Step Therapy and Grassroots Advocacy

Charlie Husser, State and Federal Policy, Alliance for Patient Access
What is Step Therapy?

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.

AllianceforPatientAccess.org
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

- 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.
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