MEDICAL MUTUAL®

Drug Policy

Policy:	Egrifta & Egrifta SV (tesamorelin)	Annual Review Date: 12/21/2023 Last Revised Date: 12/21/2023

OVERVIEW

Egrifta is a growth-hormone releasing factor (GRF) that is indicated for the reduction of excess abdominal fat in HIV-patients who have lipodystrophy, including accumulation of visceral abdominal fat or wasting of subcutaneous fat in the extremities or buttocks. Egrifta reduces trunk and visceral fat and has also been shown to lower the cholesterol: HDL ratio and improve patient-perceived self-body image. Egrifta should not be used in patients for weight loss management or to improve adherence in HIV antiretroviral therapies.

POLICY STATEMENT

This policy involves the use of Egrifta. Prior authorization is recommended for pharmacy benefit coverage of Egrifta. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Egrifta as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Egrifta be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Egrifta is recommended in those who meet the following criteria:

1. <u>HIV-associated lipodystrophy, initial therapy</u>

Criteria. *The patient must meet the following criteria (A, B, C, D, E, F, G and H):*

A. The patient is at least 18 years of age; AND
B. The patient has no disruption of the hypothalamic-pituitary axis (HPA) due to hypophysectomy, hypopituitarism, pituitary tumor/surgery, head irradiation, or head trauma; AND
C. The patient does not have an active malignancy; AND
D. The patient is not pregnant; AND
E. The drug was prescribed by or in consultation with an endocrinologist or HIV specialist; AND
F. The drug is prescribed for the reduction of excess abdominal fat.
G. The patient meets one of the following (i <u>or</u> ii):

i. If male*, waist circumference is ≥ 95 cm (37.4 in) and waist-to-hip ratio is ≥ 0.94; OR
ii. If female*, waist circumference is ≥ 94 cm (37 in) and waist-to-hip ratio is ≥ 0.88; AND

* In this context, the specified gender is defined as follows: men are defined as individuals with the biological traits of a man, regardless of the individual's gender identity or gender expression.

H. The patient has been stable on an anti-retroviral regimen for at least 8 weeks.

2. HIV-associated lipodystrophy, continuing therapy

Criteria. *The patient must meet the following criteria (A, B, C, and D):*

A. The patient is at least 18 years of age; AND
B. The patient is not pregnant; AND
C. The drug was prescribed by or in consultation with an endocrinologist or HIV specialist; AND
D. The patient has shown evidence of improvement based on waist circumference or CT scan.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 6 months
B) *Extended Approval:* 6 months

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Egrifta has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Weight loss management.** Though Egrifta improves the lipid profile of patients and causes a reduction in trunk and visceral fat, it has no efficacy regarding weight loss.

2. **Improved adherence to anti-retroviral therapy.** No evidence exists that taking Egrifta concomitantly with anti-retrovirals increases adherence.

3. **Patients > 65 Years of Age.** There is no information on the use of Egrifta in patients greater than 65 years of age with HIV and lipodystrophy,

4. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:
The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company.

Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

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