



## **Step Therapy Reform: Strengthening Enforcement and Patient Protections to Deter Step Therapy Violations**

### ***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.<sup>1</sup> 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.<sup>2</sup> 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.<sup>3</sup>

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.<sup>4</sup> 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.<sup>5</sup>

### ***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

---

<sup>1</sup> <https://aimedalliance.org/wp-content/uploads/2018/10/Aimed-Alliance-Primary-Care-Survey-Report.pdf>

<sup>2</sup> <https://aimedalliance.org/wp-content/uploads/2018/10/Aimed-Alliance-Step-Therapy-in-Medicare-Advantage-Plans-Fact-Sheet.pdf>

<sup>3</sup> <https://aimedalliance.org/wp-content/uploads/2018/10/Aimed-Alliance-Step-Therapy-in-Medicare-Advantage-Plans-Fact-Sheet.pdf>

<sup>4</sup> <https://www.asrs.org/advocacy/step-therapy>

<sup>5</sup> <https://www.asrs.org/advocacy/step-therapy>

- The required treatment is expected to be ineffective
- The patient has tried and failed on the required treatment while enrolled in their current 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<sup>6</sup>

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 asking for more stringent protections for patients, including prohibitions against requiring patients to: (1) step through off-label drugs; (2) try and fail on more than one drug; (3) go through step therapy for longer than 30 days; and (4) go through step therapy again if a patient previously received approval for coverage for the prescribed drug after a formulary change. Furthermore, we are asking that step therapy approvals remain valid for twelve (12) months following the date of approval or renewal of the plan, whichever is longer. Finally, we are asking for an increase in the penalty for noncompliance, with a minimum of \$1,000 fine for each offense, and \$2,500 fine for each knowing or intentional offense, with a minimum penalty of at least \$25,000 for any knowing offenses.

### ***Why are we requesting it?***

Providing additional patient protections are necessary to ensure patients do not need to try and fail repeatedly on medications that were not prescribed to them. Step therapy protocols that ignore prior failures can result in significant medical harm to patients.

Finally, increased enforcement fines are necessary to deter violations, as current fine levels are insignificant and ineffective. Aimed Alliance's survey also found that almost half of providers reported plans frequently requiring patients to try and fail on the same medication more than once, in violation of the current law. Many respondents also reported that insurers do not meet their legally required time limits. Increased fines will deter plans from violating the law and incentivize proactive improvements to plan's step therapy processes.

---

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