Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Tesamorelin (Egrifta SV®)	MP-RX-FP-25-23	☒ MMM MA ☒ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B Drugs

Service Description

This document addresses the use of Tesamorelin (Egrifta SV®), 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

Egrifta SV is an analog of 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.

Egrifta SV 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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Approved Indications

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

Other Uses

A. N/A

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Applicable Codes

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
J3490	Unclassified drugs [when specified as tesamorelin (Egrifta SV)]
J3590	Unclassified biologics [when specified as tesamorelin (Egrifta SV)]

CD-10	Description
B20	Human immunodeficiency virus [HIV] disease
E88.1	Lipodystrophy, not elsewhere classified
Z68.22-Z68.29	Body mass index (BMI) 22.0-22.9, adult
R73.0-R730.9	Elevated Blood Glucose

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®)

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/m^2 (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

Continuation therapy with Egrifta SV (tesamorelin) injections may be approved for reconstructive purposes when 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.

C. Conditions not Covered

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

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i. Egrifta SV® (tesamorelin) may not be approved 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

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
Exceptions	
None	

Reference Information

1. 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
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
4. 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.
5. 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.
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.

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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.

Policy History

Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date
Choose an item.			
Annual Review. 05/19/2024	Add non-approvable criteria for all other indications. Added section: Limits or restrictions. Change Egrifta for Egrifta 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