare or Complex Diseases



Patients Changing Health Plans



Medically Underserved Patients



Healthcare Providers



Clinical Teams & Healthcare Administrators

Step Therapy can...

Disrupt timely access and upend medical treatment plans. Delays caused by step therapy can result in disease progression or avoidable side effects, often leading to emergency care or the abandoning of treatment. Such delays or forced medication switches upend continuity of care and jeopardize treatment stability.

Force patients to start over. Patients who are stable on an existing therapy may be forced to restart step therapy from scratch when switching insurers or formularies — for no medical reason. This disrupts continuity of care and puts treatment stability at risk.

Add undue costs and barriers to care. Burdens associated with utilization management disproportionately affect vulnerable patients, including individuals with limited health literacy, patients with chronic illnesses, and those lacking the time or resources to navigate complicated health insurance or PBM processes.

Rob physicians and patients of choice. Providers have raised concerns that step therapy protocols frequently fail to account for the individualized clinical judgment of treating physicians, who are most familiar with a patient’s medical history and unique healthcare needs. In practice, rigid insurer or PBM-driven protocols can substitute administrative requirements for patient-specific medical decision-making.

Create a mountain of costly paperwork. Step therapy contributes substantially to healthcare administrative burden, as physicians – including specialists – and clinical staff often spend significant, uncompensated time navigating utilization management requirements that could otherwise be devoted to direct patient care. Such diversions lead to worse outcomes, longer waiting lists, and less time between doctors and patients.

Addressing Step Therapy *Requires Targeted Reforms*

Reasonable reforms are needed to restore patient-centered care and ensure step therapy does not cause avoidable delays to care.



Build a set of exemptions to step therapy:

Require exceptions to step therapy protocols for patients who are stable on their current therapy, have previously failed required treatments, have documented contraindications, or are being treated for serious or complex conditions.



Standardize the step therapy exceptions process:

Establish a clear, transparent, and standardized exceptions process with uniform response timelines with the goal of minimizing delays to care.



End the repeating cycle for patients:

Prohibit insurers and PBMs from requiring patients to repeat step therapy protocols they have already completed under a different health plan or from imposing step therapy protocols that extend beyond a clinically appropriate period.



Ensure transparency from insurers and PBMs:

Require public reporting on the use of step therapy protocols by therapeutic area, including data on the required steps before granting access to a prescribed drug, and the percentage of patients required to fail first on a drug.

Step therapy should support clinically appropriate, patient-centered care — not create unnecessary barriers that delay treatment, undermine physician judgment and place patients at risk of avoidable harm.