



Prescription Drug Step Therapy

Executive Summary

Step therapy, which requires those seeking prescription medication to try less expensive drugs before more expensive options are approved, is sometimes imposed by health insurers as a cost-control strategy. This requirement, also known as a “fail first” protocol, is commonly imposed in cases when lower-cost generic drugs are available (relative to name brand prescriptions) or when clinical guidelines recommend a specific sequence of medications. In Missouri, patients may currently seek to override step therapy requirements if they have already tried a prescription ordered by the insurer and demonstrated its lack of efficacy or a negative side effect. SB 959 expands the criteria that would allow a patient to seek a step therapy override for drug disbursement in cases where the suggested prescription is likely to cause harm or is not in the best medical interest of the patient, as determined by their medical provider.

Highlights

- The majority of private health insurers and the Medicare Part D program use step therapy protocols to save costs on prescription drugs for conditions such as hypertension, chronic pain, and depression. As of 2022, 26 states (including AR, IA, IL, NE, and OK) permit override exceptions in cases where there is evidence to suggest that the required drug will be ineffective or harmful.
- Step therapy protocols have been shown to provide cost savings to insurers on drugs such as anti-inflammatories and antidepressants without affecting patient health outcomes. In certain cases, step therapies may result in more hospital admissions, which can be costly to the patient.
- Step therapy protocols for some conditions, such as bipolar disorder, or other drugs, such as antipsychotics, may cause patients to discontinue treatment due to adverse side effects or barriers to access to their preferred medication.
- Federal legislation is also being considered for step therapy overrides, and several states have protected classes of drugs from step therapy protocols.

Limitations

- While cost savings have been documented for several classes of drugs, there is not a large body of research analyzing health outcomes following implementation of step therapy protocols.
- Requirements for evidence-based recommendations for step therapy protocols are not widespread, so the effects of such requirements on cost and health outcomes are not known.

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inhibitors (SSRIs) upon implementation. Lower-cost anti-inflammatory drugs have been shown to provide similar pain relief to more expensive alternatives, and no difference in depression-related outpatient and hospitalization costs were observed in step therapy programs for SSRIs, indicating that these may be appropriate classes of drugs for step therapy.⁴ Notably, a study of prior authorization programs for NSAIDs in twenty-two states found that requirements for evidence-based prescribing recommendations (as opposed to permitting step therapy protocols that do not explicitly incorporate clinical evidence) did not affect cost savings for this class of drugs.⁵

Studies of step therapy for other conditions indicate that cost savings may be a result of discontinuation of treatment in addition to adherence to a lower-cost drug regimen. A study of patients with bipolar disorder in Maine found that drug treatment initiation decreased by about 30% after implementation of step therapy, as patients decreased their use of recommended “first-step” drugs without seeking alternative treatment. This program saved an average of \$3.50 per patient per month, but increased the rate of treatment discontinuation by 150%. Additionally, patients with schizophrenia were 30% more likely to discontinue antipsychotic medication use after implementation of step therapy protocols.⁶ Further, a study of multiple sclerosis patients covered by Medicare found that patients in restrictive plans (requiring either a prior authorization or step therapy protocol) tended to be older, live in a Southern U.S. state, and were more likely to have several chronic conditions or be disabled, all while having higher rates of hospital visits and low adherence to medication.⁷ Finally, step therapy protocols were shown in one study on hypertension to reduce medication costs, but also induce nearly \$400 more in annual expenditures on the part of the patient for inpatient admissions and emergency room visits.⁸

It is unknown whether those who did not obtain or discontinued medication use experienced any negative health consequences, but discontinuation of drugs such as antidepressants can increase the risk of adverse health outcomes, including suicide.^{4,9} Survey data indicates that patients are most likely to discontinue use of a therapeutic drug if they do not observe positive effects, or if they experience negative side effects.¹⁰ Other work has found that even minor changes in the appearance of pharmacologically identical drugs (e.g., pill color or shape) can lead patients to discontinue their use, indicating that step therapy requirements that cause patients to change prescriptions may have the unintended consequence of disrupting the use of medically necessary drugs.¹¹

Because step therapy may have different consequences depending on the particular drug or condition to which it is applied, researchers have identified a need for studies on specific conditions where step therapy is common. In particular, there is little evidence surrounding the effect of step therapy on treatment discontinuities, health outcomes, future medical costs, and patient satisfaction for drugs such as steroids, stimulants, anticonvulsants, antidiabetics, statins, and antihypertensives.⁶

Federal and State-Level Legislation

At the federal level, legislation has been introduced ([H.R. 2163](#)) known as the Safe Step Act which requires group health plans to establish coverage exceptions for step-therapy protocols, and provides a specific sequence by which drugs can be administered if the standard step-therapy treatment is ineffective, can lead to irreversible consequences, adverse reactions, or prevents the individual from performing daily activities.

Several states have passed legislation that protect certain classes of drugs from prior insurance authorization or step therapy protocols. These laws also prohibit the state Medicaid agency from controlling the use of a drug when necessary for patient adherence (**Table 1**). Twenty-four states (including IA, IL, KS, KY, NE, OK, & TN) also report either annual or quarterly reviews of at least one drug to determine if a drug must remain on the step therapy protocol lists.¹²

Drugs/Drug Classes Protected	# of states	States
HIV/AIDS antiretrovirals	14	AL, CO, CT, FL, LA, MD, MI, ND, NV, OK, RI, TX, VA, VT
Mental Health drugs	10	CO, CT, HI, IN, MI, MO, ND, OH, OR, VA
Cancer drugs	6	CO, MI, ND, TN, TX, VA
Epilepsy drugs	4	CO, CT, IL, MI
Medication-Assisted Treatment	3	DC, IL, TX
Antihemophilic, organ transplant, multiple sclerosis, brain disorder drugs, etc.	6	KS, MI, NC, NV, RI, VA

Table 1. List of drug classes that are omitted from prior authorization or step therapy requirements for use. Table reproduced from the Kaiser Family Foundation.¹²

In the Missouri 2022 legislative session, a similar bill has been introduced ([SB 959](#)) that would amend the current law and require a health carrier to cover and allow a step therapy override in a normal treatment sequence if a delay in stepping up the treatment regimen would lead to irreversible consequences, be ineffective, cause an adverse reaction, prevent safe normal daily functions, or if the patient is stable and without adverse reactions on the existing drug regimen and is determined by the provider to benefit with stepping up therapy.

For more information on prescription drug pricing, including the effects on step therapies, see our Science Note: [Pricing & Transparency in Prescription Drug Costs](#).

Effects of State Legislation

One study of states that had enacted laws to limit step therapy decisions for drug coverage found that, except for New York and New Mexico, step therapy laws affect less than 1/3 of a state's population, and can be difficult to enforce or leave many loopholes. The study also found

that Ohio and Louisiana had some of the most comprehensive step therapy override laws. In Louisiana, laws not only override step therapy if the patient has tried and failed a drug, but also if the drug has been documented to fail for the patient in the past, is expected to be ineffective, can cause adverse effects, is not in the best interest of the patient, has a condition where treatment is inadvisable, and if the patient is responding well to the current drug. In Ohio, laws place time constraints on the response to a request for a step therapy exemption, have clear appeals procedures, and allows legal appeals, citing unfair or deceptive practices for providers who refuse an appeal.¹³

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