

June 2019

## Step Therapy and Step Therapy Exceptions: *A Review of the Research Evidence and State Policies*

The 2018 Washington State Legislature directed the Washington State Institute for Public Policy (WSIPP) to “conduct a review of the available research literature on step therapy protocol usage, [...] review any rigorous evidence regarding the effectiveness of exceptions to the use of step therapy [...], and provide a summary of step therapy protocol exceptions that have been codified in other states.”<sup>1</sup>

This report presents findings for each aspect of the assignment. [Section I](#) provides background information on step therapy and step therapy exceptions. [Section II](#) details WSIPP’s methods for conducting evidence reviews and contains the results of our reviews for step therapy and step therapy exceptions. [Section III](#) describes state policies on step therapy exceptions. [Section IV](#) summarizes our findings.

Suggested citation: Westley, E. (2019). *Step therapy and step therapy exceptions: A review of the research evidence and state policies* (Document Number 19-06-3401). Olympia: Washington State Institute for Public Policy.

### Summary

The 2018 Washington State Legislature directed the Washington State Institute for Public Policy (WSIPP) to conduct evidence reviews on step therapy and step therapy exceptions and to summarize step therapy exceptions codified in other states. One goal of the assignment is to determine whether this type of prescription drug utilization management practice has an effect on health outcomes.

We conducted a literature search on the effects of step therapy and identified only four rigorous research evaluations for inclusion in our review. We found no rigorous evaluations that measured the effects of step therapy on patient health outcomes.

We found some evidence that step therapy changes prescription drug utilization. We found mixed effects on health care costs and medical utilization outcomes. We discuss several limitations to the existing body of research.

We also conducted a thorough literature search on the effects of step therapy exceptions and found no research studies on this practice.

We found that 23 out of the 50 states have codified step therapy exception laws. We found some similarities in exception laws across the states, though there is variability in the way that states define and implement these laws. In comparison with other states, Washington has one of the more comprehensive exception laws.

<sup>1</sup> Engrossed Substitute Senate Bill 6032, Section 606, Chapter 299, Laws of 2018.

## I. Background

The 2018 Washington State Legislature directed WSIPP to conduct evidence reviews on step therapy and step therapy exceptions and to summarize step therapy exceptions codified in other states.

This section describes prescription drug spending and utilization management, defines step therapy and step therapy exceptions, and describes how step therapy is applied.

### Legislative Assignment

*... for the Washington institute for public policy to conduct a review of the available research literature on step therapy protocol usage, including any rigorous evidence concerning positive or negative health outcomes resulting from step therapy protocol usage. The institute must also review any rigorous evidence regarding the effectiveness of exceptions to the use of step therapy in improving health outcomes and reducing adverse events, and provide a summary of step therapy protocol exceptions that have been codified in other states. The institute must submit a report on its findings to the appropriate committees of the senate and house of representatives by December 1, 2018.\**

Engrossed Substitute Senate Bill 6032, Section 606,  
Chapter 299, Laws of 2018.

\*Due to prior research commitments, the WSIPP Board of Directors voted to move the final deadline of this study to June 30, 2019.

### Prescription Drug Spending and Utilization Management

In 2017, prescription drug spending in the United States accounted for 10% of total annual health care expenditures (totaling \$333.4 billion in prescription drug spending).<sup>2</sup> Prescription drug spending is affected by both how much drugs cost (prescription drug costs) and how drugs are prescribed or used (prescription drug utilization).

Prescription drug utilization is influenced, in part, by what drugs are covered by prescription drug benefit plans. The carriers that administer these benefit plans rely on prescription drug utilization management practices to control spending on prescription drugs. Utilization management practices aim to achieve patient health outcomes at lower costs by ensuring that prescription drugs are used appropriately and encouraging the use of lower-cost medications, when possible.<sup>3</sup>

Common utilization management practices are described in the glossary in [Exhibit 1](#).

<sup>2</sup> 2017 is the most current year with available data on national health expenditures. Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group. (2019). [National Health Expenditures 2017 Highlights](#).

<sup>3</sup> Happe, L.E., Clark, D., Holliday, E., & Young, T. (2014). A systematic literature review assessing the directional impact of managed care formulary restrictions on medication adherence, clinical outcomes, economic outcomes, and health care resource utilization. *Journal of Managed Care Pharmacy*, 20(7), 677-684.

## **Exhibit 1**

### Glossary of Terms

**Carrier:** A pharmacy benefit manager (PBM), managed care organization (MCO), and/or health insurance provider that administers prescription drug benefit plans.

**Formulary:** A list of medications or therapies that are covered by a prescription drug benefit plan.

**Preferred/non-preferred drug:** Preferred drugs are effective drugs that may be preferred because of their efficacy, safety, or cost. Non-preferred drugs are effective drugs that may be more costly. Prescription drug utilization management practices typically incentivize the use of preferred drugs.

**Prescription drug benefit plan:** A carrier's prescription drug benefit plan is the combination of their formulary (the list of medications or therapies that are covered) and their prescription drug utilization management practices (the techniques used to incentivize the use of appropriate medications at lower cost).

**Prescription drug utilization management practice:** A management practice that carriers use to control prescription drug spending by guiding prescription drug utilization for their beneficiaries. These practices aim to both 1) ensure prescription drugs are used appropriately (i.e., for the condition they are meant to treat) and 2) encourage the use of lower-cost medications when there are multiple effective options.

Some common prescription drug utilization management practices are listed below. This list is not exhaustive.

**Closed formulary:** A prescription drug benefit plan which only covers a single medication within a therapeutic class.

**Preferred drug list (PDL):** A list of drugs in a carrier's formulary that designates drugs within a therapeutic class as either preferred or non-preferred.

**Prior authorization:** A requirement for advanced approval from a carrier before coverage of a non-preferred drug is authorized. Advanced approval may require that a patient have a specific diagnosis or meet other stipulated criteria.

**Quantity limits:** Limits the amount of a drug that will be covered within a specific period of time. For example, if a typical dosage for a drug is two doses per day, the limit for coverage may be set at 60 doses per month.

**Step therapy:** Step therapy is a type of prior authorization. Step therapy requires a patient to try a preferred drug and find it to be ineffective before a non-preferred drug will be covered under their prescription drug benefit plan. Step therapy is sometimes called stepwise therapy, step-edit protocol, or fail first requirement. In this report, we use the term "step therapy."

**Therapeutic class:** A group of drugs or medications that have similar pharmaceutical properties (chemical structures or mechanisms of action) or are used to treat similar conditions. For example, antidepressants are a therapeutic class of drugs used to treat depression.

## Step Therapy and Step Therapy Exceptions

Step therapy is a utilization management practice that requires a patient to try a preferred medication or therapy and find it to be ineffective before a non-preferred medication or therapy will be covered under their prescription benefit plan.

Step therapy algorithms stipulate preferred and non-preferred drugs and the “steps” that a patient must adhere to before a non-preferred drug will be covered through their prescription drug benefit plan. These algorithms are determined by the carrier and typically encourage the use of lower-cost medications.<sup>4</sup>

Step therapy is typically used for therapeutic classes of drugs that include multiple medications with comparable efficacy or medications with generic alternatives. In these cases, there are multiple effective medications for a single condition. Step therapy is used to incentivize the use of lower-cost medications, while still providing quality treatment for patients.

A step therapy *exception* is a process by which a patient or provider requests coverage for a non-preferred drug without fulfilling step therapy requirements. Step therapy exceptions are sometimes called step therapy exemptions, step therapy overrides, or medical exceptions. In this report, we use the term “step therapy exception.”

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<sup>4</sup> Stacey, B.R., Liss, J., Behar, R., Sadosky, A., Parsons, B., Masters, E.T., & Hlavacek, P. (2017). A systematic review of the effectiveness of policies restricting access to pregabalin. *BMC Health Services Research*, 17(1), 600.

Many states have enacted legislation requiring that a step therapy exception process be available to patients whose medications are subject to step therapy. Some states also stipulate the specific conditions under which a step therapy exception must be granted. [Section III](#) contains our review of step therapy exception legislation codified in other states, including a description of Washington State’s step therapy exception law.

## Applications of Step Therapy

Step therapy is one of many utilization management tools available to carriers who are interested in controlling prescription drug spending (see [Exhibit 1](#) for examples of other utilization management tools).

Step therapy is particularly important in Medicaid because of its open formulary requirements. Medicaid is required by law to provide coverage for all FDA-approved drugs<sup>5</sup>—an approach known as an open formulary. Because of this, Medicaid must rely on other utilization management tools (such as step therapy) to encourage the use of less costly medications within its formulary.

One common approach taken by Medicaid is a preferred drug list (PDL), in which all drugs within a therapeutic class are designated as either preferred or non-preferred. In Washington, the Health Care Authority convenes a Pharmacy and

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<sup>5</sup> The Omnibus Budget Reconciliation Act of 1990 (OBRA '90) is a federal law that requires states to include nearly all prescription drugs under Medicaid coverage in order to receive federal funding. It allows for some prescription drug utilization management tools, such as prior authorization and step therapy.

Therapeutic (P&T) Committee/Drug Utilization Review (DUR) Board, which makes recommendations regarding the PDL for Medicaid.<sup>6</sup> Each non-preferred drug on the list has either a step therapy or prior authorization requirement. That is, although Medicaid covers all FDA-approved drugs on the PDL, there are step therapy and prior authorization requirements that patients must meet in order to qualify for coverage of non-preferred drugs.

In contrast, commercial carriers can establish their own prescription drug benefit plans and can use a variety of utilization management tools to provide coverage at a lower cost. For example, a closed formulary is a utilization management approach through which a commercial carrier might only cover a single medication within a therapeutic class (e.g., for individuals with depression, they might only provide coverage for one generic antidepressant).

Although commercial carriers have more options for prescription drug utilization management, many rely on step therapy for some drugs in their prescription benefit plan. A 2018 survey of commercial carriers found that 86% of carriers surveyed use step therapy in their prescription drug benefit plan.<sup>7</sup>

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<sup>6</sup> The P&T Committee/DUR Board makes recommendations based solely on available evidence of safety, efficacy, and effectiveness—not on cost considerations. For more information on the P&T Committee/DUR Board see Washington State Health Care Authority. [Related laws and rules](#).

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<sup>7</sup> This survey of 273 prescription drug benefit plan managers for employer-based health plans was conducted by the Pharmacy Benefit Management Institute (PBMI), as part of their 2018 annual report (funded by Takeda Pharmaceuticals). Pharmacy Benefit Management Institute. (2018). [Trends in drug benefit design](#). Plano, TX: PBMI.

## II. Evidence Reviews

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In this section, we describe the methods used to review the research literature on step therapy and step therapy exceptions. We also present the results of these reviews.

Typically when WSIPP reviews the research evidence on a topic, we use an approach called meta-analysis to combine results from multiple studies.<sup>8</sup> Although we did not find enough evidence to conduct a meta-analysis, we used the same review strategy to identify rigorous research studies.

### Research Methods

We used WSIPP's standard approach to conduct evidence reviews on step therapy and step therapy exceptions. WSIPP follows several key protocols to ensure a rigorous analysis for each program examined. Our process is as follows:

- 1) **Search for all studies on a topic**—We systematically review the research literature and consider all available studies on a program, regardless of their findings.

We use four primary means to locate studies for review: 1) we consult the bibliographies of systematic and narrative reviews of the research literature in the various topic areas; 2) we examine citations in the individual studies we locate; 3) we conduct independent literature

searches of research databases using search engines such as Google and PubMed; and 4) we contact authors of primary research to learn about other evaluation work. We gather all available studies we can locate that meet our criteria, regardless of the published source.<sup>9</sup>

- 2) **Screen studies for quality**—We only include rigorous studies in our analysis. We require that a study reasonably attempt to demonstrate causality using appropriate statistical techniques. Studies that do not meet our minimum standards are excluded from the analysis. See [Exhibit 2](#) for a summary of WSIPP's standards for methodological rigor.
- 3) **Determine the average effect size**—In a typical meta-analysis, we use a formal set of statistical procedures to calculate an average effect size for each outcome, which indicates the expected magnitude of change caused by the program (e.g., step therapy) for each outcome of interest (e.g., total health care expenditures). In this case, we computed an effect size for each outcome measured in each study; we were not able to summarize results across studies.

These standardized procedures support the rigor of our analysis and allow program effects to be compared on an “apples-to-apples” basis.

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<sup>8</sup> For more information on WSIPP's approach to meta-analysis see our Technical Documentation. Washington State Institute for Public Policy. (December 2018). [Benefit-cost technical documentation](#). Olympia, WA: Author.

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<sup>9</sup> Many of these studies are published in peer-reviewed academic journals while others are from reports obtained from government agencies or independent evaluation contractors. We examine all evaluation studies we can locate within these search procedures.

## Exhibit 2

### WSIPP's Standards for Methodological Rigor

WSIPP has a standard set of criteria for inclusion in our meta-analyses. We require that a study reasonably attempt to demonstrate causality using appropriate statistical techniques. Studies that do not meet our minimum standards are excluded from the analysis. Key criteria include the following:

[Comparison group](#): The most important criteria for inclusion in our analysis is that an evaluation must either have a control or comparison group or use advanced statistical methods to control for unobserved variables or reverse causality.

[Random assignment and quasi-experiments](#): Randomized controlled trials are the gold standard research design for identifying causal relationships between programs and their effects. When study participants are randomly assigned to receive a program (treatment) or a comparison condition (control), researchers can be confident that any differences in outcomes could be attributed to participation in the program rather than systematic differences in the characteristics of the participants.

Random assignment studies are preferred for inclusion in our review, but we also include studies with non-randomly assigned comparison groups. We only include quasi-experimental studies if sufficient information is provided to demonstrate comparability between the treatment and comparison groups on important pre-existing or pre-treatment characteristics such as demographics and health conditions.

[Intent-to-treat samples](#): We do not include a study in our meta-analytic review if the treatment group is made up solely of program completers or if that study has high attrition or insufficient response rates. There are many important unobserved self-selection factors that distinguish a program completer from a program dropout, and these unobserved factors are likely to bias estimated treatment effects.

We include the study if sufficient information is provided to allow us to reconstruct an intent-to-treat group that includes both completers and non-completers or if the demonstrated rate of program non-completion is very small. In these cases, the study still needs to meet our other inclusion requirements.

[Enough information to calculate an effect size](#): Since we follow standardized procedures to calculate effect sizes, a study must provide the necessary information to calculate an effect size, as described in our Technical Documentation. If the necessary information is not provided, and we are unable to obtain it directly from the study's author(s), the study is not included in our analysis.

For additional detail, see our [Technical Documentation](#).

## Step Therapy

The legislative assignment directed WSIPP to review available research literature for the effects of step therapy usage on positive and negative health outcomes.<sup>10</sup>

This section includes the following components of our review of the evidence on step therapy:

- Literature search,
- Outcomes examined,
- Findings, and
- Limitations.

### Literature Search

We searched for studies that compared outcomes for individuals subject to step therapy to individuals who were not. Our goal was to identify studies that evaluated outcomes related to the presence or absence of step therapy, rather than the use of preferred versus non-preferred drugs.

In order to capture as much research on the effects of step therapy as possible, we searched for evaluations of step therapy, step edits, prior authorization, and formulary restrictions.<sup>11</sup> We did not restrict our initial search to particular health conditions or outcomes.

We identified 31 studies that evaluated step therapy.<sup>12</sup> These studies applied step

therapy to a variety of different drug classes, including antipsychotics, anticonvulsants, anti-secretory drugs,<sup>13</sup> infusion biologics,<sup>14</sup> non-steroidal anti-inflammatory drugs, anti-diabetic drugs, and attention-deficit/hyperactivity disorder medications.

Of these 31 studies, four met our criteria for rigor and are included in our analyses. Because our goal is to capture the causal effect of step therapy on outcomes of interest, we excluded studies that did not meet WSIPP's standards for methodological rigor (see [Exhibit 2](#)). We excluded the following:

- 16 studies that had no comparison group (e.g., pre-post studies) or had non-equivalent comparison groups and did not use sufficient statistical methods to control for differences between groups;
- Seven studies that did not measure relevant outcomes (e.g., patient satisfaction or the generic dispense rate);
- Three studies that had insufficient response rates; and
- One economic modeling exercise.

See [Appendix II](#) for a list of studies excluded from our analysis.

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drug utilization management tools broadly and did not isolate the effect of step therapy).

<sup>13</sup> Anti-secretory drugs reduce the rate of secretion of a body fluid. For example, proton pump inhibitors are a common type of anti-secretory drug, which reduce acid secretion in the stomach.

<sup>14</sup> Biologic therapies are made of materials found naturally in living organisms, such as antibodies and other proteins, which can be used to target particular chemicals and cells in the body. For example, anti-tumor necrosis factor (anti-TNF) is an antibody that blocks a protein (TNF) that can cause inflammation. Anti-TNF is a biologic therapy used to treat inflammatory bowel disease. Infusion biologics are administered intravenously or via injection.

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<sup>10</sup> ESSB 6032.

<sup>11</sup> Step therapy is a specific type of prior authorization approach, which is itself a specific type of formulary restriction. We used these broad search terms to ensure that we captured all relevant literature. We later excluded studies that did not evaluate the effects of step therapy specifically.

<sup>12</sup> The initial literature search identified 110 articles. We excluded 40 studies that were reviews, commentary, or opinion pieces. We excluded 39 studies that did not evaluate step therapy specifically (these studies evaluated prescription

## Outcomes Examined

The assignment directed WSIPP to evaluate the effects of step therapy on positive and negative health outcomes. Ideally, we would report on patient health outcomes such as changes in disease status or clinical health measures. However, we found that none of the rigorous research reported on patient health outcomes.<sup>15</sup>

Evaluations of step therapy typically report medication utilization, disease-related health care expenditures, and all-cause health care expenditures.<sup>16</sup> These outcomes do not directly measure patient health. Instead, they measure changes in utilization and expenditures due to step therapy—which may or may not be indicative of a person’s underlying health. For instance, outcomes such as increased inpatient psychiatric expenditures or discontinuation of medications may indicate adverse events, whereas decreased outpatient expenditures may indicate reduced reliance on health care services.

Importantly, step therapy is implemented primarily as a mechanism to control prescription drug spending. Health care

expenditure outcomes may indicate the extent to which step therapy achieves broader savings. Health care expenditures could also indicate whether savings from reduced spending on prescription drugs might be offset by increased spending on other health services (e.g., less spending on prescription drugs but more spending on outpatient visits).

Here, we describe the utilization and expenditure outcomes reported in the included studies.

**Medication Utilization.** The included studies report on some medication utilization outcomes.<sup>17</sup> These include the following:

- Preferred drug utilization,
- Non-preferred drug utilization, and
- Discontinuation of medication (a gap in medication therapy for the underlying condition of at least 30 days).

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<sup>15</sup> We found a single study in our literature search that measured patient health outcomes, but the study design did not investigate the effect of step therapy. The study was on patients with gastrointestinal (GI) disorders whose prescription drug benefit plan included step therapy for some GI treatments. The analysis compared patients who received a preferred drug to patients who received a non-preferred drug or patients who received no drug in this therapeutic class. All patients were subject to the step therapy policy. The study reported on changes in GI symptoms. Delate, T., Mager, D.E., Sheth, J., & Motheral, B.R. (2005). Clinical and financial outcomes associated with a proton pump inhibitor prior-authorization program in a Medicaid population. *The American Journal of Managed Care*, 11(1), 9.

<sup>16</sup> All-cause health expenditures include all health expenditures, regardless of whether these expenditures are related to a specific disease or underlying diagnosis.

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<sup>17</sup> We do not include outcomes such as generic dispense rate (a measure of the proportion of generic drugs provided within a therapeutic class) or proportion of preferred drug prescribing within a therapeutic class. These types of outcomes describe the relative mix of generic/non-generic or preferred/non-preferred drugs that were provided but do not translate to patient-level medication utilization. That is, these proportions do not tell us whether patients who needed medications received them.

### *Disease-Related Health Care Expenditures.*

Disease-related health care expenditures are directly related to a patient's underlying medical condition. These expenditures may indicate whether a patient required health care services related to a specific diagnosis; these expenditures do not include any shifts in utilization or expenditures outside their primary diagnosis. Disease-related health care expenditure outcomes include the following categories:

- Outpatient,
- Inpatient,
- Long-term care,
- Medical care (includes inpatient, outpatient, and emergency care),
- Preferred drug,
- Non-preferred drug,
- Other prescription drug, and
- All prescription drug.

*All-Cause Health Care Expenditures.* Effects on all-cause health care expenditures could indicate the extent to which potential savings in drug expenditures are offset by shifts in broader health care expenditures. All-cause health care expenditures better capture changes due to adverse events or other health issues that are not directly related to a patient's primary diagnosis, but that may be associated with the changes to a patient's drug regimen caused by step therapy. Studies reported the following all-cause health care expenditures:

- Medical care (includes inpatient, outpatient, and emergency care),
- Prescription drug, and
- Total health care (medical care and prescription drug).

Total health care expenditures is our preferred outcome. This outcome includes all inpatient, outpatient, emergency department, and prescription drug spending, regardless of whether spending is related to a primary diagnosis. This outcome best captures trends in overall health care expenditures that might be attributable to step therapy.

### *Findings*

We include findings from four rigorous studies on step therapy. Citations for included studies are listed in [Appendix I](#).

This section includes findings from the rigorous studies on the following:

- 1) Step therapy for antipsychotics/anticonvulsants prescribed for schizophrenia or bipolar disorder and
- 2) Step therapy for anticonvulsants prescribed for nerve pain.

In these findings, positive effect sizes indicate that the outcome was greater for individuals who were subject to step therapy compared to those who were not (e.g., a positive effect size on total health expenditures would indicate higher expenditures for those subject to step therapy compared to those who were not). Negative effect sizes indicate that the outcome was lower for participants subject to step therapy compared to those who were not. Throughout this report, we consider effects to be statistically significant if they have a p-value less than 0.05.<sup>18</sup>

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<sup>18</sup> Statisticians often rely on a metric, the p-value, to determine whether an effect is significant. The p-value is a measure of the likelihood that the difference could occur by chance—values range from 0 (highly significant) to 1 (no significant difference). By convention, p-values less than 0.05

We note study funders alongside study findings, for transparency. The rigorous research we identified may have funder bias, as some of the studies were funded by pharmaceutical companies and/or by insurance carriers. Research suggests that industry funding may lead to bias in reporting or interpretation of results.<sup>19</sup> Pharmaceutical companies may have a vested interest in demonstrating that step therapy is harmful, while carriers may have a vested interest in demonstrating that step therapy is not harmful. The research methods described in the included studies appear to be sound and meet our criteria for rigor.

*Step Therapy for Antipsychotics/ Anticonvulsants Prescribed for Schizophrenia or Bipolar Disorder.* We found two rigorous evaluations examining step therapy for antipsychotics or anticonvulsants prescribed for schizophrenia or bipolar disorder.<sup>20</sup>

A 2009 study by Zhang et al. investigated a Medicaid step therapy policy in Georgia that required patients with schizophrenia to try two preferred antipsychotics before a non-preferred antipsychotic<sup>21</sup> would be approved. This study was independently funded; it did not receive funding from pharmaceutical companies or insurance companies.

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(a 5% likelihood that the difference could occur by chance) are considered statistically significant.

<sup>19</sup> A 2018 Cochrane review found that clinical research funded by pharmaceutical or medical device companies tend to report more favorable effects and more favorable conclusions than similar studies that do not receive industry funding. Lundh, A., Lexchin, J., Mintzes, B., Schroll, J.B., & Bero, L. (2018). Industry sponsorship and research outcome: systematic review with meta-analysis. *Intensive Care Medicine*, 44(10), 1603-1612.

<sup>20</sup> Farley et al., (2008) and Zhang et al., (2009). See [Appendix I](#) for full citations of included studies.

<sup>21</sup> The atypical antipsychotics were risperidone, olanzapine, or clozapine.

This study found that patients with schizophrenia who are subject to step therapy for antipsychotics are more likely to stop using their medication for some period of time compared to patients who are not subject to step therapy. In the included study, 61.3% of patients subject to step therapy discontinued all medications for their disorder for a period of at least 30 days, compared with 41.0% in the comparison group. For patients with schizophrenia, a discontinuation of medication is considered an adverse event.

A 2008 study by Farley et al. investigated a similar Medicaid step therapy program in Maine that required patients to try a preferred antipsychotic or anticonvulsant before non-preferred treatments<sup>22</sup> would be approved. This study was funded solely by Pfizer—a pharmaceutical company and the maker of one of the non-preferred treatments.<sup>23</sup>

These authors found that outpatient psychiatric expenditures (e.g., psychiatrist visits) were 11.1% higher for patients with schizophrenia or bipolar disorder who are subject to step therapy than for similar patients who were not subject to step therapy. The authors found no difference in expenditures on inpatient psychiatric care or long-term psychiatric care. This study also found that expenditures on non-preferred antipsychotics were 46.1% lower and expenditures on preferred antipsychotics were 14.2% higher for patients subject to step therapy, compared to patients who were not. Findings from these two studies are displayed in [Exhibit 3](#).

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<sup>22</sup> Among antipsychotics, ziprasidone hydrochloride and quetiapine were nonpreferred agents. Among anticonvulsants, lamotrigine, topiramate, gabapentin, carbamazepine, valproic acid, oxcarbazepine, and levetiracetam were non-preferred agents.

<sup>23</sup> Pfizer makes ziprasidone hydrochloride.

*Step Therapy for Anticonvulsants Prescribed for Nerve Pain.* We found two rigorous evaluations examining step therapy for an anticonvulsant (pregabalin) prescribed for nerve pain.<sup>24</sup> Both studies investigate a step therapy policy implemented by a large national health insurance provider, Humana Inc. This step therapy policy required patients with certain types of nerve pain<sup>25</sup> to try gabapentin before pregabalin would be approved. Both studies were jointly funded by Pfizer (the maker of pregabalin) and Humana Inc.

We report separate findings for the effect of this policy on a population under age 65 and a Medicare Advantage population (over age 65).

A 2013 study by Udall et al. investigated commercially insured patients under age 65 with nerve pain who were subject to step therapy for anticonvulsants. The authors found that the proportion of patients with a claim for pregabalin (the non-preferred drug) was lower among patients subject to step therapy (0.4% of patients had a claim for pregabalin) compared to similar patients who were not subject to step therapy (9.7% had a claim for pregabalin). The proportion of patients with a claim for gabapentin (the preferred drug) was higher among patients subject to step therapy (19.2%) compared to patients who were not (8.4%). That is, participants who were subject to step therapy were more likely to use the

preferred drug and less likely to use the non-preferred drug.

Udall et al. also found that disease-related total health care expenditures for patients subject to step therapy were 49.1% higher than for similar patients who were not subject to this step therapy policy.

In this study, the authors found no difference in all-cause total health care expenditures for patients subject to step therapy than for similar patients who were not. Among the included health care expenditures, the authors found that medical care expenditures were 15.7% higher among patients subject to step therapy and found no difference in expenditures on prescription drugs. See [Exhibit 4](#) for a summary of these findings.

A 2013 study by Suehs et al. investigated the effects of step therapy for Medicare Advantage patients (over age 65) with nerve pain. In this study, the proportion of Medicare Advantage patients with nerve pain who had a claim for pregabalin (non-preferred) was lower among patients subject to step therapy (0.1%) compared to similar patients who were not subject to step therapy (7.4%). The proportion of patients with a claim for gabapentin (preferred) was higher among patients subject to step therapy (28.7%) compared to patients who were not subject to step therapy (17.4%). In this study, as in the Udall et al. study, participants who were subject to step therapy were more likely to use the preferred drug and less likely to use the non-preferred drug.

Suehs et al. found that disease-related total health care expenditures were not different for patients subject to step therapy when

<sup>24</sup> Udall et al., (2013), and Suehs et al., (2014). See [Appendix I](#) for full citations of included studies.

<sup>25</sup> Participants in this study were diagnosed with one of the following types of nerve pain: diabetic peripheral neuropathy (numbness and pain in the feet, legs, and hands due to nerve damage caused by diabetes), post-herpetic neuralgia (pain in the skin cause by a complication related to shingles), or fibromyalgia (widespread muscle pain).

compared with similar patients who were not. Among the included expenditure categories, the authors found no effect on disease-related medical care expenditures. However, they found that disease-related prescription drug spending was 8.4% higher among patients subject to step therapy, compared to those who were not.

In addition, Suehs et al. found no difference in all-cause total health care expenditures for Medicare Advantage patients subject to step therapy for anticonvulsants compared to similar patients who were not subject to this step therapy policy. Among the included health care expenditures, the authors found an 18.5% decrease in medical expenditures (inpatient expenditures, outpatient expenditures, and emergency department visits) and no difference in prescription drug expenditures for patients subject to step therapy. Study findings are displayed in [Exhibit 5](#).

### Limitations

The rigorous research literature on step therapy is limited; we found only four studies that were rigorous enough to include in an analysis using WSIPP's standard methods. These studies measured the effects of step therapy for different therapies and different insurance populations, and they also measured different outcomes. Therefore, while we are able to summarize the small amount of research that does exist, we emphasize that each of the effects we report comes from only a single study and may not be generalizable.

Furthermore, we find that the rigorous studies we included may have some selection bias. We did not find any randomized controlled trials on step

therapy—all of the included studies are observational. These studies meet our criteria for rigor; they utilize comparison groups and statistical controls to account for differences between groups. However, without random assignment, even the best observational studies are subject to potential selection bias.

We also note that funder bias may be of concern in these studies. One of the studies was solely funded by a pharmaceutical company,<sup>26</sup> which may suggest bias (see discussion of funder bias on page 11). Two of the studies were jointly funded by a pharmaceutical company and an insurance company, which may lessen this bias.<sup>27</sup> Only one study was published without funding from a pharmaceutical company or insurance company.

The measured outcomes do not allow us to draw conclusions about the long-term effects of step therapy on health care utilization, health care expenditures, or any other outcomes. The effects reported in these studies were measured one year or less after step therapy policies took effect. Longer term effects have not been measured in rigorous studies.

Perhaps most importantly, none of these rigorous studies directly measured patient health outcomes. We are therefore unable to comment on the effect of step therapy on patient health.

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<sup>26</sup> Farley et al. (2008) (funded by Pfizer).

<sup>27</sup> Udall et al. (2013) and Suehs et al. (2014) (jointly funded by Pfizer and Humana Incorporated).

### Exhibit 3

#### Results: Step Therapy on Antipsychotics/Anticonvulsants Prescribed for Schizophrenia and Bipolar Disorder (Medicaid Population)

Outcome type	Outcome	# in treatment	Effect size	Standard error	p-value
Drug utilization*	Discontinuation of medication	1,960	0.499	0.080	0.000
Disease-related expenditures <sup>#</sup>	Outpatient psychiatric	5,178	0.111	0.023	0.000
	Inpatient psychiatric	5,178	0.042	0.137	0.757
	Long-term care psychiatric	5,178	0.190	0.180	0.291
	Atypical antipsychotic drugs (non-preferred)	5,178	-0.461	0.036	0.000
	Typical antipsychotic drugs (preferred)	5,178	0.142	0.034	0.000
	Other medication	5,178	0.028	0.019	0.142

**Notes:**

\* The effect sizes for these outcomes are approximations of standardized mean difference effect sizes, as described in Sánchez-Meca, J., Marín-Martínez, F., & Chacón-Moscoso S. (2003). Effect-size indices for dichotomized outcomes in meta-analysis. *Psychological Methods*, 8(4), 448-467. Source: Zhang et al. (2009) (independently funded).

<sup>#</sup> The effect sizes for these outcomes are percentage changes. Source Farley et al. (2008) (funded by Pfizer).

### Exhibit 4

#### Results: Step Therapy on Anticonvulsants Prescribed for Nerve Pain (Commercially Insured Population Under Age 65)

Outcome type	Outcome	# in treatment	Effect size	Standard error	p-value
Drug utilization*	Pregabalin (non-preferred) claims	3,876	-1.951	0.130	0.000
	Gabapentin (preferred) claims	3,876	0.579	0.035	0.000
Disease-related expenditures <sup>#</sup>	Medical care	3,876	0.323	0.231	0.161
	Prescription drug	3,876	-0.033	0.231	0.885
	Total health care	3,876	0.491	0.159	0.002
All-cause expenditures <sup>#</sup>	Medical care	3,876	0.157	0.065	0.016
	Prescription drug	3,876	0.010	0.008	0.199
	Total health care	3,876	0.138	0.071	0.054

**Notes:**

All effects from Udall et al. (2013) (co-funded by Pfizer and Humana Inc).

\* The effect sizes for these outcomes are approximations of standardized mean difference effect sizes, as described in Sánchez-Meca et al. (2003).

<sup>#</sup> The effect sizes for these outcomes are percentage changes.

### Exhibit 5

Results: Step Therapy on Anticonvulsants Prescribed for Nerve Pain  
(Medicare Advantage Population Age 65 and Older)

Outcome type	Outcome	# in treatment	Effect size	Standard error	P-value
Drug utilization*	Pregabalin (non-preferred) claims	13,911	-2.632	0.110	0.000
	Gabapentin (preferred) claims	13,911	0.392	0.016	0.000
Disease-related expenditures <sup>#</sup>	Medical care	13,911	-0.169	0.332	0.610
	Prescription drug	13,911	0.084	0.026	0.001
	Total health care	13,911	-0.022	0.018	0.231
All-cause expenditures <sup>#</sup>	Medical care	13,911	-0.185	0.056	0.001
	Prescription drug	13,911	-0.007	0.005	0.143
	Total health care	13,911	-0.052	0.056	0.350

Notes:

All effects from Suehs et al. (2013) (co-funded by Pfizer and Humana Inc).

\* The effect sizes for these outcomes are approximations of standardized mean difference effect sizes, as described in Sánchez-Meca et al. (2003).

<sup>#</sup> The effect sizes for these outcomes are percentage changes.

## Step Therapy Exceptions

The legislative assignment directed WSIPP to review available research literature for the effects of step therapy exceptions in "improving health outcomes and reducing adverse events."<sup>28</sup>

## Literature Search

We searched for studies that compared outcomes for individuals who were subject to step therapy exception processes to individuals who were not. In order to capture as much of the research on the effects of step therapy exceptions as possible, we searched for evaluations of step therapy exceptions, step therapy exemptions, and step therapy overrides. We did not restrict our search to particular health conditions or outcomes.

We did not find any research studies on the effect of step therapy exceptions. The literature search identified seven articles. We excluded three studies that were commentary or opinion pieces. The other four studies evaluated the effects of step therapy. These articles made brief mention of step therapy exceptions but did not evaluate the effect of step therapy exceptions.

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<sup>28</sup> ESSB 6032.

### III. Review of Step Therapy Exceptions Codified by States

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The legislative assignment directed WSIPP to “provide a summary of step therapy protocol exceptions that have been codified in other states.”<sup>29</sup>

This section describes the methods used in our review and our findings on step therapy exceptions codified by states.

#### Methods

To address this component of the assignment, we conducted a review of step therapy exceptions codified in other states. We searched for statutes and code related to step therapy and pharmacy utilization management in all 50 states. We included codified legislation pertaining to step therapy exceptions that have been signed into law by the governor in each respective state.<sup>30</sup>

As described in [Section I](#), step therapy exceptions are processes through which a patient or provider can request coverage for a non-preferred drug without fulfilling step therapy requirements. This review focuses on step therapy exception laws; we do not include other legislation related to step therapy. We refer to codified step therapy exceptions as “exception laws” throughout this section.

We reviewed the exception laws for each state to find patterns and themes in step therapy exceptions laws.

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<sup>29</sup> [ESSB 6032](#).

<sup>30</sup> This review is current as of May 15, 2019. As of the date of review, Illinois and Louisiana had additional legislation pertaining to step therapy exceptions moving through their legislative processes.

## Findings

In our review, we found that 23 of the 50 states have codified step therapy exception laws.<sup>31</sup> See [Exhibit 6](#) for a map of states with exception laws, and [Appendix III](#) for a narrative summary of exception laws in each state.

This section summarizes features of exception laws related to the following:

- Applicability to Medicaid and commercial carriers,
- Process and transparency guidance,
- Circumstances for step therapy exception request approval, and
- Restrictions.

We found some similarities in step therapy exception laws across states, though there is also variability in the ways that states define and implement these laws. [Exhibit 7](#) indicates which features are present in each state's exception laws.

Throughout this section, we note how Washington's newly codified step therapy exception law compares with exception laws in other states.

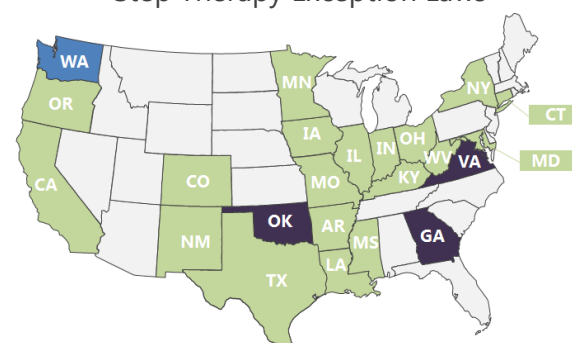
In Washington, step therapy exceptions are currently written into administrative code. Washington Administrative Code (WAC) 284-43-5080 is currently in effect and requires that carriers that use step therapy must provide a step therapy exception process.

<sup>31</sup> For some states, including Washington, the most recently codified legislation will not go into effect until a future date. Washington's new exception law will affect health plans starting on or after January 1, 2021. Georgia, Oklahoma, and Virginia's exceptions will affect health plans on or after January 1, 2020.

Washington passed an exception law in its 2019 Legislative Session, which will apply to health plans administered on or after January 1, 2021.<sup>32</sup>

WAC 284-43-5080 includes some of the same features as the new exception law, but the new law is more comprehensive. For the purposes of comparison with other states, we focus on Washington's newly codified step therapy exception law in our findings.

**Exhibit 6**  
States With Codified  
Step Therapy Exception Laws



**Note:**

Alaska and Hawaii do not have codified step therapy exceptions. The map is current as of May 15, 2019.

<sup>32</sup> [Engrossed Substitute House Bill 1879](#), Laws of 2019. See [Appendix III](#) for additional details on.

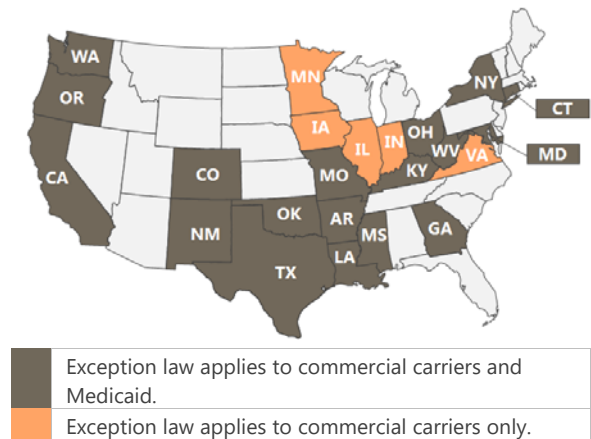
### Applicability of Exception Laws to Medicaid and Commercial Carriers

A majority of states, including Washington, have codified exception laws that apply to commercial carriers and to carriers that administer benefit plans for Medicaid. In some cases, there are separate laws for commercial carriers and carriers administering plans for Medicaid. There are some states in which the exception laws only apply to commercial carriers.

**Exhibit 7** shows which carriers step therapy exception laws apply to for each state.

### Exhibit 7

Applicability of Exception Laws to Medicaid and Commercial Carriers



## Process and Transparency Guidance

Most codified step therapy exceptions stipulate that the process to request a step therapy exception must be clear and convenient. Some exception laws have features that specify aspects of the step therapy exception process, including features meant to improve transparency.

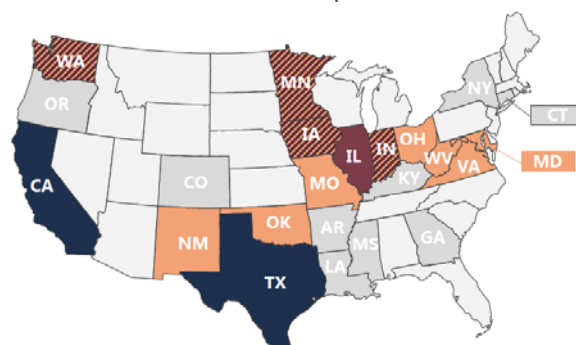
[Exhibit 8](#) shows features of exception laws related to the step therapy exception request processes and transparency.

In addition, some states with exception laws specify the timeline in which a carrier must render a decision to approve or deny a step therapy exception request. In nonurgent circumstances, the time limits to render a decision range from 48 hours to ten calendar days. In urgent circumstances, the time limits to render a decision range from 24 hours to 72 hours.

[Exhibit 9](#) shows which states specify time limits in which carriers must render a decision on a step therapy exception request. See [Exhibit 12](#) for specific time limits by state.

## Exhibit 8

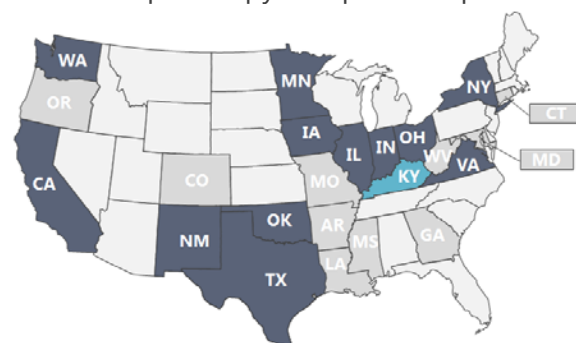
### Process and Transparency Features of Exception Laws



	Step therapy exception process must be published on carrier's website.
	Specific documentation must accompany the denial of a step therapy exception request.
	Step therapy exception process must be published on carrier's website <b>and</b> specific documentation must accompany the denial of a step therapy exception request.
	Step therapy exception request must be submitted on a standard form.
	None specified.

## Exhibit 9

### Time Limits to Render a Decision for Step Therapy Exception Requests



	Specifies separate time limits for urgent and nonurgent requests.
	Specifies a single time limit for all requests.
	No time limits specified.

## Circumstances for Step Therapy Exception Request Approval

A majority of states with codified step therapy exceptions establish specific circumstances in which step therapy exceptions must be approved.

In states that establish circumstances for approval, we observed three common types of approval circumstances:

### 1) *Expected lack of effectiveness or potential harm.*

Seventeen states, including Washington, specify that exception requests must be approved if the preferred drug is expected to be ineffective or cause harm.

Many states delineate specific ways a preferred drug could be expected to be ineffective or cause harm, including being contraindicated,<sup>33</sup> likely causing an adverse reaction, likely being ineffective based on known characteristics of the insured and the drug, or not being in the best interest of the patient.

Examples of this type of approval circumstance include:

*The drug required under the step therapy protocol: (A) is contraindicated; (B) will likely cause an adverse reaction in or physical or mental harm to the patient; or (C) is expected to be ineffective based on the known clinical characteristics of the patient*

<sup>33</sup> Contraindication means that a particular drug or treatment should not be used because the risk of its use clearly outweighs any possible benefit. The U.S. Food and Drug Administration provides guidance on contraindication for prescription medications. For example, treatments may be contraindicated if they may cause an adverse reaction for patients with a certain diagnosis or if patients are using other drugs that may have harmful interactions with the drug in question.

*and the known characteristics of the prescription drug regimen.*<sup>34</sup>

*The required prescription drug is not in the best interest of the patient, based on documentation of medical appropriateness, because the patient's use of the prescription drug is expected to: (i) Create a barrier to the patient's adherence to or compliance with the patient's plan of care; (ii) Negatively impact a comorbid condition of the patient; (iii) Cause a clinically predictable negative drug interaction; or (iv) Decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities.*<sup>35</sup>

### 2) *Insured experienced poor outcomes on the preferred drug.*

Eighteen states, including Washington, specify that step therapy exception requests must be approved if the insured has tried the preferred drug and the drug was proven to be ineffective or harmful.

Some states specify that exception requests must be approved if the insured has experienced poor outcomes while using drugs in the same pharmacologic class or with the same mechanism of action<sup>36</sup> as the preferred drug.

Examples of this type of approval circumstance include:

*The patient has tried the step-therapy-required prescription drugs while under his or her current or previous health insurance or health benefit plan, and such prescription drugs were discontinued due to lack of*

<sup>34</sup> Texas Insurance Code § 1369.0546.

<sup>35</sup> Washington, ESHB 1879, Laws of 2019.

<sup>36</sup> The "mechanism of action" is the biochemical process through which a drug (or class of drugs) produces its effect.

efficacy or effectiveness, diminished effect, or an adverse event.<sup>37</sup>

The prescribing practitioner can demonstrate, based on sound clinical evidence, that the preferred treatment required under step therapy or fail-first protocol has been ineffective in the treatment of the insured's disease or medical condition.<sup>38</sup>

### 3) Insured is currently stable on another medication for their condition.

Twelve states, including Washington, specify that exception requests must be approved if the insured is stable or experiencing positive therapeutic outcomes on a different drug for the medical condition under consideration.

Examples of this type of approval circumstance include:

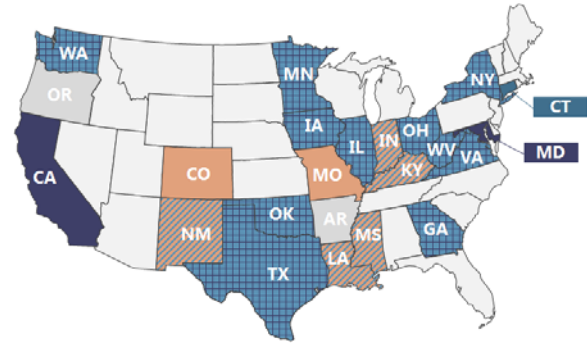
*A prescriber provides supporting medical information to the entity that a prescription drug covered by the entity: (i) was ordered by a prescriber for the insured or enrollee within the past 180 days; and (ii) based on the professional judgment of the prescriber, was effective in treating the insured's or enrollee's disease or medical condition.*<sup>39</sup>

*The patient is currently experiencing a positive therapeutic outcome on a prescription drug recommended by the patient's provider for the medical condition under consideration while on his or her current or immediately preceding health plan, and changing to the required prescription drug may cause clinically predictable adverse reactions, or physical or mental harm to, the patient.*<sup>40</sup>

Exhibit 10 shows the approval circumstances codified in each state's exception laws.

### Exhibit 10

#### Codified Approval Circumstances in Exception Laws



	1) Expected lack of effectiveness or potential harm.
	2) Insured experienced poor outcomes on the preferred drug.
	3) Insured is currently stable on another medication for their condition.
	1) Expected lack of effectiveness or potential harm <b>and</b>
	2) Insured experienced poor outcomes on the preferred drug.
	1) Expected lack of effectiveness or potential harm <b>and:</b>
	2) Insured experienced poor outcomes on the preferred drug <b>and:</b>
	3) Insured is currently stable on another medication for their condition.
	No approval circumstances specified.

<sup>37</sup> Washington, ESHB 1879.

<sup>38</sup> Mississippi Code Annotated § 83-9-36.

<sup>39</sup> Maryland Code, Insurance Law § 15-142.

<sup>40</sup> Washington, ESHB 1879.

### Restrictions in Step Therapy Exception Laws

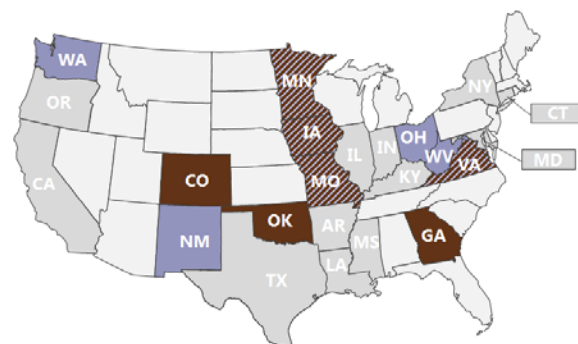
Seven states specify that drug samples do not count as a trial of a preferred drug and cannot be used to satisfy step therapy requirements or circumstances for exception approval.

Eight states indicate that the step therapy exception does not limit carriers from requiring the insured to use a generic equivalent prior to using a brand name drug.

Exhibit 11 shows the restrictions codified in each state's exception laws.

### Exhibit 11

#### Restrictions in Step Therapy Exception Laws



	Drug samples cannot be used to satisfy step therapy requirements.
	Law does not limit carriers from requiring use of a generic equivalent.
	Drugs samples cannot be used to satisfy step therapy requirements <b>and</b> law does not limit carriers from requiring use of a generic equivalent.
	None of these restrictions specified.

## Exhibit 12

### Key Features of Step Therapy Exceptions Codified by States

State	Carriers	Process and transparency		Decision time limitations		Established circumstances for approval			Restrictions	
	Applies to Medicaid and commercial carriers	Process must be available on website	Specific documentation is required when request is denied	Nonurgent circumstance	Urgent circumstance	Expected lack of effectiveness or potential harm	Insured has experienced poor outcomes on preferred drug	Insured currently stable on other drug	Drug samples do not count as trial of preferred drug	Does not limit carriers from requiring use of generic equivalents
Washington	✓	✓	✓	3 business days	1 business day	✓	✓	✓		✓
Arkansas	✓									
California	✓			72 hours	24 hours			✓		
Colorado	✓						✓		✓	
Connecticut	✓					✓				
Georgia				2 business days	24 hours	✓	✓	✓	✓	
Illinois			✓	72 hours	24 hours	✓	✓	✓		
Indiana		✓	✓	3 business days	1 business day	✓	✓			
Iowa		✓	✓	5 calendar days	72 hours	✓	✓	✓	✓	✓
Kentucky	✓			48 hours	48 hours	✓	✓			
Louisiana	✓					✓	✓			
Maryland	✓	✓						✓		
Minnesota		✓	✓	5 calendar days	72 hours	✓	✓	✓	✓	✓
Mississippi	✓					✓	✓			
Missouri	✓	✓					✓		✓	✓
New Mexico	✓	✓		72 hours	24 hours	✓	✓			✓
New York	✓			72 hours	24 hours	✓	✓	✓		
Ohio	✓	✓		10 calendar days	48 hours	✓	✓	✓		✓
Oklahoma	✓	✓		72 hours	24 hours	✓	✓	✓	✓	
Oregon	✓									
Texas	✓			72 hours	24 hours	✓	✓	✓		
Virginia		✓		72 hours	24 hours	✓	✓	✓	✓	✓
West Virginia	✓	✓				✓	✓	✓		✓

## IV. Summary

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The legislative assignment directed WSIPP to conduct evidence reviews on step therapy and step therapy exceptions and to summarize step therapy exceptions codified in other states.

We found that the rigorous research literature on step therapy is limited; only four studies were rigorous enough to include in an analysis using WSIPP's standard methods. We found no rigorous evaluations that measured the effects of step therapy on patient health outcomes.

We found some evidence that step therapy changes prescription drug utilization. We found mixed effects on health care costs and medical utilization outcomes. However, there are several limitations to the existing research. Our results may not be conclusive or generalizable.

We also conducted a thorough literature search on the effects of step therapy exceptions. We found no research studies on this practice.

We found that 23 states have codified step therapy exception laws—including Washington.

We found many similarities in exception laws across the states. Most states with codified exception laws have laws that apply to both Medicaid and commercial carriers. Most exception laws establish some circumstances for approval, and a majority of them stipulate time limitations in which a decision must be rendered. We also found that while most exception laws require a clear and convenient process, there is variability in how states operationalize clarity and convenience.

Washington State's newly codified step therapy exception law is one of the more comprehensive step therapy exceptions.<sup>41</sup> It specifically codifies components of the process and transparency, establishes circumstances for approval, defines time limitations for decisions, and applies to commercial carriers as well as Medicaid carriers.

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<sup>41</sup> [ESHB 1879](#),



# Appendices

Step Therapy and Step Therapy Exceptions: A Review of the Research Evidence and State Policies

I:	Step Therapy Studies Included in Analysis .....	26
II:	Step Therapy Studies Excluded from Analysis.....	27
III:	Summaries of Step Therapy Exceptions Codified in Other States.....	29

## I. Step Therapy Studies Included in Analysis

### Step Therapy for Antipsychotics/Anticonvulsants Prescribed for Schizophrenia Bipolar Disorder (Medicaid Population)

Farley, J.F., Cline, R.R., Schommer, J.C., Hadsall, R.S., & Nyman, J.A. (2008). Retrospective assessment of Medicaid step-therapy prior authorization policy for atypical antipsychotic medications. *Clinical Therapeutics*, 30(8), 1524.

Zhang, Y., Adams, A.S., Ross-Degnan, D., Zhang, F., & Soumerai, S.B. (2009). Effects of prior authorization on medication discontinuation among Medicaid beneficiaries with bipolar disorder. *Psychiatric Services*, 60(4), 520-527.

### Step Therapy for Anticonvulsants Prescribed for Nerve Pain (Commercially Insured Population, Under age 65)

Udall, M., Louder, A., Suehs, B.T., Cappelleri, J.C., Joshi, A.V., & Patel, N.C. (2013). Impact of a step-therapy protocol for pregabalin on healthcare utilization and expenditures in a commercial population. *Journal of Medical Economics*, 16(6), 784-92.

### Step Therapy for Anticonvulsants Prescribed for Nerve Pain (Medicare Advantage Population)

Suehs, B.T., Louder, A., Patel, N.C., Udall, M., Cappelleri, J.C., & Joshi, A.V. (2014). Impact of a pregabalin step therapy policy among Medicare Advantage beneficiaries. *Pain Practice*, 14(5), 419-426.

## II. Step Therapy Studies Excluded from Analysis

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We apply standard criteria for rigor in meta-analyses across all topic areas to ensure that the included studies represent the impact of implementing a program or policy compared to a counterfactual. Our criteria for rigor allow us to include many different study designs in a single meta-analysis, including randomized controlled trials, quasi-experimental studies, and sophisticated econometric studies.

Of the 31 studies we identified that evaluated step therapy, we excluded 27 studies from our analysis because they did not meet our criteria for rigor or did not evaluate the effect of step therapy. We excluded the following:

- 16 studies that had no comparison group (e.g., pre-post studies) or that had non-equivalent comparison groups and did not use sufficient statistical methods to control for differences between groups;
- Seven studies that did not measure relevant outcomes (e.g., measure only patient satisfaction or only the generic dispense rate);
- Three studies that had insufficient response rates; and
- One economic modeling exercise.

### Citations for Excluded Studies

- Blomquist, S. (2010). *Generic first strategy in PPI class drives lowest net cost*. Abstracts from Professional Poster Presentations at the Academy of Managed Care Pharmacy's 2010 Educational Conference, St. Louis, Missouri.
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### III. Summaries of Step Therapy Exceptions Codified in Other States

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#### Washington



#### Relevant Statutes/Code

Engrossed Substitute House Bill 1879, Laws of 2019.<sup>42</sup>

When coverage of a prescription drug for the treatment of any medical condition is subject to prescription drug utilization management, the patient and prescribing practitioner must have access to a step therapy exception process. This applies to health plans delivered, issued for delivery, or renewed on or after January 1, 2021.

#### Process and Transparency

The patient and prescribing practitioner must have access to a clear, readily accessible, and convenient process to request a step therapy exception. The process must be available on the carrier's website.

When responding to a step therapy exception request, carriers must clearly state whether the exception was approved or denied. Denial must be based on clinical review criteria and carriers must include information regarding how to appeal the denial.

#### Codified Circumstances for Step Therapy Exception Approval Include the Following:

- ✓ The preferred drug is contraindicated or will likely cause an adverse reaction;
- ✓ The preferred drug is expected to be ineffective based on the known clinical characteristics of the insured and the known characteristics of the drug regimen;
- ✓ The insured has tried the preferred drug, another drug in the same pharmacologic class, or a drug with the same mechanism of action while under his or her current or previous health plan, and said prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;
- ✓ The patient is currently experiencing a positive therapeutic outcome on a drug recommended by the patient's provider for the medical condition under consideration while on his or her current or immediately preceding health plan; or
- ✓ The required prescription drug is not in the best interest of the patient, based on documentation of medical appropriateness.

#### Decision Time Limitations

Insurers must render a decision within three business days for nonurgent exception requests and one business day for urgent exception requests. Carriers must cover an emergency prescription fill if the health provider determines it is necessary to keep the patient stable while the exception request is being processed.

#### Specified Exclusions

The law does not prevent an insurer from requiring the insured to try a generic equivalent prior to providing coverage for the equivalent branded prescription drug. The law does not prevent a carrier from denying an exception for a drug that has been removed from the market due to safety concerns from the U.S. Food and Drug Administration.

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<sup>42</sup> Washington's administrative code currently includes codified step therapy exceptions. Washington Administrative Code (WAC) 284-43-5080 is currently in effect and requires that carriers that use step therapy must provide a step therapy exception process. [WAC 284-43-5080](#) includes some of the same features as the new exception law ([ESHB 1879](#)) but the new law is more comprehensive.

## Arkansas



### Relevant Statutes/Code

Arkansas Code § 23-99-1115 (2017).

When a healthcare service is restricted or denied due to step therapy, the insured's healthcare provider shall have access to a clear and convenient process to expeditiously request an override of that restriction or denial from the payer.

### Process and Transparency

The process must be clear and convenient.

### Codified Circumstances for Approval

None specified.

### Decision Time Limitations

None specified.

### Specified Exclusions

None specified.

## California

### Relevant Statutes/Code

Cal. Ins. Code § 10123.197, Cal. Ins. Code § 10123.201, Cal. Ins. Code § 10123.191.

Step therapy exception requests may be submitted in the same manner as a request for prior authorization and shall be treated and responded to by the insurer in the same manner as a request for prior authorization.



### Process and Transparency

Requires a uniform prior authorization form for all prior authorizations and step therapy exceptions. The form must be available electronically and may be submitted electronically.<sup>43</sup>

### Codified Circumstances for Approval

In circumstances where an insured is changing policies, the new policy shall not require the insured to repeat step therapy when:

- ✓ The insured is already being treated for a medical condition by a prescription drug provided that the drug is appropriately prescribed and is considered safe and effective for the insured's condition.

### Decision Time Limitations

Insurers must render a decision in 72 hours or 24 hours in an emergency.

### Specified Exclusions

None specified.

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<sup>43</sup> California law does not specify whether the form must be available on a website—only that it must be available electronically.

## Colorado

### Relevant Statutes/Code

Co. Rev. Stat. § 10-16-145



A carrier shall not require the insured to undergo step therapy. A carrier shall provide coverage for the drug prescribed as long as it is on the carrier's prescription drug formulary and certain conditions are met to grant an exception.

Relevant documentation may be required from the patient or provider to support the exception request.

### Process and Transparency

The health carrier, health benefit plan, or utilization review organization may request relevant documentation from the patient or provider to support the exception request. This law does not specify the documentation required.

### Codified Circumstances for Approval

An insurer shall grant an exception when the insured has tried the required drugs while under the current or previous plan, and the drug was discontinued due to the following:

- ✓ Lack of efficacy or effectiveness;
- ✓ Diminished effect; or
- ✓ An adverse event.

### Decision Time Limitations

None specified.

### Specified Exclusions

Pharmacy drug samples shall not be considered trial and failure of a preferred drug in lieu of trying the step-therapy-required preferred drug.

This law does not preclude a carrier from requiring prior authorization for the coverage of a prescribed drug that was covered by the covered person's former health benefit plan.

## Connecticut



### Relevant Statutes/Code

Conn. Gen. Stat. § 38a-510, Conn. Gen. Stat. § 38a-544, Conn. Gen. Stat. § 17b-274f

Requires a step therapy exception process to be used by carriers administering group or individual health insurance policies or that provide coverage for prescription drugs.

### Process and Transparency

The step therapy exception request process shall be convenient to use by health care providers.

### Codified Circumstances for Approval

Step therapy exceptions may be approved when the insured's health care provider demonstrates that the drug regimen required under step therapy meets the following conditions:

- ✓ Has been ineffective in the past for treatment of the insured's medical condition;
- ✓ Is expected to be ineffective based on known physical or mental characteristics of the insured and characteristics of the drug regimen;
- ✓ Will cause or will likely cause an adverse reaction or physical harm; or
- ✓ Is not in the best interest of the insured, based on medical necessity.

### Decision Time Limitations

Requires that the process shall be convenient to use by health care providers, and the decision shall be made expeditiously.

### Specified Exclusions

None specified.

## Georgia

### Relevant Statutes/Code

GA Code § 33-24-59.25



Requires a step therapy exception process for state-regulated health plans, excluding Medicaid.

Applies to health plans delivered, issued for delivery, or renewed on or after January 1, 2020.

### Process and Transparency

Requires a clear and convenient step therapy exception process.

### Codified Circumstances for Step Therapy Exception Approval Include the Following:

- ✓ The preferred drug is contraindicated or will cause an adverse reaction;
- ✓ The preferred drug is expected to be ineffective based on the known clinical condition of the patient and the known characteristics of the drug regimen;
- ✓ The patient has tried the preferred drug or another drug in the same pharmacological class or with the same mechanism of action while on their current or immediately preceding health plan, and said drug was discontinued due to lack of efficacy, diminished effect, or an adverse event; or
- ✓ The patient is currently receiving a positive therapeutic outcome on a prescription drug for the medical condition under consideration if, while on their current or immediately preceding health plan, the patient received coverage for the prescription drug and the practitioner gives documentation that the change in prescription drug required by the step therapy protocol is expected to be ineffective or cause harm to the patient based on the known characteristics of the patient and characteristics of the drug.

### Decision Time Limitations

Insurers must render a decision in two business days in a nonurgent circumstance or 24 hours in an urgent circumstance.

### Specified Exclusions

Drug samples shall not be considered trial and failure of a preferred prescription drug in lieu of trying the step therapy required prescription drug.

## Illinois

### Relevant Statutes/Code

215 Ill. Comp. Stat. § 134/45.1

Requires insurers to establish and maintain a step therapy exception process. This law applies to health plans sold in Illinois and excludes Medicaid.



### Process and Transparency

Any request for approval of coverage made verbally or in writing (regardless of whether made using a paper or electronic form or some other writing) at any time shall be reviewed by appropriate health care professionals.

In the case of a denial, the health carrier shall provide the covered person and their prescribing provider with the reason for the denial, an alternative covered medication, and information regarding the appeals process.

In the case of an approval, the approval shall be honored for 12 months or until the renewal of the health plan.

### Codified Circumstances for Step Therapy Exception Approval Include the Following:

- ✓ The required drug is contraindicated;
- ✓ The insured has tried the required prescription drug while under their current or a previous health benefit plan and the doctor submits evidence of failure or intolerance; or
- ✓ The insured is currently stable on a prescription drug.

### Decision Time Limitations

Insurers must render a decision in 72 hours or 24 hours in an emergency.

### Specified Exclusions

None specified.

## Indiana

### Relevant Statutes/Code

Ind. Code § 5-10-8-17, Ind. Code § 27-8-5-30

Requires step therapy exception processes for commercial insurance and state employee health plans.



### Process and Transparency

The process for requesting an exception must be published on the insurer's website.

When an exception is approved, the carrier shall notify the covered individual and their health care provider of the authorization for coverage of the drug. When a request results in a denial, the carrier shall provide to the covered individual and their provider notice of the denial, including a detailed, written explanation of the reason for the denial and supporting clinical rationale.

### Codified Circumstances for Step Therapy Exception Approval Include the Following:

- ✓ A preferred drug is contraindicated or will likely cause an adverse reaction or physical or mental harm to the insured;
- ✓ A preferred drug is expected to be ineffective, based on both the known clinical characteristics of the insured and characteristics of the preferred drug;
- ✓ The insured has previously received a preferred drug or another prescription drug that is in the same pharmacologic class or has the same mechanism of action and the drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event; or
- ✓ Based on clinical appropriateness, a preferred drug is not in the best interest of the insured because the insured's use of the preferred drug is expected to cause barriers to adherence, worsen the condition, or reduce the insured's ability to perform daily activities.

### Decision Time Limitations

Requires insurers to render a decision in three business days for nonurgent circumstances and one business day for urgent circumstances.

### Specified Exclusions

These step therapy exception laws do not apply to Medicare or Tricare plans.

## Iowa



### Relevant Statutes/Code

Iowa Code § 514f.7

Requires a step therapy exception process and establishes circumstances for approval. This law does not apply to health carriers contracting with the Iowa Department of Human Services to provide services to Medicaid recipients.

### Process and Transparency

The process for requesting an exception must be published on the website of the health carrier, health benefit plan, or utilization review organization.

If a request for a step therapy override exception is denied, the carrier shall provide the insured and their health care professional with the reason for the denial and information regarding the procedure to request an external review of the denial.

### Codified Circumstances for Step Therapy Exception Approval Include the Following:

- ✓ A preferred drug is contraindicated or will likely cause an adverse reaction or physical or mental harm to the insured;
- ✓ The prescription drug required under the step therapy protocol is expected to be ineffective based on the known clinical characteristics of the insured, such as the insured's adherence to or compliance with the insured's individual plan of care;
- ✓ The insured previously tried the drug and the drug was discontinued due to ineffectiveness; or
- ✓ The insured is currently receiving a positive outcome on a drug selected by the insured's provider.

### Decision Time Limitation

Insurers must render a decision within five calendar days for nonurgent claims and 72 hours for urgent claims.

### Specified Exclusions

Pharmacy drug samples shall not be considered trial and failure of a preferred drug in lieu of trying the step-therapy-required preferred drug. The law does not prevent an insurer from requiring an insured to try a generic equivalent prior to providing coverage for the equivalent branded prescription drug.

## Kentucky

### Relevant Statutes/Code

Ky. Rev. Stat. § 304.17A-163



Requires a step therapy exception process.

### Process and Transparency

The process must be clear and convenient.

### Codified Circumstances for Step Therapy Exception Approval Include the Following:

- ✓ The prescribing practitioner can demonstrate, based on sound clinical evidence, that the treatment required under step therapy has been ineffective in the treatment of the insured's disease or medical condition; or
- ✓ The practitioner can demonstrate the required treatment is expected to be ineffective or will likely cause an adverse reaction in the insured.

### Decision Time Limitations

Insurers must render a decision within 48 hours.

### Specified Exclusions

None specified.

## Louisiana



### Relevant Statutes/Code

La.R.S. § 22:1053, La.R.S. § 46:460.34

Requires a step therapy exception process for commercial insurance and Medicaid health plans.

### Process and Transparency

The process must be clear and convenient.

### Codified Circumstances for Approval

Step therapy exceptions may be approved when the prescribing practitioner, based on sound clinical evidence, can demonstrate that the preferred drug required under step therapy meets the following conditions:

- ✓ Has been ineffective in the treatment of the insured's disease or medical condition;
- ✓ Is reasonably expected to be ineffective based on the known relevant physical or mental characteristics and medical history of the insured and known characteristics of the drug regimen;  
or
- ✓ Will cause or will likely cause an adverse reaction or other physical harm to the insured.

### Decision Time Limitations

None specified.

### Specified Exclusions

None specified.

## Maryland



### Relevant Statutes/Code

Md. Code Ins. Law § 15-142, Md. Code Ins. Law §19–108.2

Insurers, nonprofit health service plans, and health maintenance organizations that provide coverage for prescription drugs may not require step therapy in certain conditions.

### Process and Transparency

The process for requesting an exception must be published on the website of the health plan carrier. Carriers must have a process for accepting requests electronically, and the request must have a unique identification number.

### Codified Circumstances for Step Therapy Exception Approval Include the Following:

- ✓ Step therapy cannot be imposed when a prescriber provides supporting medical information to the carrier that a covered prescription drug was ordered for the insured within the past 180 days, and, based on the professional judgment of the prescriber, was effective in treating the disease or medical condition of the insured.

### Decision Time Limitations

None specified.

### Specified Exclusions

None specified.

## Minnesota

### Relevant Statutes/Code

Minn. Stat. § 62Q.184



Requires a clear and convenient step therapy exception process be available to enrollees and providers. This law does not apply to Medicaid.

### Process and Transparency

The process for requesting an exception must be clear and convenient and must be published on the website of the health plan carrier.

In a denial of an exception request and any subsequent appeal, a carrier's decision must specifically state why the request did not meet the conditions for approval cited and must include information regarding the procedure to request an external review of the denial.

### Codified Circumstances for Step Therapy Exception Approval Include the Following:

- ✓ The preferred drug is contraindicated or will likely cause an adverse reaction by physical or mental harm to the insured;
- ✓ The insured has tried the required prescription drug while under their current or a previous health benefit plan, or another prescription drug in the same pharmacologic class or with the same mechanism of action, and the drug was discontinued by the insureds' health care provider due to lack of effectiveness, or an adverse event; or
- ✓ The insured is currently receiving a positive therapeutic outcome on a prescription drug, while on their current health plan or the immediately preceding health plan.

### Decision Time Limitations

Insurers must render a decision within five calendar days for nonurgent claims and 72 hours for urgent claims.

### Specified Exclusions

Pharmacy drug samples shall not be considered trial and failure of a preferred drug in lieu of trying the step-therapy-required preferred drug. The law does not prevent an insurer requiring an insured to try a generic equivalent drug prior to providing coverage for the equivalent branded prescription drug.

## Mississippi



### Relevant Statutes/Code

Miss. Code. Ann. § 83-9-36

Requires a clear and convenient step therapy exception process that applies to all insurers or carriers that administer health benefit plans.

### Process and Transparency

The process must be clear and convenient.

### Codified Circumstances for Approval

Step therapy exceptions may be approved when the prescribing practitioner can demonstrate, based on sound clinical evidence, that the preferred drug required under step therapy:

- ✓ Has been ineffective in the treatment of the insured's disease or medical condition;
- ✓ Is expected or likely to be ineffective based on the known relevant physical or mental characteristics of the insured and known characteristics of the drug regimen; or
- ✓ Will cause or will likely cause an adverse reaction or other physical harm to the insured.

### Decision Time Limitations

None specified.

### Specified Exclusions

None specified.

## Missouri



### Relevant Statutes/Code

Mo. Rev. Stat. § 376.2034

Requires a clear and convenient step therapy exception process applicable to all carriers.

### Process and Transparency

The process must be clear, convenient, and readily accessible. The process for requesting an exception must be published on the website of the health plan carrier.

### Codified Circumstances for Step Therapy Exception Approval Include the Following:

- ✓ The insured has tried the step therapy required prescription drugs while under his or her current or previous health insurance or health benefit plan and such prescription drugs were discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

### Decision Time Limitations

None specified.

### Specified Exclusions

Pharmacy drug samples shall not be considered trial and failure of a preferred prescription drug in lieu of trying the step therapy required prescription drug. The law does not prevent an insurer from requiring an insured to try a generic equivalent prior to providing coverage for the equivalent branded prescription drug.

## New Mexico

### Relevant Statutes/Code

N.M. Stat. Ann. § 13-7-18

Requires a clear and convenient step therapy exception process for all state-regulated health plans, including Medicaid.

### Process and Transparency

The process for requesting an exception must be published on the website of the health plan carrier.

### Codified Circumstances for Step Therapy Exception Approval Include the Following:

- ✓ The required drug is contraindicated or will likely cause an adverse reaction by or physical or mental harm to the insured;
- ✓ The required drug is expected to be ineffective based on the known clinical characteristics of the insured and the known characteristics of the prescription drug regimen;
- ✓ While under the insured's current or previous health coverage, the insured has tried the preferred drug or another drug in the same pharmacologic class or with the same mechanism of action and that drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event; or
- ✓ The required drug is not in the best interest of the insured, based on clinical appropriateness, because the insured's use of the prescription drug is expected to cause a significant barrier to compliance with the insured's plan of care, worsen the insured's condition, or decrease the insured's ability reasonably perform daily activities.

### Decision Time Limitations

Insurers must render a decision in 72 hours or 24 hours in an emergency.

### Specified Exclusions

The law does not prevent an insurer from requiring an insured to try a generic equivalent prior to providing coverage for the equivalent branded prescription drug.



## New York

### Relevant Statutes/Code

N.Y. ISC § 4903, N.Y. PBH § 4903



Requires a step therapy exception process. Applies to all insurers or carriers that administer health benefit plans.

### Process and Transparency

None specified.

### Codified Circumstances for Step Therapy Exception Approval Include the Following:

- ✓ The required drug is contraindicated or will likely cause an adverse reaction by or physical or mental harm to the insured;
- ✓ The required drug is expected to be ineffective based on the known clinical history and conditions of the insured and the insured's prescription drug regimen;
- ✓ The insured has tried the required drug while under their current or previous health insurance, or another prescription drug in the same pharmacologic class or with the same mechanism of action and such drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;
- ✓ The insured is stable on a drug or drugs selected by their health care professional for the medical condition under consideration, provided that this shall not prevent an insurer from requiring an insured to try a generic equivalent prior to providing coverage for the equivalent brand name prescription drug; or
- ✓ The required drug is not in the best interest of the insured because it will likely cause a significant barrier to the insured's adherence to their plan of care, will likely worsen the insured's condition, or will likely decrease the insured's ability to reasonably perform daily activities.

### Decision Time Limitations

Requires insurers to render a decision in 72 hours or 24 hours in an emergency.

### Specified Exclusions

None specified.

## Ohio



### Relevant Statutes/Code

Ohio Rev. Code § 3901.832, Ohio Rev. Code § 5164.7514

Requires a step therapy exception process, and applies to commercial health plans issuers and Medicaid.

### Process and Transparency

The process for requesting an exception must be published on the website of the health plan carrier.

### Codified Circumstances for Step Therapy Exception Approval Include the Following:

- ✓ The preferred drug is contraindicated for the insured;
- ✓ The patient has tried the preferred drug while under their current, or a previous, health benefit plan, or another U.S. Food and Drug Administration approved AB-rated prescription drug, and the drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event; or
- ✓ The patient is stable on a prescription drug selected by the patient's health care provider for the medical condition under consideration, regardless of whether or not the drug was prescribed when the patient was covered under the current or a previous health benefit plan or has already gone through a step therapy protocol.

### Decision Time Limitations

Requires insurers to render a decision in ten calendar days for nonurgent requests or 48 hours for urgent requests.

### Specified Exclusions

The law does not prevent an insurer from requiring an insured to try a generic equivalent prior to providing coverage for the equivalent branded prescription drug.

## Oklahoma



### Relevant Statutes/Code

Oklahoma Engrossed Senate Bill 509, Laws of 2019<sup>44</sup>

Requires step therapy exception process be available for any health insurance plan that restricts coverage of a prescription drug for the treatment of any medical condition pursuant to a step therapy protocol.

Applies to health plans delivered, issued for delivery, or renewed on or after January 1, 2020.

### Process and Transparency

A clear and convenient step therapy exception process must be accessible on the carrier's website.

### Codified Circumstances for Step Therapy Exception Approval Include the Following:

- ✓ The preferred drug is contraindicated or will likely cause an adverse reaction or physical or mental harm to the patient;
- ✓ The preferred drug is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the drug;
- ✓ The insured has tried the preferred drug while under the current or a previous health insurance plan and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event;
- ✓ The preferred drug is not in the best interest of the insured, based on medical necessity; or
- ✓ The insured is stable on a drug selected by their healthcare provider for the medical condition under consideration while on the current or a previous health insurance plan.

### Decision Time Limitations

Requires insurers to render a decision in 72 hours for nonurgent requests or 24 hours for urgent requests.

### Specified Exclusions

Drug samples shall not be considered trial and failure of a preferred prescription drug in lieu of trying the step therapy required prescription drug.

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<sup>44</sup> ESB 509 was signed by the governor on April 16, 2019. As of May 15, 2019, it has not been added to Oklahoma Statutes. Specific numbering may change, but it will likely be added to Oklahoma Statutes as Section 7310 of Title 63.

## Oregon

### Relevant Statutes/Code

Or. Rev. Stat. § 743B.602



Carriers that require step therapy must make a step therapy exception process available to prescribing health providers.

### Process and Transparency

The process must be easily accessible.

### Codified Circumstances for Approval

The provider must submit their rationale for determining that a particular step therapy protocol is not appropriate for a particular insured based on the insured's medical condition and history. Conditions for approval are not delineated.

### Decision Time Limitations

None specified.

### Specified Exclusions

None specified.

## Texas

### Relevant Statutes/Code

Tex. Ins. Code § 1369.0546



Requires a user-friendly step therapy exception process.

### Process and Transparency

Exception requests shall be submitted by providers on behalf of the insured on a standard form.

### Codified Circumstances for Step Therapy Exception Approval Include the Following:

- ✓ The preferred drug is contraindicated, will likely cause an adverse reaction in or physical or mental harm to the insured, or is expected to be ineffective based on the known clinical characteristics of the insured and the known characteristics of the prescription drug regimen;
- ✓ The insured previously discontinued taking the preferred drug under the protocol or another drug in the same pharmacologic class or with the same mechanism of action while under the current or prior health benefit plan because the drug was not effective or had a diminished effect or because of an adverse event;
- ✓ The required drug is not in the best interest of the insured because it will likely cause a significant barrier to the insured's adherence to their plan of care, will likely worsen the insured's condition, or will likely decrease the insured's ability to reasonably perform daily activities; or
- ✓ The insured is stable on another prescribed drug and the change the required step therapy drug is expected to be ineffective or cause harm to the insured based on the known clinical characteristics of the insured and characteristics of the required drug regimen.

### Decision Time Limitation

Requires insurers to render a decision in 72 hours or 24 hours in an emergency.

### Specified Exclusions

None specified.

## Virginia



### Relevant Statutes/Code

Va. Code § 38.2-3407.9:05

Requires step therapy exception process be available for any health insurance plan that restricts coverage of a prescription drug for the treatment of any medical condition pursuant to a step therapy protocol.

Applies to health plans delivered, issued for delivery, or renewed on or after January 1, 2020. Does not apply to Medicaid, Medicare, or CHIP.

### Process and Transparency

The step therapy exception process shall be made easily accessible on the carrier's or utilization review organization's website.

### Codified Circumstances for Step Therapy Exception Approval Include the Following:

- ✓ The preferred drug is contraindicated;
- ✓ The preferred drug would be ineffective based on the known clinical characteristics of the insured and the known characteristics of the drug regimen;
- ✓ The insured has tried the step therapy-required prescription drug while under their current or a previous health benefit plan and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event; or
- ✓ The insured is currently receiving a positive therapeutic outcome on a prescription drug recommended by his provider for the medical condition under consideration while on a current or the immediately preceding health benefit plan.

### Decision Time Limitations

Requires insurers to render a decision in 72 hours, including weekends, for nonurgent requests or 24 hours, including weekends, for urgent requests.

### Specified Exclusions

Drug samples shall not be considered trial and failure of a preferred drug.

This law shall not be construed to prevent a carrier or utilization review organization from requiring an enrollee to try a generic equivalent or interchangeable biological product prior to providing coverage or substitute a generic for a branded drug.

## West Virginia



### Relevant Statutes/Code

W. Va. Code § 33-16-3aa

Requires a clear and convenient step therapy exception process for health plan issuers.

### Process and Transparency

The exception process shall be made easily accessible on the health plan issuer's or utilization review organization's website. The health plan issuer or utilization review organization must provide a prescription drug for the treatment of the medical condition at least until the determination is made.

### Codified Circumstances for Step Therapy Exception Approval Include the Following:

- ✓ The preferred drug is contraindicated or will likely cause an adverse reaction by or physical or mental harm to the insured;
- ✓ The preferred drug is expected to be ineffective based on the known relevant physical or mental characteristics of the insured and the known characteristics of the drug regimen;
- ✓ The insured has tried the preferred drug while under their current or previous health insurance or health benefit plan, or another drug in the same pharmacologic class or with the same mechanism of action and such drug was discontinued due to a lack of efficacy or effectiveness, diminished effect, or an adverse event;
- ✓ The preferred drug is not in the best interest of the insured, based upon medical appropriateness; or
- ✓ The insured is stable on a drug selected by their health care provider for the medical condition under consideration.

### Decision Time Limitations

None specified.

### Specified Exclusions

The law does not prevent an insurer from requiring an insured to try a generic equivalent prior to providing coverage for the equivalent branded prescription drug.

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