Step Therapy Exception-REG

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

This coverage policy is developed in accordance with the following:

- Illinois: (215 ILCS 134/) Managed Care Reform and Patient Rights Act
- New York: McKinney's Insurance Law § 4902

This policy only applies to the state(s) above. See Appendix for additional details.

Disclaimer: This policy is intended to address specific state and/or regulatory requirements as outlined herein. It is not exhaustive of all federal, state, or local regulatory exceptions or requirements that may apply to the Plan. The Plan remains committed to full compliance with all applicable laws, regulations, and contractual obligations, including but not limited to those not explicitly referenced in this document. Additional regulatory exceptions, requirements, or coverage determinations may be addressed in other Plan policies, procedures, or documents, which are available upon request or as otherwise required by law. For comprehensive information regarding coverage, regulatory exceptions, or Plan obligations, please refer to the member's policy documents or contact the Plan directly.

Definitions

"Clinical Guidelines" are recommendations on how to diagnose and treat a medical condition. They are developed systematically.

"Compendia" are summaries of drug information and medical evidence to support decision-making about the appropriate use of drugs and medical procedures. Compendia extracts from the relevant clinical guidelines. Examples include, but are not limited to:

1. American Hospital Formulary Service Drug Information
2. Elsevier Clinical Pharmacology
3. National Comprehensive Cancer Network Drugs and Biologics Compendium
4. Thomson Micromedex DrugDex
5. United States Pharmacopeia-National Formulary (USP-NF)

"Drug" is defined as:

- A substance recognized by an official pharmacopoeia or formulary*; or*
- A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease*; or*
- A substance (other than food) intended to affect the structure or any function of the body*; or*
- A substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device*; or*
- Biological products are included within this definition and are generally covered by the same laws and regulations, but differences exist regarding their manufacturing processes (chemical process versus biological process.)

"Formulary" means the list of covered pharmaceutical products, developed in consultation with Physicians and pharmacists, approved for their quality and cost effectiveness.

"FDA Indication" refers to specific use for which a drug or device has been formally approved by the U.S. Food and Drug Administration.

"Medical benefit drugs" are those that are given by a health care provider in a health care setting. Examples include drugs given by intravenous infusion such as chemotherapy or immunotherapy infusions. Some drugs can be covered by either the pharmacy benefit or a medical benefit such as vaccines or drugs given by subcutaneous injections.

"Non-formulary" means the list of pharmaceutical products that is not included on a health plan's list of covered products. Access to these products can be obtained through the formulary exception process.

"Pharmacy benefit drugs" are those you can pick up at a drugstore or sent by mail order. Examples include oral antibiotics or antihypertensives. Some drugs can be covered by either the pharmacy benefit or a medical benefit such as vaccines or drugs given by subcutaneous injections.

"Prescription drug" requires a doctor's authorization to purchase.

Coverage Criteria

Illinois

Step Therapy - Quantity

The Plan will NOT impose step therapy for the requested prescription drug when ALL the following criteria are met:

1. The member's plan is issued for Illinois; *AND*
2. The drug is on the formulary; *AND*
3. The class-, drug-, or indication- specific guideline stipulates step therapy that is NOT in the FDA indication or compendia supported for the requested indication.

New York

Step Therapy - Attestation

The Plan will accept any written or electronic attestation submitted by the member's health care professional that a prescription drug has been tried and failed if the member's plan is issued for New York.

Step Therapy - Previous History

The Plan will NOT impose step therapy for the requested prescription drug when ALL the following criteria are met:

1. The member's plan is issued for New York; *AND*
2. The member meets ONE of the following criteria:
    a. There is documentation that the plan has covered the drug for the insured within the past three hundred sixty-five (365) days, unless a therapeutic equivalent to the prescribed drug is available*; or*
    b. The member has already completed a step therapy for the requested drug under a prior plan within the past three hundred sixty-five (365) days*; or*
    c. The member meets ALL of the following criteria:
        i. The requested drug was previously approved for coverage by the plan for a specific medical condition*; and*
        ii. The plan has implemented a formulary change OR utilization management that impacts the coverage criteria for the requested drug*; and*
        iii. The approved override for the requested drug has not expired*; and*
        iv. There is no specifically identified and current evidence-based safety concern AND no different therapeutic alternative drug exists.

Step Therapy - Quantity

The Plan will NOT impose step therapy of MORE than TWO (2) drugs for the requested prescription drug when ALL the following criteria are met:

1. The member's plan is issued for New York; *AND*
2. The drug-, class-, or indication- specific guideline stipulates step therapy on MORE than TWO (2) drugs used to treat the same medical condition or disease.

Step Therapy - Trial Duration

The Plan will NOT impose step therapy trial duration of more than 30 days for the requested prescription drug when ALL the following criteria are met:

1. The member's plan is issued for New York; *AND*
2. The class-, drug-, or indication- specific guideline stipulates step therapy trial duration for more than 30 days AND is NOT supported by compendia.

References

1. 215 ILCS 134/ *et seq.* Available at: https://www.ilga.gov/Legislation/ILCS/Articles?ActID=1265&ChapterID=22. Accessed July 24, 2025.
2. McKinney's Insurance Law § 4902. Available at: https://www.nysenate.gov/legislation/laws/ISC/4902.
3. New York State Senate Open Legislation 1267A. Available at: https://legislation.nysenate.gov/pdf/bills/2023/S1267A. Accessed July 24, 2025.
4. New York State Senate Open Legislation 443. Amendment. Available at: https://legislation.nysenate.gov/pdf/bills/2025/A443. Accessed September 12, 2025.

5. New York State. Questions and Answers on Step Therapy Legislation (Chapter 512 of the Laws of 2016). Available at: https://www.dfs.ny.gov/apps_and_licensing/health_insurers/qa_step_therapy_legislation. Accessed October 2, 2025.
6. UpToDate. Overview of clinical practice guidelines. Available at: https://www.uptodate.com/contents/overview-of-clinical-practice-guidelines. Accessed July 24, 2025.
1. United States Food & Drug Administration. Drugs@FDA Glossary of Terms. Available at: https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms. Accessed August 14, 2025.

Appendix A: Illinois

Table 1: Illinois Law Applicable to this Policy

Law	Description
215 ILCS 134/10 215 ILCS 134/87	• No utilization review program or any policy, contract, certificate, evidence of coverage, or formulary shall impose step therapy requirements. Nothing in this subsection prohibits a health care plan, by contract, written policy, procedure, or any other agreement or course of conduct, from requiring a pharmacist to effect substitutions of prescription drugs consistent with Section 19.5 of the Pharmacy Practice Act, under which a pharmacist may substitute an interchangeable biologic for a prescribed biologic product, and Section 25 of the Pharmacy Practice Act, under which a pharmacist may select a generic drug determined to be therapeutically equivalent by the United States Food and Drug Administration and in accordance with the Illinois Food, Drug and Cosmetic Act. • "Medically necessary" means that a service or product addresses the specific needs of a patient for the purpose of screening, preventing, diagnosing, managing, or treating an illness, injury, or condition or its symptoms and comorbidities, including minimizing the progression of an illness, injury, or condition or its symptoms and comorbidities, in a manner that is all of the following: ○ (1) in accordance with generally accepted standards of care; ○ (2) clinically appropriate in terms of type, frequency, extent, site, and duration; and ○ (3) not primarily for the economic benefit of the health care plan, purchaser, or utilization review organization or for the convenience of the patient, treating physician, or other health care provider. • "Step therapy requirement" means a utilization review or formulary requirement that specifies, as a condition of coverage under a health

Law	Description
	care plan, the order in which certain health care services must be used to treat or manage an enrollee's health condition. ● "Utilization review" means the evaluation of the medical necessity, appropriateness, and efficiency of the use of health care services, procedures, and facilities. ● "Step therapy requirement" does not include: (1) utilization review to identify when a treatment or health care service is contraindicated or clinically appropriate or to limit quantity or dosage for an enrollee based on utilization review criteria consistent with generally accepted standards of care developed in accordance with Section 87 of this Act; (2) the removal of a drug from a formulary or changing the drug's preferred or cost-sharing tier to higher cost sharing; (3) use of the medical exceptions process under Section 45.1 of this Act; any decision during a medical exceptions process based on cost is step therapy and prohibited; (4) a requirement to obtain prior authorization for the requested treatment; or (5) for health care plans operated or overseen by the Department of Healthcare and Family Services, including Medicaid managed care plans, any utilization controls mandated by 42 CFR 456.703 or a preferred drug list as described in Section 5-30.14 of the Illinois Public Aid Code.

Appendix B: New York

Table 2: New York Law Applicable to this Policy

Law	Description
McKinney's Insurance Law § 4902(15), (16)	● When establishing a step therapy protocol, a utilization review agent shall ensure that the protocol cannot: ○ (i) require a prescription drug that has not been approved by the United States Food and Drug Administration for the medical condition being treated or is not supported by current evidence-based guidelines for the medical condition being treated; ○ (ii) require an insured to try and fail on more than two drugs used to treat the same medical condition or disease before providing coverage to the insured for the prescribed drug; ○ (iii) require the use of a step therapy-required drug for longer than thirty days or a duration of treatment supported by

Law	Description
	current evidence-based treatment guidelines appropriate to the specific disease state being treated; ○ (iv) be imposed on an insured if a therapeutic equivalent to the prescribed drug is not available, or if the health care plan has documentation that it has covered the drug for the insured within the past three hundred sixty-five days; ○ (v) require a newly enrolled insured to repeat a step therapy protocol for a prescribed drug where that insured already completed a step therapy protocol for that drug under a prior health care plan, so long as the enrollee or provider submits information demonstrating completion of a step therapy protocol of the prior health care plan within the past three hundred sixty-five days; and ○ (vi) be imposed on an insured for a prescribed drug that was previously approved for coverage by the insured's current health care plan for a specific medical condition after the insured's current health care plan implements a formulary change or utilization management that impacts the coverage criteria for the prescribed drug until the approved override expires, unless a specifically identified and current evidence-based safety concern exists and a different therapeutic alternative drug exists. ● When establishing a step therapy protocol, a utilization review agent shall ensure that the protocol accepts any written or electronic attestation submitted by the insured's health care professional, as defined in section four thousand nine hundred of this title, who prescribed the drug and stating that a required drug has failed, as evidence that the required drug has failed.

Per New York State Insurance Law § 4900(g-9) and Public Health Law § 4903(7-f-3) define a step therapy protocol as a policy, protocol or program established by a utilization review agent that establishes the specific sequence in which prescription drugs for a specified medical condition are approved for an insured.

Clinical Guideline Revision / History Information

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