PHARMACY POLICY STATEMENT
Arkansas PASSE

DRUG NAME	Egrifta SV (tesamorelin)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Tesamorelin 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, Egrifta, has been replaced with Egrifta 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. Tesamorelin 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. Tesamorelin should not be continued beyond 6 months in the absence of treatment response.

Egrifta 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. Member has a diagnosis of HIV-associated lipodystrophy with excess abdominal fat (visceral adipose tissue); AND
3. Member has attempted to switch from taking any causative anti-retroviral drugs (i.e. stavudine, zidovudine) to an alternate regimen, or is unable to switch; AND
4. Medication is not being prescribed for simple obesity or weight loss; AND
5. Member does not have active malignancy.
6. **Dosage allowed/Quantity limit:** 1.4mg subQ once daily

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, as measured by waist circumference.

If all the above requirements are met, the medication will be approved for an additional 1 year.

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.

12/21/2021	Removed prescriber specialty requirement.

References:

1. Egrifta SV [package insert]. Montreal, Quebec, Canada: Theratechnologies Inc; 2020.
2. Glesby MJ. Treatment of HIV-associated lipodystrophy. UpToDate. https://www-uptodate-com. Updated April 17, 2020. Accessed December 9, 2020.
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.

Effective date: 01/01/2022
Revised date: 12/21/2021