Pharmacy Medical Necessity Guidelines:

Tesamorelin Injection (Egrifta SV, Egrifta WR)

Effective: March 10, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION (FDA)-APPROVED INDICATIONS

Egrifta SV (tesamorelin 2 mg vial) and **Egrifta WR (tesamorelin 11.6 mg vial)** is a growth hormone releasing factor analog indicated for the reduction of excess abdominal fat in human immunodeficiency virus (HIV)-infected individuals with lipodystrophy.

Since the long-term cardiovascular safety and potential long-term cardiovascular benefit of Egrifta SV or Egrifta WRtreatment have not been studied and are not known, careful consideration should be given whether to continue Egrifta SV or Egrifta WRtreatment in patients who do not show a clear efficacy response as judged by the degree of reduction in visceral adipose tissue measured by waist circumference or CT scan. Egrifta SV or Egrifta WR is not indicated for weight loss management (weight neutral effect). There are no data to support improved compliance with anti-retroviral therapies in HIV-positive patients taking Egrifta SV or Egrifta WR

COVERAGE GUIDELINES

The plan may authorize coverage of **Egrifta SV (tesamorelin 2 mg vial)** or **Egrifta WR (tesamorelin 11.6 mg vial)** for Members, when the following criterion is met:

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

LIMITATIONS

- Authorizations will be provided for 24 months.

CODES

None

REFERENCES

1. Egrifta SV (tesamorelin) [package insert]. Rockland, MA: EMD Serono Inc.; February 2024.
2. Egrifta WR (tesamorelin) [package insert]. Montreal, Quebec: Theratechnologies, Inc.; March 2025.

APPROVAL HISTORY

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

- June 13, 2023: No changes
- April 9, 2024: No changes
- March 11, 2025: No changes (eff 3/11/25)
- March 10, 2026: Added Egrifta WR to the Medical Necessity Guideline (MNG). Updated MNG title from "Egrifta SV (tesamorelin)" to "Tesamorelin Injection (Egrifta SV, Egrifta WR)" (eff 3/10/26).

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.

Provider Services