



## **New York Step Therapy Alliance Roundtable Discussion**

### **EXECUTIVE SUMMARY**

#### **I. Introduction**

On October 17, 2022, the New York Step Therapy Alliance hosted a roundtable meeting to discuss the current state of step-therapy law and reform efforts in New York; the impact of step-therapy on patients; how step-therapy protocols can be inconsistent with clinical best practices; health care providers' perspectives and experiences; and how to achieve legislative success in 2023. The New York Step Therapy Alliance is a group of likeminded organizations that advocates on behalf of patients with chronic conditions and supports limiting the interference of step-therapy protocols on patient access to their necessary treatments.

The roundtable meeting included a brief presentation by Aimerd Alliance counsel, Ashira Vantrees, on step therapy laws and legislation in New York; a discussion by patient advocacy groups regarding the use of step therapy policies; and a conversation with Senator Neil Breslin and Assemblymember John McDonald on the need for step-therapy reform in New York.

Patient advocacy groups that participated in the roundtable meeting include Aimerd Alliance, the Mental Health Association in NYS, the National Alliance on Mental Illness, the New York State Bleeding Disorder Coalition, the National Psoriasis Foundation, the Epilepsy Foundation of Northeastern New York, the New York Chapter of the American College of Physicians, the New York State Academy of Family Physicians, New York State Rheumatology Society, the Medical Society of the State of New York, and National Multiple Sclerosis Society.

#### **II. Background on Step Therapy Laws and Legislation in New York**

After introductions by the roundtable meeting attendees, Aimerd Alliance counsel, Ashira Vantrees, began the meeting with an overview of New York's existing step-therapy law as well as step-therapy reform efforts during the 2022 legislative session by Senator Breslin and Assemblymember McDonald.

Step therapy policies, also referred to as "fail first," require insured individuals to try and fail on alternative treatments before the insurer or pharmacy benefit manager will cover the prescribed treatment. These policies can be unethical and inconsistent with sound scientific and clinical evidence and interfere with the practitioner-patient relationship and create significant delays in access to prescribed treatments.

In 2016, New York passed a step-therapy law to establish certain requirements related to health insurer's use of step-therapy in the state. The law requires health insurers to grant an override of a step-therapy protocol when a health care provider can demonstrate (1) the treatment is contraindicated or will likely cause an adverse reaction by mental or physical harm to the patient; (2) the treatment is expected to be ineffective based on the patient's known clinical history and condition; (3) the treatment has been previously tried and discontinued by the patient due to lack of efficacy, effectiveness, or an adverse event; (4) the patient is currently stable on



their medication; or (5) the treatment is not in the best interest of the patient.<sup>1</sup> Additionally, the 2016 step-therapy law requires that a health plan respond to a step-therapy override request within 72 hours, or 24 hours during emergencies. Further, the law requires that step-therapy protocols be based on peer-reviewed and evidence-based clinical criteria that considers the needs of atypical patients.<sup>2</sup>

While the 2016 step-therapy law was a big step in the right direction for protecting patients in New York, the law has several gaps. To address these gaps, Senator Breslin and Assemblymember McDonald introduced four step-therapy reform bills (“Reform Bills”) during the 2022 legislative session; however, they did not pass during that session. First, [S.8193/A.9250](#) would have prevented plans from implementing step-therapy policies for certain progressive diseases, including those in the following therapeutic categories: dermatology, gastroenterology, hematology, neurology, oncology, ophthalmology, and rheumatology.<sup>3</sup> Second, [S.8191/A.9267](#) would have prohibited step-therapy protocols from requiring patients to step through an off-label medication; trying and failing on more than one drug before covering the original prescription; requiring patients to fail on a drug for more than 30 days; and requiring patients to try a drug they have previously failed on.<sup>4</sup> Third, [S.8798/A.9206](#) would have required health plans to report to the Department of Financial Services (DFS) the number of step-therapy override requests, approvals, and reversals; results of appeals; specialties impacted; and any savings the plan received from step-therapy.<sup>5</sup> Lastly, [S.8194/A.9265](#) would have required health plans to provide certain information to plan enrollees in their claim denial letters, such as the reasons for the denial; instructions on how to appeal; and information on alternative treatments they were being required to step-through.<sup>6</sup>

### **III. Roundtable Discussion**

#### **A. Impact on Patients**

After the review of current step-therapy law and legislation in New York, attendees discussed how patients are currently impacted by step-therapy protocols. Attendees explained that patients with mental health conditions need access to treatments prescribed by their health care providers as quickly as possible. Otherwise, these patients face an increased risk of suicide, homelessness, entry into the criminal justice system, or other dangerous consequences. Moreover, because

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<sup>1</sup> Insurance Law §§ 4900; Public Health Law §§ 4900; Department of Financial Services, *Questions and Answers on Step Therapy Legislation (Chapter 512 of the Laws of 2016)*, [https://www.dfs.ny.gov/apps\\_and\\_licensing/health\\_insurers/qa\\_step\\_therapy\\_legislation](https://www.dfs.ny.gov/apps_and_licensing/health_insurers/qa_step_therapy_legislation).

<sup>2</sup> *Id.*

<sup>3</sup> Senate Bill S8193, <https://www.nysenate.gov/legislation/bills/2021/S8193>; Assembly Bill A9250, <https://www.nysenate.gov/legislation/bills/2021/a9250>.

<sup>4</sup> Senate Bill, S8191, <https://www.nysenate.gov/legislation/bills/2021/s8191>; Assembly Bill, A9267, <https://www.nysenate.gov/legislation/bills/2021/a9267>.

<sup>5</sup> Senate Bill, S8798, <https://www.nysenate.gov/legislation/bills/2021/S8798>; Assembly Bill, A9206, <https://www.nysenate.gov/legislation/bills/2021/a9206>.

<sup>6</sup> Senate Bill, S8194A, <https://www.nysenate.gov/legislation/bills/2021/s8194>; Assembly Bill, A9265, <https://www.nysenate.gov/legislation/bills/2021/a9265>.



mental health treatment relies on person-centered care and not a one-size-fits all approach, it is crucial to give deference to a health care provider’s decision as to the most appropriate treatments and to eliminate unnecessary steps that patients must satisfy before accessing their medications.

### **B. Inconsistency with Reasonable Best Practices**

Next, patient advocacy groups discussed how step-therapy protocols can be inconsistent with the clinical practice guidelines, sound medical knowledge, or reasonable best practices. For instance, many patients with depression and anxiety disorders are prescribed selective serotonin reuptake inhibitors (“SSRIs”). It often takes several months to determine whether an SSRI is effective for a particular patient. As a result, such patients who are subject to step-therapy protocols can continue to experience symptoms for extended periods of time before finding a treatment that works best for them.<sup>7</sup>

One group discussed how patients with psoriasis, a skin condition that causes flaky patches of skin to form scales,<sup>8</sup> can also develop psoriatic arthritis. Studies have found that early intervention and treatment with a biologic can help prevent the development of psoriatic arthritis in patients with psoriasis.<sup>9</sup> However, health plans consistently require patients to first try and fail on lower cost topical treatments before covering biologics. Thus, many attendees reiterated that health care providers are experts in their fields, up to date on the most current research in the field, and understand their patients’ needs. Therefore, their professional opinion on the best course of care should be respected.

### **C. Need for Better Data, Reporting, and Transparency**

Attendees discussed the importance of reporting, data, and transparency on health plans’ use of step-therapy in New York. For patient advocacy organizations, data is incredibly important because it allows organizations to clearly identify how New York step-therapy law is being implemented by health plans. However, health plans currently are not required to report the types of data that can provide such transparency. Attendees recognized that if additional reporting was required, then consumers, patient advocacy groups, and providers could better identify opportunities to engage the New York legislature and regulators if data indicates that health plans are not compliant with state law.

### **D. Health Care Provider Experiences and Perspectives**

Attendees examined health care providers’ experiences and perspectives on step-therapy protocols. Many providers are still experiencing difficulties in receiving step-therapy overrides and filing complaints DFS. Attendees explained that denial letters often do not have a clear

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<sup>7</sup> Tami L. Mark, et al., *The effects of antidepressants step therapy protocols on pharmaceutical and medical utilization and expenditures* (Oct. 2010), <https://pubmed.ncbi.nlm.nih.gov/20713497/>.

<sup>8</sup> National Health System, Psoriasis, <https://www.nhs.uk/conditions/psoriasis/>.

<sup>9</sup> Matthew Gavidia, *Biologic Use May Decrease Risk of Psoriatic Arthritis in Patients With Psoriasis*, <https://www.ajmc.com/view/biologic-use-may-decrease-risk-of-psoriatic-arthritis-in-patients-with-psoriasis>.



rationale for the denial and, when appealed, some health plans do not respond to a request for appeal. Some providers have gone as far as sending plans the text of current step-therapy law and explaining how their request for an override meets the requirements; yet, they still did not receive a response from the plan.

Attendees reported that health plans have sometimes placed the responsibility back on the patient to check if the plan's policy is correct. For example, one attendee reported a case where a plan incorrectly told a patient subject to step-therapy that her treatment was not approved by the FDA to treat her condition. Thus, the patient was required to go back to the plan and demonstrate that the plan was wrong before her step-therapy override was approved.

#### **E. Other Recommendations and Opportunities for Reform in 2023**

Attendees suggested that legislative reforms introduced during the 2023 session should include clearer examples of when step-therapy protocols are inappropriate such as stepping through off-label treatments, trying and failing on a medication for more than 30 days, and trying and failing on more than one medication. Attendees felt that this level of detail could help ensure that legal requirements are explicitly clear to patients, providers, and insurers.

After attendees shared their perspectives and experiences, Senator Breslin and Assemblymember McDonald discussed their support for step-therapy reform and why they introduced the Reform Bills during the 2022 legislative session. Assemblymember McDonald, recalling on his experience as a pharmacist, noted that step-therapy and prior authorization should be expedited processes that do not interfere with a patient's ability to access their treatments. He further recognized that for patients, the diagnostic journey can often be several months, or even years, during which patients are experiencing symptoms without adequate relief. Thus, once a provider identifies a treatment for their patient, the patient should be able to receive that treatment as soon as possible. Assemblymember McDonald stated he intended to support the Reform Bills again during the 2023 session and urged the New York Step Therapy Alliance to engage more legislators to increase the number of cosponsors on the legislation in 2023. Senator Breslin also encouraged the New York Step Therapy Alliance to engage industry, insurance, and patients in discussions surrounding the legislation to determine if, and where, compromises can be made.

#### **IV. Conclusion**

In conclusion, the New York Step Therapy Alliance roundtable meeting provided a valuable opportunity for advocates and lawmakers to discuss the current state of step-therapy law and reform efforts in New York; share perspectives and experiences regarding the impacts and consequences of step-therapy; and explore recommendations and opportunities for future step-therapy reform. The Alliance will be working proactively and reactively with partners to accomplish step-therapy reform during the 2023 legislative session.