Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:

Lipodystrophy Agents: Egrifta SV (tesamorelin), Egrifta WR (tesamorelin) and Serostim (somatropin)

Effective: October 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

Egrifta SV (tesamorelin) and Egrifta WR (tesamorelin) are growth hormone releasing factor analog indicated for the reduction of excess abdominal fat in human immunodeficiency virus (HIV)-infected adult patients with lipodystrophy.

Serostim (somatropin) is a human growth hormone indicated for the treatment of adults with HIV and wasting or cachexia to increase lean body mass and body weight, and improve physical endurance . Concomitant antiretroviral therapy is necessary.

Clinical Guideline Coverage Criteria

Human Immunodeficiency Virus (HIV)-associated Lipodystrophy

The plan may authorize coverage of Egrifta SV and Egrifta WR for Members when **ALL** of the following criteria are met:

1. Documentation the patient has excess abdominal fat secondary to human immunodeficiency virus (HIV)-associated lipodystrophy

Human Immunodeficiency Virus (HIV)-associated Wasting or Cachexia

The plan may authorize coverage of Serostim for Members when **ALL** of the following criteria are met:

1. Documented diagnosis human immunodeficiency virus (HIV)-associated wasting or cachexia

AND

2. Documentation of **one (1)** of the following:
   a. Unintentional weight loss of at least 10% from baseline
   b. Body mass index less than 20 kg/m^2

AND

3. Documentation that other treatable causes of weight loss have been ruled out (e.g., depression, mycobacterium avium complex, chronic infectious diarrhea)

AND

4. Documentation the patient is concurrently receiving antiretroviral medications indicated for the treatment of human immunodeficiency virus (HIV)

Limitations

1. Authorizations will be provided 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. Egrifta SV (tesamorelin) [prescribing information]. Montreal, Quebec, Canada: Theratechnologies; February 2024.
2. Egrifta WR (tesamorelin) [prescribing information]. Montreal, Quebec, Canada: Theratechnologies; March 2025.
3. Serostim (somatropin) [prescribing information]. Rockland, MA: EMD Serono Inc; July 2026.

Approval And Revision History

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

- June 13, 2023: No changes
- April 9, 2024: No changes
- March 11, 2025: Removed Serostim from coverage criteria for Human Immunodeficiency Virus (HIV)-associated Lipodystrophy (eff 6/1/2025)
- September 9, 2025: Added Egrifta WR to coverage criteria for Human Immunodeficiency Virus (HIV)-associated Lipodystrophy. (eff 10/1/2025)
- September 2026 E-Vote: Administrative update to remove CareLink from the Medical Necessity Guideline template.

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.