PRIOR AUTHORIZATION POLICY

POLICY: Lipodystrophy – Egrifta Prior Authorization Policy
- Egrifta SV® (tesamorelin subcutaneous injection – Theratechnologies)

REVIEW DATE: 05/31/2023

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. 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.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Egrifta SV, an analog of human growth hormone-releasing factor, is indicated for the reduction of excess abdominal fat in patients with **human immunodeficiency virus (HIV) who have lipodystrophy**.[1,3]

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

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.[2] Lipodystrophy is not a concern for most people who start HIV treatment now, because newer HIV medications are less likely to cause this effect.

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 SV 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 SV was assessed at Week 26. Because Egrifta SV induces the release of endogenous growth hormone (a known growth factor) and increases serum IGF-1, the benefits of treatment should be weighed against the increased risk of malignancies 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 SV 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 SV 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.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Egrifta SV. Because of the specialized skills required for evaluation and diagnosis of patients treated with Egrifta SV as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Egrifta SV 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: men are defined as individuals with the biological traits of a man, regardless of the individual's gender identity or gender expression. All approvals are provided for the duration noted below. When approvals are authorized in months, 1 month is equal to 30 days.

- **Egrifta SV® (tesamorelin subcutaneous injection – Theratechnologies)**

is(are) covered as medically necessary when the following criteria is(are) met for fda-approved indication(s) or other uses with supportive evidence (if applicable):

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 criteria (A or B):
   - **A)** Initial Therapy. Approve for 6 months if the patient meets ALL of the following criteria (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 criteria (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 the Policy Statement.

CONDITIONS NOT COVERED

- **Egrifta SV® (tesamorelin subcutaneous injection – Theratechnologies)**

is(are) considered experimental, investigational or unproven for ANY other use(s) 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 SV has been studied in a very limited number 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 SV 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 SV compared with placebo (net treatment effect vs. placebo: -35 [95% confidence interval: -58, -12]; P = 0.003). Treatment with Egrifta SV 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 SV has not been studied in these conditions.

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

REFERENCES

1. Egrifta SV® injection [prescribing information]. Montreal, Quebec, Canada: Theratechnologies; October 2019.
2. HIV and Lipodystrophy. National Institute of Health Office of AIDS Research. Available at: HIV and Lipodystrophy | NIH. Accessed on May 26, 2023.
3. 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.
4. 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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	05/18/2022
Annual Revision	No criteria changes.	05/31/2023