In 2016, five states enacted legislation designed to mitigate a controversial health insurance procedure known as step therapy, which requires patients to try less expensive, often generic medications before being approved for costlier treatments. With the growing availability of generics step therapy, alongside prior authorization and benefit tiers, has emerged as a popular cost savings tool for private insurers, as well as Medicaid and Medicare programs.

Insurance companies and pharmacy benefit managers tout the policy as an important tool for controlling the rising costs associated with covering prescriptions medications, which in some cases can be over $2000 per dose. Step therapy is not without its critics, however. A growing cohort of patients, healthcare providers, as well as many state lawmakers, have been pushing back and often cite cases in which patients have reported worsening conditions while being forced to ‘step through’ a series of ineffective treatments.

In total, 18 states have enacted some form of step therapy reform, while three others – New York, Ohio, and Rhode Island – have legislation pending approval.
Step therapy is a complex issue and involves important ethical questions about the relationship between doctors and their patients, as well as questions about how to appropriately weigh the health benefits for patients receiving certain treatments against the costs of covering expensive medications. Rising prescription drug prices continue to exert upward pressure on healthcare costs, while pharmaceutical companies continue benefit from patent protections which, according to many observers, often enable them to charge excessive prices for newly developed drugs.

On the one hand, step therapy protocols provide insurers with a way to bargain down drug costs and save money by shepherding patients onto cheaper generics. On the other, patients have testified that they experienced worsening conditions after having to try and fail on medications that were ineffective. Their physicians have also complained about the excessive paper work and unnecessary red tape involved with adhering to step therapy protocols and having certain medications approved for their patients.

This research brief is based on thorough review of existing research on step therapy and its consequences, alongside in-depth interviews with academics, providers, America's Health Insurance Providers (AHIP), and policy directors at several patient advocacy groups.

**Step Therapy as a Cost Saving Tool**

A good place to start a discussion of step therapy is the formulary process, whereby insurers, under the advice of review board comprised of physicians and pharmacists, create approved lists of medications that they agree to cover. These lists are tiered so that cheaper medications require lower levels of copayments, while more expensive medications require higher copays and thus more cost sharing on the part of the patient. This system encourages patients to opt for cheaper alternatives. In cases where the alternative is as effective as a more expensive treatment, step therapy protocols can help both patients and insurers save money.

In order to be approved for certain medications on a formulary, insurers sometimes require step therapy protocols to be followed. This requires a patient to try lower tiered treatments before the insurer will approve higher tiered, more expensive medications. In some cases, these higher tiered treatments are also newer and less studied than lower tiered treatments.

Insures argue that step therapy protocols prevent physicians from needlessly prescribing more expensive treatments when a less expensive alternatives would be equally as effective. They also argue that by having patients adhere to the formularies, the insurer’s review boards provide a valuable oversight process, helping to ensure that patients are prescribed the safest, most appropriate treatments for their conditions.

According to Leanne Gassaway, Senior Vice President of State Affairs at AHIP, “Step therapy encourages physicians and patients to undertake a more evidence-based approach to treatment. When you tailor a plan to the patient, you can gauge the patient’s response to medications before graduating to the more potent and higher-risk drugs.”

The use of prior authorization protocols and step therapy policies also serve as an important bargaining tool for insurers when they negotiate drug prices with pharmaceutical companies. As Emory University health economist David Howard argues, by steering patients towards the use of
cheaper generic treatments, insurers provide an incentive for pharmaceutical companies to offer certain drugs at a lower price than they would without competition from generics.

What the Research Shows

Research on step therapy, both as a cost savings tool and its impact on patient care, is relatively sparse. The wide array of conditions that step therapy protocols impact, which range from psychiatric conditions to skin diseases, makes drawing broad conclusions about the policy difficult. The research done to date suggests that step therapy procedures, while often shown to reduce the costs involved with covering prescription drugs, also have the potential to result in unintended consequences.

Research [9] looking at how step therapy protocols impacted Medicaid prescriptions for bipolar patients in Maine found a nontrivial cost reduction with certain medications. The savings, however, were found to be due in large part to patients stopping treatments altogether, as opposed to their having switched to cheaper medications.

A study [10] of Medicaid patients being treated for schizophrenia in Georgia found that while step therapy protocols resulted in a reduction in prescription costs, the savings was associated with an increased demand for outpatient care. The net effect of implementing step therapy protocols on Georgia’s schizophrenic population covered under Medicaid was found to be an increase in total monthly treatment costs for the patient group.

An industry sponsored study [11] of patients on private insurance plans who were receiving antihypertensive medications under step-therapy protocols found an initial 3.1% reduction in medication costs, which grew larger in subsequent quarters. However, the initial cost reductions were coupled with an increase in inpatient and emergency room care among the group subject to step therapy. This was found to result in a $99 increase in quarterly total care costs compared with the control group. (It should be noted that the methodology employed in this study, as well as the results, have been subject to criticism [12]).

Drawing inferences from the research published to date is difficult due to the nature of the topic being investigated, the limited amount of studies to evaluate, and the focus on only two classes of medications: antipsychotics and antihypertensives. Additional research on how step therapy impacts people suffering from other conditions such as psoriasis and rheumatoid arthritis could be valuable, as well as how step therapies impact patients who are prescribed biologics.

The research discussed above does however offer some evidence that step therapy protocols may result in unintended consequences, where a simple rule is imposed to govern a complex system, resulting in a variety of undesired effects. The research suggests that patients may get discouraged and stop taking medications altogether, as opposed to switching to lower cost treatments, and also may require other forms of care due to having their medications altered under step therapy protocols. Additional research could provide a more conclusive picture of how step therapy impacts patients.

The Perspective of Patients and Providers

Patients have expressed frustration that their insurance plans require that they try and fail on medications that prove to be ineffective and, in some cases, force them to switch from effective treatments to less effective alternatives. One area of particular concern involves patients who, after
switching health insurance companies, were forced to restart the step therapy process and fail on medications that they had already tried unsuccessfully.

Many patients impacted by step therapy protocols also suffer from conditions that can be effectively managed with biologic treatments, which are genetically engineered proteins derived from human genes. Biologics have proved to be particularly effective for psoriasis, rheumatoid arthritis, and other chronic inflammatory conditions.

Biologics are not cheap however, and many health insurance policies have refused to pay for them until patients try and fail on less expensive alternatives. As a result, some of the most vocal critics of step therapy have been patient groups such as the Arthritis Foundation, the Lupus Foundation of America, and the National Psoriasis Foundation.

“Step therapy protocols add to the burden of psoriasis by erecting barriers for individuals in urgent need of treatment. Failing to consider the unique needs and preferences of individual patients, and imposing a one-size-fits-all approach to care, these protocols negatively impact patients quality of life and can result in detrimental effects on health”, According to Patrick Stone, Director of State Government Relations at the National Psoriasis Foundation.

Physicians and other healthcare providers have also voiced concern about how step therapy policies have encroached on their ability to effectively treat patients. Provider groups such as the American Academy of Dermatology and the American College of Rheumatology have lobbied state legislatures extensively to pass step therapy reforms. Physicians frequently cite the frustration of having patients fail on treatments that they believed initially to ineffective, as well as the time-consuming paperwork required to help their patients obtain the medications they need.

As Sacramento-based dermatologist Margaret Parsons notes, “It’s frustrating to be forced to delay the care of a patient due not only to the time involved with the authorization process but also when, after doing the steps, you finally get to the treatment you had wanted to start the patient’s care with in the beginning of the process”.

### Legislation Regarding Step Therapy

Most of the step therapy laws enacted to date allow for exceptions to be granted under certain conditions such as: when a patient has been stable on their current treatment, the preferred treatment under step-therapy protocols is believed by their physician to be ineffective or cause harm, or when a patient has already tried and failed on certain treatment. Insurers may also be required to respond to exception requests expeditiously, which typically ranges from 24 to 72 hours, after a request is submitted.

California and Maryland took somewhat different approaches and passed more limited measures. California’s **AB 374** [13], which was signed into law in 2014 and endorsed by AHIP, only requires that step therapy exception requests be processed and responded to in the same manner as prior authorization requests. Maryland’s **House Bill 1233** [14], also passed in 2014, created a grandfathering process in which patients who are effectively being treated on a medication prescribed within the last 180 days are not required to restart a step therapy process.

A listing of step therapy laws compiled by the American Academy of Dermatology can be found [here](#).
Step therapy protocols can serve as a valuable tool to help control the substantial costs of providing coverage for prescription medications, while also acting as a bargaining chip to help insurers to negotiate lower drug prices with pharmaceutical companies. However, certain medical conditions or other issues concerning patient health may result in circumstances where step therapy exceptions are appropriate.

The potential negative impact of step therapy protocols on patients who benefit from advanced treatments, such as biologics, is particularly important to note and seek to prevent. Some physicians who treat conditions such as plaque psoriasis and rheumatoid arthritis have argued [16] that more traditional medications, which are often required under step therapy, are less effective compared to biologics and often result in their patients experiencing unwanted and unnecessary side effects.

The Institute for Clinical and Economic Review (ICER), a nonprofit organization tasked with providing independent cost-effectiveness analysis on a variety of treatments, has issued two reports that advise against putting those diagnosed with psoriasis [17] and multiple myeloma [16] through step therapy protocols.

ICER concluded that targeted immunomodulators, which are often subject to step therapy restrictions, offer a good value to psoriasis patients relative to older and less expensive treatments and should be available as a first line treatment. For patients with multiple myeloma, ICER concluded that since many patients have to cycle through multiple treatments, typically requiring them to make tradeoffs between extended survival and varying side effects, step therapy restrictions on their avenues of treatment are inappropriate.

The exceptions process existing in states that have enacted step therapy reform will likely prove beneficial to patients with complex conditions and those who have diseases treatable with prescription biologics, immunomodulators, or other advanced therapies. Under existing step therapy reforms, most of the cost saving benefits associated with having patients opt for cheaper generics still apply, except in cases where a patient's health is compromised due to being denied treatments deemed necessary by their doctor.

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