Step Therapy Reform: Clinical Peer Review of Step Therapy Decision Making

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

[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

- 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[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 asking that commercial plans utilize a physician who specializes in the condition when making any step therapy determinations.

Why are we requesting it?

Utilizing a clinical peer reviewer familiar with the condition at hand ensures that any step therapy determination is made with the specific medical needs of the patient in mind. Any step therapy decisions should focus on the medical needs of the patient and utilizing physicians familiar with the medical condition at issue will ensure any decision contemplates all necessary clinical considerations.

Previously, some plans have utilized nurse practitioners who were completely unfamiliar with the underlying conditions. This led to improper denials of care, as significant clinical considerations were ignored. The use of physicians who are familiar with the underlying conditions will prevent improper denials of care.

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