Medical Drug Clinical Criteria

Subject:	Egrifta (tesamorelin)		
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Table of Contents

Overview | Coding | References

Clinical criteria | Document history

Overview

This document addresses the use of Egrifta (tesamorelin). Egrifta is approved for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.

Egrifta 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 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.

Clinical Criteria

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.

Egrifta (tesamorelin)

Initial therapy with Egrifta (tesamorelin) injections 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.

Continuation therapy with Egrifta (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.

Egrifta (tesamorelin) may not be approved when the above criteria are not met and for all other indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS	
J3490	Unclassified drugs [when specified as tesamorelin (Egrifta)]
J3590	Unclassified biologics [when specified as tesamorelin (Egrifta)]
ICD-10 Diagnosis	
ALL Diagnosis	When using NOC (unspecified) HCPCS codes
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-R73.09	Elevated Blood Glucose

Document History

Revised: 05/17/2024
Document History:

- 05/17/2024 – Annual Review: No changes. Coding Reviewed: No changes.
- 05/19/2023 – Annual Review: Add non-approvable criteria for all other indications. Coding Reviewed: No changes.
- 05/20/2022 – Annual Review: No changes. Coding Reviewed: No changes.
- 08/01/2021 – Administrative update to add documentation.
- 05/21/2021 – Annual Review: No changes. Coding Reviewed: No changes.
- 05/15/2020 – Annual Review: No Changes. Coding Reviewed: Added HCPCS J3590
- 05/17/2019 – Annual Review: No Changes. Added ICD-10-CM codes Z68.22-Z68.29, R73.0-R73.09
- 11/16/2018 – Select Review: First review of Egrifta; updated to align with clinical trial inclusion criteria for waist-to-hip ratio and waist circumference. HCPCS Coding Review: no change. ICD-10 Coding Review: no change.

References

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2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 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-quality-management/2014guide.pdf. Accessed April 5, 2024.
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 placebo-controlled 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.