HB 751: Evidence-based requirements for 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. HB 751 would require that step therapy protocols be based on clinical practice guidelines that are developed by a multidisciplinary panel of experts using published research and public review to inform them. This bill would also expand the criteria that would allow a patient to seek to override a step therapy requirement in cases where the suggested prescription is likely to cause harm or is not in the best medical interest of the patient.

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 2021, more than 25 states, including Kansas and Iowa, 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**.
- However, **step therapy protocols for other 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

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.

This science note was prepared by MOST Policy Initiative, Inc. a nonprofit organization aimed to improve the health, sustainability, and economic growth of Missouri communities by providing objective, non-partisan information to Missouri's decisionmakers. For more information, contact Dr. Joshua Mueller, Health & Mental Health Fellow – josh@mostpolicyinitiative.org. This was prepared 4/11/21.

Research Background

What is step therapy?

Step therapy, also known as a "fail first" protocol, is a form of prior authorization sometimes required by health insurers before approval of a prescription. Specifically, insurers using step therapy can require patients to try a lower-cost alternative to a treatment they are seeking or have been recommended before they are approved for the higher-cost option. This strategy has been proposed as a cost control mechanism for insurers, as certain name brand drugs may have lower-cost, generic alternatives with similar or identical efficacy available. In addition, certain classes of drugs required by step therapy may have active ingredients that are different from the patient's preferred course of treatment which make them less expensive and/or less likely to have adverse health effects.[1] Step therapy is applied to requests for drugs for a wide variety of conditions, including chronic pain, arthritis, cancer, hypertension, diabetes, and mental health disorders. As of 2013, around 70% of employer-sponsored health insurance plans contained step therapy policies for at least one of these conditions.[2]

Currently under Missouri law, patients can seek a step therapy override exception if they have tried the required prescription drugs and discontinued their use due to lack of efficacy or an adverse event.(20 RevStat 376.2034) More than 25 states, including Kansas and Iowa, permit override exceptions in cases where there is evidence to suggest that the required drug will be ineffective or harmful.

At the federal level, the Centers for Medicare and Medicaid Services (CMS) previously restricted the use of step therapy policies in Medicare Part D, which covers self-administered prescription drugs for seniors. As of 2019, CMS now allows Medicare Part D insurers to use step therapy for patients beginning therapy using immunosuppressants, antidepressants, antipsychotics, anticonvulsants, or antineoplastics, but not antiretrovirals.(CMS-4180-F)

Effects of step therapy on cost, continuity of treatment, and health outcomes

Several studies indicate that step therapy can reduce costs to insurers. In particular, step therapy programs have been observed to save 20% of monthly prescription costs for nonsteroidal anti-inflammatory drugs (NSAIDs), gastroprotective agents, and selective serotonin reuptake 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.[3] 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.[4]

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.[5]

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.[3,6] 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.[7] 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.[8]

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 antihyptertensives.[5]

References

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