

PHARMACY POLICY STATEMENT

Marketplace

DRUG NAME	Egrifra SV (tesamorelin)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Egrifra SV is an analog of human growth hormone (GH)-releasing factor, indicated to reduce excess abdominal fat in HIV-infected patients with lipodystrophy. The original formulation, Egrifra, has been replaced with Egrifra SV, a more concentrated product allowing for reduced injection volume. Lipodystrophy can exist as lipoatrophy (loss of subcutaneous fat), lipohypertrophy (fat accumulated as excess visceral adipose tissue), or a mix of both. In contrast, obesity is an increase in subcutaneous fat. Egrifra SV has a weight neutral effect and should not be prescribed for obesity. It has a selective effect to reduce visceral fat but does not reduce subcutaneous fat. Egrifra SV should not be continued beyond 6 months in the absence of treatment response.

Egrifra SV (tesamorelin) will be considered for coverage when the following criteria are met:

Lipodystrophy

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with an infectious disease specialist or endocrinologist; AND
3. Member has a diagnosis of HIV-associated lipodystrophy with excess abdominal fat (visceral adipose tissue); AND
4. If male, member has documentation of waist circumference > 95 cm **AND** waist to hip ratio > 0.94; OR
5. If female, member has documentation of waist circumference > 94 cm **AND** waist to hip ratio > 0.88; AND
6. Member has been stable on antiretroviral treatment for at least 8 weeks; AND
7. Medication is **NOT** being prescribed for simple obesity or weight loss; AND
8. Member does **NOT** have active malignancy.
9. **Dosage allowed/Quantity limit:** 1.4mg subcutaneously once daily. Quantity limit: 30 vials per 30 days.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes must show there has been a reduction of excess visceral adipose tissue from baseline measured by **ONE** of the following:
 - a) Computed tomography (CT) scan;
 - b) Waist circumference;
 - c) Waist to hip ratio.

If all the above requirements are met, the medication will be approved for 12 months.

CareSource considers Egrifta SV (tesamorelin) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
12/08/2020	New policy for Egrifta SV created.
09/20/2023	Added quantity limit; added reference; removed attempt to switch from causative anti-retroviral drugs; added CT and waist to hip ratio as options to show reduction in reauthorization criteria; added waist circumference and waist to hip ratio criteria to confirm diagnosis; added that member is to be stable on ART for at least 8 weeks.

References:

1. Egrifta SV [package insert]. Montreal, Quebec, Canada: Theratechnologies Inc; 2020.
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3. 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. doi:10.1210/jc.2010-0490
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. doi:10.1097/QAI.0b013e3181cbdaff
5. Lake JE, Stanley TL, Apovian CM, et al. Practical Review of Recognition and Management of Obesity and Lipohypertrophy in Human Immunodeficiency Virus Infection [published correction appears in Clin Infect Dis. 2017 Oct 15;65(8):1431-1433]. *Clin Infect Dis*. 2017;64(10):1422-1429. doi:10.1093/cid/cix178
6. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. Available at <https://clinicalinfo.hiv.gov/sites/default/files/inline-files/AdultandAdolescentGL.pdf>. Accessed 12/30/2020.
7. Guzman N, Vijayan V. HIV-Associated Lipodystrophy. In: StatPearls. Treasure Island (FL): StatPearls Publishing; November 7, 2022.
8. Leung VL, Glesby MJ. Pathogenesis and treatment of HIV lipohypertrophy. *Curr Opin Infect Dis*. 2011;24(1):43-49. doi:10.1097/QCO.0b013e3283420eef

Effective date: 04/01/2024
 Revised date: 09/20/2023