



Step Therapy and Grassroots Advocacy

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What is Step Therapy?



Step Therapy

A POSITION STATEMENT
from the Alliance for Patient Access

OVERVIEW

To get the medicine prescribed by their health care provider, patients must first prove that older, less expensive or insurer-preferred alternatives don't work. That's the crux of step therapy, or "fail first."

In some cases, step therapy makes sense. A logical progression of treatment options may represent best practice for certain diseases or reflect the wisdom of clinical guidelines.

In other cases, step therapy can be excessive, arbitrary and even damaging to patients' health. Insurers may use step therapy as a deliberate access hurdle meant to protect their own profits.

Doing so hurts patients, whose condition may worsen or who may suffer unnecessarily in the process of failing insurer-preferred treatments. It also undermines the relationship between the physician and patient, to whom treatment decisions rightfully belong.

POSITION

The Alliance for Patient Access presents the following principles for step therapy and the laws that govern insurers' use of it:

- 1 Step therapy must be rooted in clinical evidence.** If insurers dictate a progression of treatment options, they must be able to trace their requirement to clinical guidelines from relevant medical associations. Insurers should not be able to require therapies that are inappropriate or unproven for the condition being treated.
- 2 Repeated failures are inappropriate.** Patients who have tried a treatment with a previous insurer should not be asked to fail on the same drug again just to satisfy the new insurer's requirement.
- 3 Insurers must offer a straightforward exemption process.** Some patients will have allergies, side effects, comorbidities or other health factors that render a step therapy protocol inappropriate. They and their health care providers need a straightforward process for bypassing the requirement.
- 4 Insurers' communication must be timely and clear.** Delays associated with step therapy can impact a patient's life and health. That means that responses to a patient's request for a step therapy exemption should occur within a reasonable timeframe. Similarly, details about the exemptions process should be readily available and in plain language for patients and health care providers to access.

With these safeguards in place, legislators can ensure that insurers do not overuse or misuse step therapy to the detriment of patient health.

Grassroots Advocacy

- **Local Coalition**
- **Patient and provider stories**
- **In-person (or virtual) testimony**
- **Written testimony and sign-on letters**
- **Social media support and outreach**



Model Legislation

2020 Regular Session
HOUSE BILL NO. 263
BY REPRESENTATIVE HUVAL

ENROLLED
ACT No. 181

1 AN ACT
2 To amend and reenact R.S. 22:1053, relative to coverage of step therapy or fail first
3 protocols; to provide for clinical review criteria and use of clinical practice
4 guidelines to be used as minimum standards in developing a step therapy or fail first
5 protocol; to provide for clarification on providers lawfully allowed to prescribe; to
6 provide for an override request process for restricted prescription drugs; to provide
7 for override clinical evidence; to provide for decision-making timelines; to provide
8 for appeal rights; to provide for definitions; to provide for application; to provide for
9 effectiveness; to provide for technical changes; and to provide for related matters.
10 Be it enacted by the Legislature of Louisiana:
11 Section 1. R.S. 22:1053 is hereby amended and reenacted to read as follows:
12 §1053. Requirement for coverage of step therapy or fail first protocols
13 A.(1) Any health coverage plan specified in Subsection H 1, of this Section
14 which includes prescription benefits as part of its policy or contract, which utilizes
15 step therapy or fail first protocols, and which is issued for delivery, delivered,
16 renewed, or otherwise contracted for in this state on or after January 1, 2011, shall
17 comply with the provisions of this Section.
18 (2) The provisions of this Section shall not be construed to prohibit the
19 substitution of an AB-rated generic equivalent or interchangeable biological product
20 as designated by the federal Food and Drug Administration.
21 B.(1) Any step therapy or fail first protocol established by a health coverage
22 plan shall consider clinical review criteria and clinical practice guidelines that are

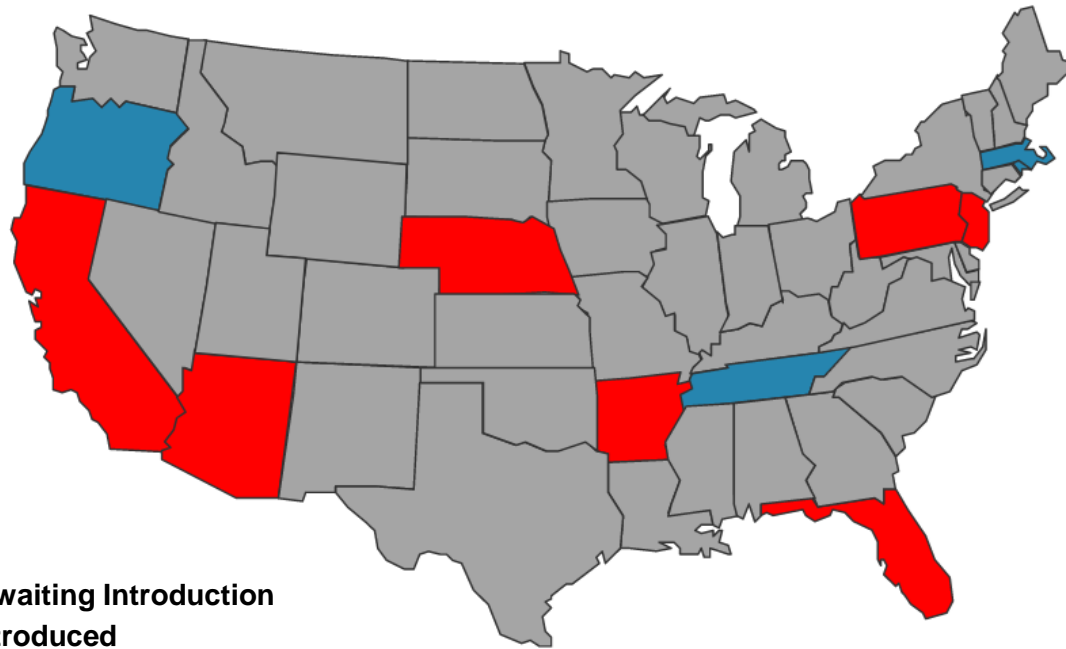
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CODING: Words in struck through type are deletions from existing law; words underscored are additions.

- Clinical review criteria and use of clinical practice guidelines from peer reviewed entities
- Clarification on what treatments have step therapy protocols
- Transparent decision-making timelines and clear appeals process
- Reporting requirements

Successes and Target States

- 3 step therapy bills passed in 2020 (LA, NC, SD)
- Now over 50% of states have passed step therapy legislation



Federal Step Therapy Efforts

- Safe Step Act - H.R. 2279/ S. 2546 (116th Congress)
- Yet to be officially introduced in the 117th Congress, but introduction is expected soon.

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116TH CONGRESS
1ST SESSION **H. R. 2279**

To amend the Employee Retirement Income Security Act of 1974 to require a group health plan (or health insurance coverage offered in connection with such a plan) to provide an exceptions process for any medication step therapy protocol, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 10, 2019

Mr. RUIZ (for himself and Mr. WENSTRUP) introduced the following bill; which was referred to the Committee on Education and Labor

A BILL

To amend the Employee Retirement Income Security Act of 1974 to require a group health plan (or health insurance coverage offered in connection with such a plan) to provide an exceptions process for any medication step therapy protocol, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Safe Step Act”.

Questions?

If you have questions regarding step therapy efforts in the states or questions on other Utilization Management Tool efforts, please contact me at chusser@allianceforpatientaccess.org