

Proposed Amendments to New York's Step Therapy Law

In 2017, New York passed <u>legislation</u> to reform the step therapy process. The law included strong patient protections. However, according to a <u>recent survey</u> from Aimed Alliance, New York health care practitioners still find the step therapy process to be burdensome and harmful for patients. In 2021, Aimed Alliance 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. In 2023, Senator Breslin and Assembly Member McDonald introduced the following four bills to fix the gaps in the New York Step Therapy Law:

I. PROTECTED CLASSES – <u>S.2682</u> /<u>A.582</u>

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

- Dermatology
- Gastroenterology
- Hematology
- Neurology
- Oncology
- Ophthalmology
- Rheumatology

Rationale: Step therapy interferes with the prescriber-patient relationship and delays access to necessary 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.

II. REPORTING REQUIREMENTS – <u>S.2800/A.1384</u>

Request: 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
- Any savings the plan received from step therapy

Rationale: 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 the patients, health care professionals, and policymakers the opportunity to identify potential violations of the law and room for improvement.

III. TRANSPARENCY – <u>S.2677</u> /<u>A.463</u>

Request:

- Require plans to establish a written procedure to assure that notice of an adverse step therapy determination includes:
 - The reason for the determination
 - Instructions to appeal
 - Information on alternative covered medications, applicable clinical review criteria, and other necessary info

Rationale: 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.

IV. RULES – <u>S.1267</u> /<u>A.901</u>

Request:

- 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 plan's preferred drug for longer than 30 days;
 - Imposing step therapy if the plan enrollee has been on the prescribed drug within the past year
 - Repeating step therapy for a prescribed drug if the plan enrollee already completed step therapy for the drug under a prior health plan
 - Imposing step therapy for a previously approved drug after the plan implements a formulary change impacting the prescribed drug
- Require plans to
 - Accept an attestation from the plan enrollee's prescriber that the required drug has failed as evidence of such failure
 - Honor a step therapy override for 12 months following an override approval or renewal of the plan, whichever is longer
 - Consider a utilization review agent's failure to comply with the step therapy law grounds for automatically granting an override

Rationale: 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.

