

Step Therapy Reform: Protect Arizona Patients through Healthcare Transparency, Efficiency and Fairness



What is Step Therapy? Step therapy, also known as “fail first,” is a type of utilization management protocol used by health insurers and pharmacy benefit managers (PBMs) to manage the use of prescription medications. When a patient is prescribed a medicine, the insurer or PBM may require the patient to try – and fail – one or more of their “preferred” medications before considering coverage for the medication recommended and prescribed by their healthcare provider.

Step therapy requirements vary significantly among prescription drug plans, and there is often little transparency into how they are determined. This causes further confusion and challenges for both patients and providers, increases administrative burdens, and can contribute to delayed care and negative patient outcomes.

SB 1270 by Sen. Nancy Barto, cosponsored by Sens. Vince Leach, J.D. Mesnard, Tony Navarrete, Tyler Pace & Rep. Regina Cobb, provides common-sense guardrails to ensure transparent, efficient and fair processes for patients and their providers.

SB 1270 Protects Arizonans’ Access to Treatments by:

- Ensuring step therapy protocols are based on widely accepted clinical guidelines, so that medical expertise dictates requirements.
- Providing reasonable exceptions to step therapy requirements if:
 - The patient has already tried and failed on the preferred medication;
 - The patient is already stabilized on a medication;
 - The patient has already tried and failed the insurer’s preferred medication or one with the same mechanism of action; or
 - The preferred drug is not in the patient’s best interest, based on medical necessity.
- Improving transparency and navigation of administrative process by:
 - Requiring the health plan to grant or deny an exception request within 72 hours for a non-emergency and 24 hours for emergency situations. Currently, there is no requirement for when an insurer must respond to an exception request.
 - Clearly disclosing the list of drugs when step therapy is used, along with required documentation and information.

What SB 1270 Does Not Do:

- Does **NOT** prohibit commercial payer utilization management programs.
- Does **NOT** require insurers to create new clinical guidelines for step therapy.
- Does **NOT** prevent insurers from requiring the use of a step therapy protocol before covering a prescription.
- Does **NOT** limit an insurer, health plan, or utilization review organization from requiring a pharmacist to effect substitutions of prescription drugs consistent with Arizona law.
- Does **NOT** prevent insurers from requiring patients to try a generic equivalent to the brand-name drug.
- Does **NOT** hinder insurers and the provider community from developing other provider-driven alternatives, like preferred provider programs or “attestation of appropriate use” criteria programs.

Healthcare providers believe step therapy protocols block patients from accessing the most effective treatments:¹

- 89% of physicians and 78% of pharmacists believe that step-therapy requirements prevent patients with autoimmune diseases from receiving the most innovative prescription therapies
- 87% of physicians and 56% of pharmacists surveyed also said that the utilization management protocols prevent patients from receiving the treatments that could help them most.

Barriers to Care.

Step therapy protocols are becoming an increasingly common utilization management practice across health insurance plans.

An analysis focused on 12 medications used to treat plaque psoriasis, Crohn's disease and colitis found a 200% increase in the number of employer plans using utilization management protocols for these products, rising from 18% in 2015 to 60% in 2016.²

Without proper guidelines, step therapy limits the ability of healthcare providers to tailor care to an individual patient's needs. For patients living with serious or chronic illnesses, prolonging ineffective treatments and delaying access to the right treatment may result in: increased disease progression, loss of function, and irreversible damage or medical setbacks.

Limiting Healthcare Decisions at What Cost?

- Georgia Medicaid reported pharmacy benefit savings attributable to step therapy use of \$19.62 per member/per month for schizophrenia medications. However, these savings were offset by an increase of \$31.59 per member/per month in outpatient costs, resulting in an \$11.97 overall increase in healthcare costs.³
- The time and administrative burden associated with step therapy protocols may lead to delays or unnecessary breaks in treatment. In one study, depending on therapeutic class, 17% to 22% of patients did not submit any prescription claim to their insurance provider following a step therapy edit, instead forgoing treatment altogether.⁴
- One analysis of formulary restrictions found increased total costs of treatment (inpatient, medical, pharmacy) of anxiety disorders due to formulary restrictions while medication adherence declined. The study concluded that step therapy may be associated with an increased number of patients requiring a therapy change and who discontinue therapy early.⁵

Patients who experience step therapy are more likely to stop their treatments:¹

- 40% of step-therapy patients stopped taking medicines that did not help
- 27% stopped taking medicines because the insurance company did not pay for the medicines they needed to take
- 29% stopped taking medicines due to out-of-pocket costs

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Fiscal Impact. Several states developing step therapy regulations issued fiscal notes that indicate no, indeterminate or only minimal fiscal impact: CO, CT, IA, IN, KY, ME, NM, OK, TX, VA.⁶

1. Xcenda survey of patients, physicians, pharmacists and payers. ELC step therapy. December 2018.
2. Avalere. PlanScape Review of Formulary Coverage of Selected Treatments, 2015-2017. March 2018
3. Farley, J. et al. Retrospective assessment of Medicaid step-therapy prior authorization policy for atypical antipsychotic medications. *Clinical Therapeutics*, volume 30 Issue 8, August 2008. P1524-1539. <https://pubmed.ncbi.nlm.nih.gov/18803994/>
4. Yokoyama, K., et al. Effects of a step-therapy program for angiotensin receptor blockers on antihypertensive medication utilization patterns and cost of drug therapy. *Manag Care Pharm*, 2007. 13(3): P235-44. <https://pubmed.ncbi.nlm.nih.gov/17407390/>
5. Panzer PE, Regan TS, Chiao E, Sarnes MW. Implications of an SSRI generic step therapy pharmacy benefit design. *Am J Managed Care*. 2005;11(12suppl):S370-S379.
6. CO: leg.colorado.gov/sites/default/files/documents/2017A/bills/fn/2017a_sb203_f1.pdf
CT: www.cga.ct.gov/2014/fna/2014SB-00394-Rool/CO05450-FNA.htm
IA: www.legis.iowa.gov/docs/publications/FN/857080.pdf
IN: iga.in.gov/legislative/2016/bills/senate/41#document-10ba4633
KY: apps.legislature.ky.gov/record/12RS/sb114.html
ME: www.mainelegislature.org/legis/bills/bills_129th/fiscalpdfs/FN100902.pdf
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