

NEW YORK'S AMENDED STEP THERAPY LAW

(Effective January 1, 2026)

2016 Step Therapy Law

On December 31, 2016, the New York legislature passed a step therapy law, which requires:

- Utilization review agents to use evidence-based and peer reviewed clinical review criteria when establishing a step therapy protocol;
- The clinical review criteria to be appropriate for the patient's medical condition when conducting the utilization review; and
- Timelines for approving exception requests within 24 and 72 hours.

An exception request must be approved within 72 hours if:

- The required treatment is likely to cause harm to the patient; or
- The required treatment is expected to be ineffective; or
- The patient is stable on a treatment; or
- 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 treatment prescribed by the patient's health care profession.

2024 Amendments

Building on the 2016 requirements, the New York Legislature passed [A.901\(a\)/S.1267\(a\)](#) in 2024 which prohibits plans and utilization review agents from including the following elements in a step-therapy protocol:

- Stepping through an off-label medication;
- Trying and failing on more than two drugs used to treat the same medical condition or disease before covering the originally prescribed medication;
- Using the insurance plan's preferred drug for more than 30 days or duration of treatment supported by current evidence-based guidelines for the specific disease state being treated;
- Requiring an insured to try and fail when a therapeutic equivalent is unavailable;
- Imposing step therapy for a previously approved drug after the plan implements a formulary change impacting coverage criteria for the prescribed drug (unless a specific safety concern exists) **and** a therapeutic equivalent is available.

Additionally, this legislation would require plans to:

- Accept any written or electronic attestation from the patient's prescriber that the required drug has failed as evidence of such failure;
- Honor a step therapy override for the treatment duration based on current evidence-based guidelines, twelve months, or plan renewal whichever is shorter; and
- Mandate that any failure to comply with the step therapy protocol rules is a reason to bypass the protocol (unless there is fraud).

These requirements will become effective January 1, 2026.