

Utilization Management and Clinical Medical Policy

Policy Name: Tesamorelin (Egrifita SV®, Egrifita WR™)	Policy Number: MP-RX-FP-25-23	Scope: <input checked="" type="checkbox"/> MMM MA <input checked="" type="checkbox"/> MMM MultiHealth	Origination Date: 11/30/2023 Last Review Date: 2/22/2026	Effective Date: 2/22/2026 Frequently Revision: 2/22/2027
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Service Category:

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| <input type="checkbox"/> Anesthesia | <input type="checkbox"/> Medicine Services and Procedures |
| <input type="checkbox"/> Surgery | <input type="checkbox"/> Evaluation and Management Services |
| <input type="checkbox"/> Radiology Procedures | <input type="checkbox"/> DME/Prosthetics or Supplies |
| <input type="checkbox"/> Pathology and Laboratory Procedures | <input checked="" type="checkbox"/> Part B Drugs |

Service Description:

This document addresses the use of **Tesamorelin (Egrifita SV®, Egrifita WR™)**, an analog of growth hormone releasing factor (GFR) approved by the Food and Drug Administration (FDA) for the treatment of reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.

Background Information:

Egrifita SV and Egrifita WR are analogs of the growth hormone releasing factor (GRF). GRF, also known as growth hormone-releasing hormone (GHRH), is a hypothalamic peptide that acts on the pituitary somatotroph cells to stimulate the synthesis and pulsatile release of endogenous growth hormone (GH), which is both anabolic and lipolytic (Product Information [PI] Label, 2018). GH exerts its effects by interacting with specific receptors on a variety of target cells, including chondrocytes, osteoblasts, myocytes, hepatocytes, and adipocytes, resulting in a host of pharmacodynamic effects. Some, but not all of these effects are primarily mediated by IGF-1 produced in the liver and in peripheral tissues. GH secretion is stimulated and subsequently increases IGF-1 and insulin-like growth factor binding protein (IGFBP)- 3 levels without clinically significant changes in the levels of other pituitary hormones. Individuals with HIV-associated lipodystrophy and increased VAT have diminished secretion of GH and IGF-1. In HIV-infected individuals, restoring GH and IGF-1 levels can favorably impact increased visceral adipose tissue of HIV-associated lipodystrophy.

Lipodystrophy is a disorder of fat metabolism involving a loss of subcutaneous adipose tissue (SAT) from the face, extremities and buttocks as well as an accumulation of fat around the liver, stomach, and other abdominal organs (visceral adipose tissues [VAT]), and the dorsocervical region, the trunk and the breasts. Lipodystrophy is linked to antiretroviral therapy and is problematic for people with HIV infection (HHS 2014). Lipodystrophy may result from other congenital or acquired conditions. The accumulation of VAT is associated with insulin resistance and dyslipidemia, increasing the risk of diabetes mellitus and coronary artery disease. Strategies to reduce visceral fat may decrease the cardiovascular risk in affected individuals.

Egrifita use is considered **reconstructive**. Reconstructive therapies are intended to address a significant variation from normal. This variation can be related to accidental injury, disease, trauma, treatment of disease or a congenital defect and have no significant functional impairment to the individual. Not all benefit contracts include benefits for reconstructive services. Benefit language supersedes this document.

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Egrifta is available as SV and WR formulations. Egrifta WR is a new formulation set to replace Egrifta SV. Both are administered daily as subcutaneous injections, but Egrifta WR only requires weekly reconstitution while Egrifta SV must be reconstituted daily. These formulations are not substitutable due to differences in strength, dosage, the number of vials required to prepare a dose, reconstitution instructions, and storage requirements.

Approved Indications

- A. Reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy

Other Uses

- A. N/A

Codes Information:

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS	Description
J3590	Unclassified drugs [when specified as Egrifta SV (tesamorelin) or Egrifta WR (tesamorelin)]
C9399	Unclassified biologics [when specified as tesamorelin (Egrifta SV)]

CD-10	Description
B20	Human immunodeficiency virus [HIV] disease
E88.14	HIV-associated lipodystrophy
Z68.22-Z68.70	Body mass index (BMI) 22.0 - >70.0, adult
R73.0-R730.9	Elevated Blood Glucose

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Medical Necessity Guidelines:

When a drug is being reviewed for coverage under a member’s medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Tesamorelin (Egrifta SV[®], Egrifta WR[™])

A. Criteria For Initial Approval

Initial requests may be approved for reconstructive purposes when the following criteria are met:

- i. Individual is age 18 or older (Falutz 2010); **AND**
- ii. Documentation is provided that individual has lipodystrophy associated with HIV (human immunodeficiency virus); **AND**
- iii. Individual is using to reduce excess abdominal visceral adipose tissue (VAT); **AND**
- iv. Documentation is provided that individual has a body mass index (BMI) greater than 20 kg/m² (Falutz 2010); **AND**
- v. Individual has a waist circumference and a waist-to-hip ratio of one of the following (Falutz 2010):
 - A. Documentation is provided that for males, waist circumference ≥ 95 cm and waist-to-hip ratio ≥ 0.94
 - OR**
 - B. Documentation is provided that for females, waist circumference ≥ 94 cm and waist-to-hip ratio ≥ 0.88; **AND**
- vi. Fasting blood glucose (FBG) is less than 150 mg/dL (8.33 mmol/L) (Falutz 2010); **AND**
- vii. Individual has no history of type 1 diabetes or insulin-treated type 2 diabetes (Falutz 2010); **AND**
- viii. Individual has no active malignancy (for example, a potential cancer which is being evaluated or a diagnosed cancer which is being treated) (Falutz 2010); **AND**
- ix. Individual is not currently pregnant or breast-feeding.

B. Criteria For Continuation of Therapy

- a. MMM considers continuation of therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) if the following criterion is met:
 - i. Documentation is provided that individual has exhibited a clear response in reduction of visceral adipose tissue measured by waist circumference or computed tomography (CT) scan; **AND**

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- ii. Documentation is provided that the patient has no significant adverse events with the use of tesamorelin.

C. Conditions not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

- i. Tesamorelin may not be approved for the following:
 - a. Individual has disruption of the hypothalamic-pituitary axis;
OR
 - b. Individual has active malignancy;
OR
 - c. When the above criteria are not met and for all other indications.

D. Authorization Duration

- i. Initial Approval Duration: 1 year
- ii. Reauthorization Approval Duration: 1 year

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Limits or Restrictions

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

- i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Drug	Recommended Dosing Schedule
Egrifta SV [®] inj 2mg/vial	1.4 mg (0.35 ml of the reconstituted solution) sc daily
Egrifta WR [™] inj 11.6 mg/vial	1.25 mg (0.16 ml of the reconstituted solution) sc daily
Exceptions	
<ul style="list-style-type: none"> • EGRIFTA WR and EGRIFTA SV are not substitutable. • One reconstituted Egrifta WR[™] vial provides daily doses for 7 days. 	

Reference Information

- DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: April 10, 2023
- DrugPoints[®] System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
- Lexi-Comp ONLINE[™] with AHFS[™], Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
- US Department of Health and Human Services (HHS). Guide for HIV/AIDS Clinical Care. Health Resources and Services Administration, HIV/AIDS Bureau. April 2014. Available from <https://hab.hrsa.gov/sites/default/files/hab/clinical-qualitymanagement/2014guide.pdf>. Accessed April 10, 2023.
- Falutz J, Mamputu JC, Potvin D, et al. Effects of tesamorelin (TH9507), a growth hormone-releasing factor analog, in human immunodeficiency virus-infected patients with excess abdominal fat: a pooled analysis of two multicenter, double-blind placebocontrolled phase 3 trials with safety extension data. J Clin Endocrinol Metab. 2010; 95(9):4291-4304.

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6. Falutz J, Potvin D, Mamputu JC, et al. Effects of tesamorelin, a growth hormone-releasing factor, in HIV-infected patients with abdominal fat accumulation: a randomized placebo-controlled trial with a safety extension. *J Acquir Immune Defic Syndr*. 2010; 53(3):311-322.
7. Theratechnologies Inc. (2025). *EGRIFTA WR (tesamorelin) prescribing information* (Revised March 2025). U.S. Food and Drug Administration. Retrieved January 19, 2025, from <https://www.egriftawr.com/documents/Prescribing-Information.pdf>
8. Theratechnologies Inc. (2024). *EGRIFTA SV (tesamorelin) prescribing information* (Revised 02-2024). Theratech. Retrieved January 19, 2025, from <https://www.theratech.com/static-files/2de95bab-bd94-4c00-84ca-321c9fe9f5b6>
9. UpToDate. (n.d.). *Treatment of HIV-associated lipodystrophy*. UpToDate. Retrieved January 19, 2025, from https://www.uptodate.com/contents/treatment-of-hiv-associated-lipodystrophy?search=egrifla&source=search_result&selectedTitle=2~3&usage_type=default&display_rank=1#H18

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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Policy History

Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date
Annual Review 1/19/2026	Added Egrifla WR to Medical Policy. Added non-approvable criteria for Egrifla. Add dosage for new agent Egrifla WR. Coding Reviewed: Removed HCPCS J3490 and updated description for J3590. Added ICD-10-CM Z68.30-Z68.45 to existing range Z68.22-Z68.29 and updated description. Removed R73.0-R73.09. Removed ICD10-CM E88.1. added E88.14. Updated reference list. Wording and formatting changes.	2/13/2026	2/22/2026
Annual Review 03/31/2025	Addition of contraindication for: Disruption of the hypothalamic-pituitary axis due to hypophysectomy, hypopituitarism, pituitary tumor/surgery, head irradiation or head trauma (label).	4/16/2025	5/6/2025
Annual Review. 05/19/2024	Add non-approvable criteria for all other indications. Added section: Limits or restrictions. Change Egrifla for Egrifla SV®. Wording and formatting updates.	2/18/2025	3/6/2025
Policy Inception 5/19/2023	Elevance Health’s Medical Policy adoption.	N/A	11/30/2023