

2023 NEW YORK STEP THERAPY REFORM

Step therapy, also known as "fail first" protocols, requires individuals to try and fail on alternative treatments, specified by a health plan prior to the health plan covering the treatment that the healthcare provider originally prescribed. This may result in adverse health effects, progression of irreversible diseases, and other complications.

In 2017, New York enacted statutory changes to reform the step therapy process. The law included some patient protections and additional requirements for insurance plans to follow when implementing step therapy protocols.

However, according to a recent survey from Aimed Alliance, New Yorker's still find the step therapy process to be burdensome and harmful to New Yorkers.

Since 2019, Aimed Alliance has worked with a group of nonprofit patient advocacy groups and professional associations to determine how the current New York Step Therapy law could be improved to better protect patient access to the medications they need. After many discussions, the following four bills were developed to help ensure patients in New York had access to their life-saving treatments.

PROTECTED CLASSES

Currently, step therapy can interfere with the prescriber-patient relationship and delays access to necessary medical care, which can negatively impact patients' health. This is especially true for those with progressive diseases who require timely access to their prescribed treatment to avoid advancing the condition and potentially causing irreversible harm.

S.2682/A.582:

Would prevent plans from implementing step therapy policies for certain progressive diseases, including the following therapeutic categories:



Dermatology



Oncology



Gastroenterology



Ophthalmology



Hematology



Rheumatology



Neurology

REPORTING REQUIREMENTS

Reporting requirements are essential to understand whether insurers are complying with the law. It also allows patients and providers equal access to information. Publication of step therapy data also provides patients, health care professionals, and policymakers the opportunity to identify potential violations of the law and room for improvement.

S.2800/A.1384:

This legislation would require insurers and utilization review agents to report to the Department of Financial Services (DFS) and make publicly available certain information on step therapy override requests, appeals, and their outcomes, including:

- Number of step therapy override requests, approvals, and reversals;
- Results of appeals;

- · Specialties impacted; and
- Any savings the plan received from step therapy.

TRANSPARENCY

Providing information on step therapy protocols allows patients to make informed decisions when selecting a health plan. It also allows patients and health care professionals to more easily request step therapy overrides and appeals and plan for efficient treatment.

S.2677 /A.463:

Would require plans to establish a written procedure to ensure that notice of an adverse step therapy determination includes:

- The reason for the determination;
- Instructions to appeal; and
- · Information on alternative covered medications, applicable clinical review criteria, and other necessary information.



PATIENT PROTECTIONS & ENSURING ACCESS

These additional patient protections are intended to ensure that patients do not need to try and fail repeatedly on inappropriate medications and that step therapy protocols to do not cause significant delays in access to the prescribed medication. Step therapy protocols that ignore prior failures or cause long delays can result in adverse events, including disease progression and relapse.

S.1267/A.901

Prohibit plans and utilization review agents from requiring the following when establishing a step therapy protocol:

- Stepping through an off-label medication;
- Trying and failing on more than one drug before covering the prescribed medication;
- Using the insurance plan's preferred drug for longer than 30 days;
- Imposing step therapy if the patient has been on the prescribed drug within the past year;

Additionally, this legislation would require plans to:

 Accept an attestation from the patient's prescriber that the required drug has failed as evidence of such failure; and

- Repeating step therapy for a prescribed drug if the patient already completed step therapy for the drug under a prior health plan; and
- Imposing step therapy for a previously approved drug after the plan implements a formulary change impacting the prescribed drug.
- Honor a step therapy override for 12 months following an override approval or renewal of the plan, whichever is longer.



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