Step Therapy Reform: Increased Reporting and Transparency

What is step therapy?

Step therapy policies, also referred to as "fail first," require insured individuals to try and fail on alternative treatments, sometimes with adverse effects, before the insurer or pharmacy benefit manager will cover the prescribed treatment.

Why is it a problem?

Step therapy policies can be unethical and inconsistent with sound scientific and clinical evidence, resulting in interference with the practitioner-patient relationship and significant delays in access to prescribed treatments.

For some patients step therapy requirements can be especially burdensome because they need individualized care, and taking alternative treatments may not be in their best interest.[1] This could be due to lack of efficacy, lack of therapeutic equivalence, the patient's preference regarding the medication and its associated side effects, or clinical characteristics unique to the patient that necessitate one treatment over another.[2] Yet, the time that the patient spends trying and failing on the alternative treatment could cause the patient's condition to progress or relapse due to the treatment's ineffectiveness.[3]

For example, patients with progressive diseases, such as cancer or macular degeneration, may need immediate access to specific treatments depending on comorbidities, potential medication interactions, or intolerances.[4] If these patients do not receive that particular treatment, their condition could progress, which could result in death in the case of cancer and irreversible blindness in the case of macular degeneration.[5]

What is the current law?

On December 31, 2016, NY passed its step-therapy law, which includes the following key protections:

- Utilization review agents must utilize evidence-based and peer-reviewed clinical review criteria when establishing a step therapy protocol
- The clinical review criteria must be appropriate for the patient's medical condition when conducting the utilization review
- An exception request must be approved within 72 hours if:
    - The required treatment is likely to cause harm to the patient
    - The required treatment is expected to be ineffective
    - The patient has tried and failed on the required treatment while enrolled in their current

[1] https://aimedalliance.org/wp-content/uploads/2018/10/Aimed-Alliance-Primary-Care-Survey-Report.pdf
[2] https://aimedalliance.org/wp-content/uploads/2018/10/Aimed-Alliance-Step-Therapy-in-Medicare-Advantage-Plans-Fact-Sheet.pdf
[3] https://aimedalliance.org/wp-content/uploads/2018/10/Aimed-Alliance-Step-Therapy-in-Medicare-Advantage-Plans-Fact-Sheet.pdf
[4] https://www.asrs.org/advocacy/step-therapy
[5] https://www.asrs.org/advocacy/step-therapy

or previous health plan
    - The patient is stable on a treatment
    - The required treatment is not in the patient's best interest
- An exception request must be approved within 24 hours if a patient has a medical condition that places his or her health in serious jeopardy without the treatment prescribed by the patient's health care professional
- If a utilization review agent fails to act on a step therapy protocol exception request within the required timeframe, the exception request is deemed approved[6]

The law became effective on January 1, 2017 and required compliance of plans issued or renewed after January 1, 2017 (i.e., full compliance by January 1, 2018). The current law applies to all state-regulated commercial plans, such as exchange plans, Medicaid managed care plans, and Child Health Plus plans.

What are we requesting?

We are requesting that insurers and utilization review agents report and make publicly available certain information on step therapy override requests and outcomes. This includes the number of requests, approvals, and reversals, plus the results of external reviews and appeals, the specialties impacted, and any savings the plan received from step therapy. Furthermore, we are asking that plans publish their step therapy policies and protocols on their website.

Why are we requesting it?

Transparency and reporting requirements are essential to understand whether insurers are complying with the law and allows patients and providers equal access to information. A recent Aimed Alliance survey found that more than half of surveyed health care professionals do not believe the current law made a significant difference in the frequency of step therapy exception denials, and almost half of respondents reported plans frequently required patients to try and fail on the same medication more than once, in violation of the current law. Publication of step therapy data will allow the patients, providers, and policymakers the opportunity to monitor for potential violations of the law and identify room for improvement.

Making the information public knowledge also provides patients and providers easy access to the information necessary to file complaints, request overrides, and plan for efficient treatment. Few providers found the new law simplified or reduced the prior authorization paperwork and process, imposing a high cost on providers attempting to navigate the exceptions on behalf of their patients. A public protocol and policy will allow efficient use of provider time, as well as setting the clear expectations of the insurer.

[6] N.Y. INS. LAW § 4903, available at https://www.nysenate.gov/legislation/laws/ISC/4903.