Drug Coverage Policy

Effective Date.....8/01/2025
Coverage Policy Number IP0209
Policy Title.....Egrifta

Lipodystrophy – Egrifta

- Egrifta SV® (tesamorelin subcutaneous injection – Theratechnologies)
- Egrifta WR™ (tesamorelin subcutaneous injection – Theratechnologies)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW

Egrifta SV and Egrifta WR, analogs of human growth hormone-releasing factor, are indicated for the reduction of excess abdominal fat in patients with **human immunodeficiency virus (HIV) who have lipodystrophy**.[1,2]

Limitations of use: 1) Long-term cardiovascular safety of Egrifta SV and Egrifta WR have not been established; 2) Not indicated for weight loss management; and 3) There are no data to support improved compliance with anti-retroviral therapies in HIV-positive patients taking Egrifta SV or Egrifta WR.[1,2] In the pivotal trial of Egrifta, all patients had lipodystrophy and excess abdominal fat, evidenced by a waist circumference ≥ 95 cm (≥ 94 cm for female) and a waist-to-hip ratio ≥ 0.94 (≥ 0.88 for female). Patients were required to be on a stable antiretroviral regimen for at least 8 weeks. Safety and effectiveness of Egrifta SV and Egrifta WR have been established in patients between 18 and 65 years of age.

The new formulation, Egrifta WR is still a daily injectable product, but only needs weekly reconstitution.[6] The new formulation is set to replace Egrifta SV.

Disease Overview
Lipodystrophy is the change in body fat which affects some patients with HIV infection, either due to HIV infection or due to medications to treat HIV.[3] Lipodystrophy is not a concern for most people who start HIV treatment now, because newer HIV medications are less likely to cause this effect. Egrifta increases secretion of growth hormone and has been shown to decrease visceral adipose tissue and spare subcutaneous adipose tissue.[4]

Safety
Because the long-term cardiovascular safety and potential long-term cardiovascular benefit are not established, careful consideration should be given whether to continue Egrifta treatment 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 computerized tomography scan. In the pivotal studies, efficacy of Egrifta was assessed at Week 26. Because Egrifta induces the release of endogenous growth hormone (a known growth factor) and increases serum insulin growth factor-1 (IGF-1), the benefits of treatment should be weighed against the increased risk of malignancies in patients who are HIV-positive. Since the effect of prolonged IGF-1 elevations on the development or progression of malignancies is unknown, monitor IGF-1 levels closely during Egrifta therapy and consider discontinuation in patients with persistent elevations of IGF-1 levels (e.g., > 3 standard deviation scores), especially if the patient has not experienced a robust response. Egrifta should be used with caution in patients who develop glucose intolerance or diabetes; discontinuation of therapy should be considered for patients who do not show a clear efficacy response.

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POLICY STATEMENT
Prior Authorization is required for benefit coverage of Egrifta SV and Egrifta WR. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Egrifta SV and Egrifta WR as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Egrifta SV and Egrifta WR to be prescribed by or in consultation with a physician who specializes in the condition being treated. In the approval indication, as appropriate, an asterisk (*) is noted next to the specified gender. In this context, the specified gender is defined as follows: females/males are defined as individuals with the biological traits of a woman/man, regardless of the individual's gender identity or gender expression.

Egrifta SV and Egrifta WR are considered medically necessary when the following criteria is met:

FDA-Approved Indication

1. **Lipodystrophy Associated with Human Immunodeficiency Virus (HIV) Infection.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv, and v):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** The medication is prescribed for the reduction of excess abdominal fat; AND
     - **iii.** Patient meets ONE of the following (a or b):
       - **a)** If male*, waist circumference is ≥ 95 cm (37.4 in) and waist-to-hip ratio is ≥ 0.94; OR
       - **b)** If female*, waist circumference is ≥ 94 cm (37 in) and waist-to-hip ratio is ≥ 0.88; AND
     - **iv.** Patient has been stable on an antiretroviral regimen for at least 8 weeks; AND
       Note: Examples include antiretroviral regimens containing protease inhibitors, nucleoside reverse transcriptase inhibitors, and/or non-nucleoside reverse transcriptase inhibitors.
     - **v.** The medication is prescribed by or in consultation with an endocrinologist or a physician specializing in the treatment of HIV infection (e.g., infectious disease, oncology).
   - **B)** Patient is Currently Receiving Egrifta. Approve for 1 year if the patient has responded, as determined by the prescriber.
     Note: Examples of a response include reduction in visceral adipose tissue measured by waist circumference or computed tomography (CT) scan.

***** Refer to Policy Statement.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Egrifta SV and Egrifta WR for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Abdominal Obesity in a Patient without Human Immunodeficiency Virus (HIV) Infection.** More data are needed. Egrifta has been studied in a very limited number of patients who have abdominal obesity without HIV infection.[4] To be eligible for the published trial, patients were required to have a peak stimulated growth hormone no higher than 9 mcg/L on a standardized growth hormone-releasing hormone-arginine stimulation test. Patients (n = 60) were randomized in a 1:1 ratio to treatment with Egrifta 2 mg once daily or placebo. The primary endpoint was the change in visceral adipose tissue from baseline. Over 12 months (using last observation carried forward), visceral adipose tissue improved significantly in patients treated with Egrifta compared with placebo (net treatment effect vs. placebo: -35 [95% confidence interval: -58, -12]; P = 0.003). Treatment with Egrifta increased IGF-1 by 90%, decreased triglycerides by 20%, and decreased log C-reactive protein by 24% compared with placebo.

There was no effect on total cholesterol, high-density lipoprotein cholesterol, or low-density lipoprotein cholesterol in the treatment groups.

2. **Human Immunodeficiency Virus (HIV)-Related Cachexia, Weight Loss, or Fat Distribution other than Lipodystrophy.** Egrifta has not been studied in these conditions.

3. **Patient is > 65 Years of Age.** There is no information on the use of Egrifta SV or Egrifta WR in patients > 65 years of age with HIV and lipodystrophy.[1]

References

1. Egrifta SV® subcutaneous injection [prescribing information]. Montreal, Quebec, Canada: Theratechnologies; February 2024.
2. Egrifta WR™ subcutaneous injection [prescribing information]. Montreal, Quebec, Canada: Theratechnologies; March 2025.
3. HIV and Lipodystrophy. National Institute of Health Office of AIDS Research. Available at: HIV and Lipodystrophy | NIH. Accessed on May 31, 2024.
4. 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.
5. Makimura H, Feldpausch MN, Rope AM, et al. Metabolic effects of a growth hormone-releasing factor in obese subjects with reduced growth hormone secretion: a randomized controlled trial. *J Clin Endocrinol Metab*. 2012;97(12):4769-4779.
6. Theratechnologies press release. Theratechnologies receives FDA approval for Egrifta WR™ (tesamorelin F8) to treat excess visceral abdominal fat in adults with HIV and lipodystrophy. Available at: Theratechnologies Receives FDA Approval for EGRIFTA WR™. Accessed on May 13, 2025.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	**Updated** coverage policy title from *Tesamorelin* to *Lipodystrophy – Egrifta*. **Lipodystrophy Associated with Human Immunodeficiency Virus (HIV) Infection.** **Removed** upper age limit of 65 years for use with Egrifta SV from *Medical Necessity Criteria* because the criterion is listed in *Conditions Not Covered*. **Added** an (*) next to specified gender where in this context, the specified gender is defined. **Updated** reauthorization approval duration from *6 months* to *1 year*.	10/1/2024
Annual Revision	**Added** Egrifta WR to the policy with the same criteria as Egrifta SV.	8/1/2025

The policy effective date is in force until updated or retired.