Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Insulin-Incretin Mimetic Combinations

Effective: April 1, 2026

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

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

Soliqua (insulin glargine, lixisenatide) is a combination of a long-acting human insulin analog with a glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Xultophy (insulin degludec, liraglutide) is a combination of insulin degludec, a long-acting human insulin analog, and liraglutide, a glucagon-like peptide 1 (GLP-1) receptor agonist, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Clinical Guideline Coverage Criteria

Initial Authorization:

The plan may authorize coverage of **Xultophy** or **Soliqua** when the following criteria are met:

1. Patient has Type 2 Diabetes

AND

2. Patient is inadequately controlled on combination therapy with a long-acting insulin (e.g., Lantus, Toujeo, etc), and an incretin mimetic (e.g., Victoza, Byetta, Bydureon, Trulicity, Ozempic, Rybelsus, Mounjaro, etc)

Reauthorization:

1. Patient has Type 2 Diabetes

AND

2. The patient has shown improvement or is stable on the requested medication

Limitations

- The duration of approval for Soliqua and Xultophy is limited to 24 months.
- Members who have already initiated the requested medication using samples, free goods, similar offerings, or self-paying for the medication directly do not qualify for an established clinical response and should be reviewed against initial approval criteria.
- 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. Soliqua (insulin glargine, lixisenatide) [prescribing information]. Sanofi-Aventis U.S. LLC. Bridgewater, NJ. May 2025.
2. Xultophy (insulin degludec, liraglutide) [prescribing information]. Novo Nordisk Inc. Plainsboro, NJ. October 2025.

Approval And Revision History

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

Subsequent endorsement date(s) and changes made:

- March 12, 2024: Administrative edit to add Mounjaro to the list of incretin mimetics (effective 4/1/24).
- March 11, 2025: No changes
- March 10, 2026: No changes. Added limitation statement that members who have already initiated the requested medication using samples, free goods, similar offerings, or self-paying for the medication directly do not qualify for an established clinical response and should be reviewed against initial approval criteria. Administrative update to remove CareLink from the Medical Necessity Guideline template. (effective 4/1/26)

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.