

Step Therapy: The Patient Impact



Step Therapy 101

Step therapy is used by insurers to limit how much they spend on certain medications. Under step therapy, patients must try one or more drugs chosen by their insurer – usually based on financial considerations – before coverage is granted for the drug prescribed by the patient’s health care provider.

Patients must take drugs selected by the insurer. Patients may be required to try one or more alternative prescription drugs that are of lower cost to the insurer, which may not be the most medically-appropriate therapy for some patients. These substitutes sometimes include an over-the-counter medicine, which shifts 100 percent of the cost to the patient.

Step therapy use is increasing steadily. In 2010, nearly 60 percent of commercial insurers were using step therapy.¹ As of 2013, 75 percent of large employers reported offering employees plans that utilize step therapy.²

Step therapy is applied to drugs that treat a wide range of diseases and chronic conditions. This includes:

- HIV/AIDS
- Glaucoma
- Diabetes
- Cancer
- Hemophilia
- Epilepsy
- Alzheimer’s disease
- Autoimmune diseases
- Mental health

Why Be Concerned?

Insurers claim that step therapy helps to lower health care costs while maintaining or possibly improving care quality. In some cases, step therapy has played a role in achieving these outcomes. But in other situations, data clearly shows that step therapy can have the opposite impact.

- **Step therapy can delay or lower care quality.** Since step therapy requires patients to try one or several medications before being covered for the drug selected by their health care provider, it can delay access to the most appropriate therapy. In the course of these delays, patients may experience disease progression, a serious risk for anyone living with a debilitating or life-threatening illness. Step therapy can also prevent patients from receiving any treatment at all. Studies have shown this to be true in up to 1 in 5 patients.³⁻⁶
- **Step therapy can lead to increases in cost.** In a study comparing spending on schizophrenia medications in Georgia’s Medicaid program, step therapy saved the state \$19.62 per member per month (PMPM) in atypical antipsychotic expenditures. However, these savings were “accompanied by a \$31.59 per member per month increase in expenditures for outpatient services.” As a result, step therapy did not have the intended effect of reducing overall costs; rather, it increased health care costs.⁷ Similar findings have been observed when step therapy was applied to blood pressure medications.⁸

How Can States Improve This Situation?

Increase oversight

Very few states regulate step therapy, despite its impact on patient care. In fact, insurers can implement step therapy protocols without demonstrating that they are, in fact, safe for patients. States should implement basic standards and some regulatory oversight for step therapy programs.

Ensure an appropriate clinical foundation

Insurer accrediting organizations do not assess the appropriateness or safety of specific protocols used by insurers. Consequently, there is no guarantee that step therapy programs are based on the most appropriate clinical practices. States should ensure that insurers base step therapy protocols on clinical guidelines that are developed independently by medical experts.

Establish minimum exceptions standards

There are universal circumstances under which patients should be exempted from their insurers' step therapy practices. This includes situations when a required drug is contraindicated, has been tried and failed previously, is expected to be ineffective, or the patient is already stable on another drug. States should establish basic exemption requirements to ensure step therapy is safe for patients.

Ensure transparency in exceptions processes

Insurers typically have procedures in place for patients or their health care providers to request an exception from coverage restrictions. However, it is not always clear that such procedures can be used to request an exception from step therapy. States should require that insurers allow providers to use current processes for step therapy exceptions requests, and such processes should be transparent and easily accessible to patients and health care providers.

Legislative Overview

The proposed legislation seeks to improve step therapy by ensuring that it is: 1) safe for patients, 2) clinically grounded, and 3) transparent to patients and health care providers.

What does the bill do?

- ✓ It ensures that step therapy programs are based on clinical guidelines developed by independent experts.
- ✓ It ensures that the exceptions process for step therapy is transparent and accessible to patients and health care providers.
- ✓ It establishes a basic framework for when it is medically appropriate to exempt patients from step therapy.

What does the bill NOT do?

- × It does NOT prevent insurers from using step therapy nor limit the number of allowed steps.
- × It does NOT require insurers to develop a new exceptions process.
- × It does NOT prevent insurers from requiring prior authorization before covering a drug.
- × It does NOT prevent insurers from requiring patients to try a generic drug if it is equivalent to a brand.

¹ Pharmaceutical Step-Therapy Interventions: A Critical Review of the Literature," J Manag Care Pharm. 2011;17(2):143-55.

² Step therapy comeback continues." Journal of Managed Care. September, 2012. Available at <http://www.managedcaremag.com/archives/1209/1209.outlook.html>. Last accessed January 25, 2015.

³ Cox ER et al. "Health plan member experience with point-of-service prescription step-therapy," J Manag Care Pharm. 2004;10(4):291-98.

⁴ Clinical and financial outcomes associated with proton pump inhibitors prior-authorization program in a Medicaid population," Am J Manag Care. 2005;11(1):29-36.

⁵ Mothoral B.R. "Pharmaceutical Step-Therapy Interventions: A Critical Review of the Literature," J Manag Care Pharm. 2011;17(2):143-55.

⁶ Yokohama K et al. "Effects of step-therapy program for angiotensin receptor blockers on antihypertensive medication utilization patterns and cost of drug therapy," J Manag Care Pharm. 2007;13(3):235-44.

⁷ Farley, J. et al., "Retrospective assessment of Medicaid step-therapy prior authorization policy for atypical antipsychotic medications," Clinical Therapeutics, 30: 1524-1539, 2008.

⁸ Mark, T. et al., "The Effects of Antihypertensive Step-Therapy Protocols on Pharmaceutical and Medical Utilization and Expenditures," American Journal of Managed Care, 15: 123-131, 2009.