

Is Health Insurance Health Assurance? An Investigation into the Effects of Step Therapy

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AUTHOR BIO

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ABSTRACT

This paper explores Step Therapy (ST) in the U.S. healthcare system, an insurance policy requiring patients to try specific medications before accessing potentially more effective, costlier treatments. It discusses how this approach, aimed at cost control, affects patient care and physician-patient relationships, highlighting concerns about limited access to necessary medications and health complications. The work essentially emphasizes the need to understand step therapy's pros and cons that can inform potential legislative changes addressing its unintended effects.

THE ROLE OF STEP THERAPY IN HEALTHCARE

The essence of ST, or step edits, boils down to its aims of curbing costs on expensive drugs. As a type of insurance protocol, it does this by requiring patients to try a less expensive, often generic, alternative treatment before coverage of a more expensive treatment is authorized. Step therapy is used by both public and major private insurers to curb costs for expensive drugs, and its presence continues to rise in health care: in an analysis led by researchers at Tufts University, step therapy protocols were tracked across 17 insurers, and over 38.9% of coverage policies deployed step edit protocols (Lenahan et al., 2021).

There are multiple facets of rationale behind its popular implementation. One of the main reasons it is especially valued in the US healthcare system is because of the absence of negotiation for better prices with drug manufacturers. Unlike other countries, who negotiate drug prices by threatening non-coverage and subsequently the threat of discouraging consumer demand, the system in the US gives complete control over drug prices to the manufacturers. Insurers are only required to cover a select few “medically necessary” therapies, which lead to higher out-of-pocket tolls for patients using uncovered drugs.

For insurance companies, ST is designed as a tool for negotiating pricing; it is one of the few ways to help keep pharmaceutical prices in check. Insurance companies tier drugs in a formulary, or preferred drug list, where preferred drugs (often generics) are placed on lower tiers and require less patient monetary contribution relative to more expensive therapies, which are tiered higher (What is step therapy?, 2023). By requiring patients to use a less expensive formulation of a common drug

before trying newer or more expensive versions, ST reduces demand for the higher tier drugs and helps patients and their insurers avoid exploitation by pharmaceutical companies (Hirsch, 2018).

Another aspect of ST’s popular implementation is the consideration for care quality. In other words, what drugs will be most effective for a patient after taking into consideration economical burden? The responsibility to practice cost-effective treatment has been a more recent phenomenon; this duty was only incorporated in the ACP Ethics Manual starting 2012, in its 6th edition. The most recent edition (the 7th) of the ACP Ethics Manual has revised policies for cost effective treatment, specifically stating that insurance companies may take into account the cost-effectiveness of different treatments (Santoro, 2019). In this regard, both doctors and insurers follow the same ethical mandate to make treatment plan decisions keeping both scientific knowledge and cost-effectiveness in mind—which is why there is an extensive, integrated patient care process in the prescription of drugs, referred to as formulary management. Its primary purpose is to encourage the use of affordable and beneficial medications, and it is supported by evidence-based medicine as well the experience of experts in the field (AMCP, n.d.). A big part of formulary management is to carefully apply step therapy protocols when necessary, in order to maintain a standard of patient care without ethically imposing on a patient’s financial status.

When considering the step edit implementation as a whole, it is important to note a fine line between patient and insurer benefit from step therapy in terms of a monetary perspective. While it is true that step therapy was designed to control costs of drugs, its implementation does not necessarily mean

savings for the patient. For example, insurance companies can use step therapy as an intervention to reduce accessibility to expensive drugs, at the sole benefit of the insurer.

Having provided a substantial background on the reasoning behind the practice, the following sections of the paper will investigate the various effects of step therapy, often in a clinical setting, in detail.

THE ADVANTAGES OF STEP THERAPY

As per its original purpose, step therapy is an effective and popular way to cut costs on drugs for drugs. In a study of fourteen evaluations of step therapy programs over five therapy classes — antidepressants, antihypertensives, antipsychotics, nonsteroidal anti-inflammatory drugs (NSAIDs), and proton pump inhibitors (PPIs)—the research demonstrated consistent and statistically significant drug cost savings for all drug classes except for the antipsychotics (Motheral, 2011). Additionally, the five studies that were examined for effects of step therapy on higher disease-related spending found no statistically significant higher outpatient expenditures. The study supported the idea of significant drug savings through ST programs, through greater use of lower-cost medications.

In a separate study, step therapy programs were deployed in the workplace. For reference, employers with 50+ full-time employees are required to provide health insurance to 95% of their full-time employees under the ACA Rules on Employer-Sponsored Health Insurance (Sachi, 2023). This study was designed to examine ST's effect on plan-sponsor savings. For a decrease of 0.83 dollars per-member-per-month in net cost after implementing step therapy, the program produced significant drug savings (Motheral, 2011). It acknowledged the idea that, with step

therapy, healthcare can be easier to afford and properly implement within the workplace.

Step therapy programs have also risen in application outside of commercial businesses: formulary management of Medicare Part B for Medicare Advantage plans recently changed to implement ST programs. This implementation of ST in Medicare Advantage lowered costs and improved the quality of care for Medicare beneficiaries (Federal Register, 2018). Previous Centers for Medicare & Medicaid Services (CMS) guidelines prohibited step therapy; consequently, Medicare Advantage plans were not very successful in negotiating better value therapies for patients. By overruling this decision, the new negotiations helped decrease Average Sales Price for Part B drugs, and helped decrease copayments (CMS, 2018). Overall, step therapy programs have been strongly supported in managing cost efficiency for treatments, contributing to their recognition in various forms of US healthcare.

THE DISADVANTAGES OF STEP THERAPY

Despite its main purpose, there have been studies that show that step therapy can actually create more economic burden than relief. When patients are forced to follow step therapy protocols, they can undergo rounds of various medications before they receive a successful treatment, which is largely unnecessary for the patients with certain diseases that tend to do better with the more expensive medications (Mott, 2022). Patients then pay for several medications that are not the most effective for their condition, leading to higher out-of-pocket expenses. With multiple trials of treatment, the economic burden of step therapy becomes evident; extra trials result in delays in receiving the necessary treatments, excess medications, and a prolonged disease duration that all contribute to increased medical

costs (Mott, 2022). In some cases, patients may not be able to afford the additional medications and decide to forgo treatment altogether to avoid the costs, which is neither beneficial to the patient in the short-term or long-term.

Some general ST medications can actually cause side effects and adverse reactions when medications that are not appropriate for specific patient conditions are applied. Similarly, this will not only increase payments for patients to address the new complications, but calls attention to the ethics of step therapy in regards to protecting patient health. Cases like these highlight the need for insurance policies to consider the medical needs of patients.

As a comparison point for the quality of clinical decisions, Clinical Practice Guidelines (CPGs) are generally considered the standard (Woolf et al., 1999). CPGs are made by authoritative physician groups to incorporate competing demands of evidence-based and cost-effective medicine (Santoro, 2019). However, the potential for physician specialty bias allows insurers the control over how much of ST policies would mirror CPGs (Santoro, 2019). This is why, in a study conducted at Tufts Medical Center, there were less than half of cases (34.1%) where ST protocols matched clinical guidelines (Zimmerman, 2023). Additionally, more than half of cases (55.6%) applied ST protocols that were more stringent than clinical guidelines (Minemyer, 2021). Insurers reprioritize costs in instances where CPGs' policies may result in decrease in cost effectiveness.

Furthermore, this becomes a major issue when different insurers create different step therapy policies based on their own reasoning and priorities. There is dramatic variation between plans (nearly 40% as indicated in one study), even for the same condition

(Zimmerman, 2023); this can make moving insurers and/or changing plans disruptive for a patient who has tried one or more step therapies. Most often, inconsistencies across plans means a loss of eligibility for a therapy under the new plan and requirements of completing the new plan's step therapy protocol to regain access (Minemyer, 2021). In these cases, patients may need to connect with their physician and get prior authorization, or a step therapy exception, to continue coverage for an efficient drug therapy. However, with any exception approval process, physicians waste valuable time that could be otherwise allocated to direct patient care.

This brings into perspective the most serious of the flaws of step therapy—disruption to patient care. Its policies can be contradictory to those of a more knowledgeable healthcare provider. In other words, step therapy often requires patients to go through a series of treatment failures before gaining access to the medication that their healthcare provider believes to be the most effective and appropriate for their condition. There have been multiple cases in which step therapy strategies have no supporting clinical evidence or patient outcomes. For example, in the consideration of some anti-TNFs, a category of anti-inflammatory drugs used to treat rheumatoid arthritis, policies required specific drugs to fail before the tried-and-proven vedolizumab or ustekinumab (Bhat et al., 2017). There were no clinical studies that indicated that other anti-inflammatory drugs needed to be tried and proved unsuccessful before considering anti-TNFs. This resulted in delays in receiving optimal treatment—leading to prolonged suffering, disease progression, and increased healthcare costs (Bhat et al., 2017). Likewise, In a study of patients with psoriatic arthritis, patients under step therapy restrictions had 25% lower odds of treatment effectiveness.

Additionally, significantly more patients filled prescriptions for anti-inflammatory drugs, which is an indication of poorly managed disease; implying that there is a need to better align step therapy protocols with clinical practice guidelines published by medical professionals (Boytsov et al., 2019). For certain step edits, such as those for psoriasis, protocols were more stringent than clinical treatment guidelines over 95% of the time (Lenahan et al., 2021). For those with rare diseases, insurance policies often do not consider the unique needs and circumstances of individual patients and further alienates patients from the medical expertise and clinical judgment of healthcare providers. These patients more often than not require expensive, uncommonly used medications to treat their specific conditions, and the nature of step therapy can delay their access to the necessary treatments. For cancer specifically, the individualized nature of modern cancer treatment becomes especially incompatible with ST protocols (Santoro, 2019). Chris Hansen, president of the American Cancer Society Cancer Action Network, stresses dissatisfaction with the extra hurdles step therapy can create, as patients are forced to try multiple therapies before accessing the one initially prescribed by their doctor; patients who are living with chronic illness are subject to relatively more severe complications when health plan preferred medications are ineffective (Santoro, 2019).

When insurance policies are medically uninformed, relying solely on cost considerations rather than evidence-based medicine or personalized treatment plans, the options and autonomy of doctors in making the best decisions for their patients' health become limited. Switching medications or undergoing unnecessary treatment changes due to insurance requirements can further disrupt the patient-provider relationship as it can lead to confusion, frustration, and reduced trust of the

patient in the healthcare system (Hagland, 2006). It is crucial for health insurance policies to carefully consider the medical appropriateness and patient-centeredness of step therapy protocols to minimize disruptions to patient care and ensure that treatment decisions are based on sound medical principles.

Last but not least, step therapy can be discriminatory against certain demographics. Demographic differences in step therapy can arise from geographic variation: protocols can vary greatly by state, with some states having more lenient policies and others having more restrictive policies. This can create a situation where patients with the same condition living in different states may have vastly different experiences accessing drugs with the same effectiveness. Different US states have different step therapy policies—some are based more strictly on medical criteria and expert guidelines and have a framework for exempting patients from step therapy if needed, but not all (NORD, 2023).

CONCLUSION AND IMPROVEMENTS ON STEP THERAPY

While there are both benefits and pitfalls of implementing step therapy, it is unique to the expensive US healthcare system. It can curve costs, but it can also be restrictive in access based on ability of pay and disruptive in the relationship between patients and physicians. These findings have strongly suggested and incited action for state and federal legislative initiatives to help ensure appropriate prescription drug use. Policy-makers and insurance companies are currently considering these disparities and are working towards creating more equitable and accessible healthcare for all individuals, regardless of their socioeconomic status or geographic location (Bhat et al., 2017). By doing so, they are helping to ensure that step therapy protocols are used appropriately and not

as a barrier to the necessary and effective healthcare.

As of January 2023, 30% of states have yet to enact step therapy protection laws. However, a majority of states have, and the success at the state level has led to increased pressure on federal support. Proposed federal legislation, with bipartisan support, called the Safe Step Act would create more transparency about ST plans and would cover more patients—especially for those employed with health insurance plans (Zimmerman, 2023). This act will make amends to the Employee Retirement Income Security Act (ERISA), where it will require group health plans to provide an exception process for any medication step therapy protocol. It establishes a clear exemption process, and outlines five exceptions, which include issues addressed in section 3 of this review. These five exceptions are: 1. Failure of the required drug, 2. Delayed treatment, 3. A contraindication of the required drug, 4. Prevention of participation of their Activities of Daily Living (ADLs), and 5. Stability on their current medication (Step Therapy, 2022). Legislation like this would make the exception process for patients and physicians more efficient. By continually refining ST protocols while considering patient perspectives, the balance between cost containment and patient-centered care will continue to improve; ensuring that treatment decisions are based on both the best available evidence and individual patient needs.

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