Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Non-Preferred Insulins

Effective: October 14, 2025

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Insulins are indicated to improve glycemic control in patients with diabetes mellitus. The following non-preferred insulins require prior authorization for coverage:

- **Novolin R (insulin human injection)** is a short-acting human insulin.
- **Novolin N (isophane insulin human suspension)** is an intermediate-acting human insulin.
- **Novolin 70/30 (human insulin isophane suspension and human insulin injection)** is a mixture of 70% of human insulin isophane, an intermediate-acting human insulin, and 30% of human insulin, a short-acting human insulin.
- **Novolog (insulin aspart)** is a rapid-acting human insulin analog
- **Novolog 70/30 (insulin aspart protamine and insulin aspart)** is a human insulin analog containing 70% insulin aspart protamine crystals and 30% soluble insulin aspart.
- **Tresiba (insulin degludec)** is a long-acting basal human insulin analog

The following preferred insulins are covered on our formularies with no restrictions: Humalog, Humalog Mix, Humulin N, Humulin R, Humulin Mix, Lyumjev, Toujeo, and Lantus.

Clinical Guideline Coverage Criteria

Non-Preferred Insulins:

The plan may authorize coverage of a non-preferred insulins when the following criteria are met:

Initial criteria:

1. Patient has tried and failed therapy with ALL comparable formulations of Humulin, Humalog, Lyumjev, Lantus, and Toujeo

OR

2. Patient has contraindication to ALL comparable formulations of Humulin, Humalog, Lyumjev, Lantus, and Toujeo

OR

3. Provider has indicated that the patient would be unable to utilize Humulin, Humalog, Lyumjev, Lantus, and Toujeo because of visual, physical, or functional impairment

Reauthorization criteria:

1. Provider has indicated that the patient has shown improvement or is stable on the requested medication

Limitations

1. Initial approval of a non-preferred insulin will be authorized for 12 months. Reauthorization requests will be approved for 24 months.
2. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

Codes

None

References

1. Novolin R (insulin regular) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; November 2022.
2. Novolin N (isophane insulin human suspension) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; November 2022.
3. Novolin 70/30 (70% human insulin isophane and 30% human insulin) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; November 2022.
4. NovoLog (insulin aspart) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; February 2023.
5. NovoLog Mix 70/30 (70% insulin aspart protamine suspension and 30% insulin aspart injection) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; February 2023.
6. Tresiba (insulin degludec) [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; July 2022.

Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- July 11, 2023: no changes.
- July 9, 2024: Administrative update made to separate out prerequisite trial and contraindication requirements to clarify intent. Effective July 9,2024.
- October 8, 2024: Removed Levemir verbiage from overview section (effective January 1, 2025).
- October 14, 2025: No changes.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.