Drug Use Research & Management Program
Oregon State University, 500 Summer Street NE, E35
Salem, Oregon 97301-1079
Phone 503-947-5220 | **Fax** 503-947-2596

Prior Authorization Update: Tesamorelin (EGRIFTA), injection

Plain Language Summary:

- Lipodystrophy is a condition that changes the way body makes, uses and stores fat. People with human immunodeficiency virus (HIV) who take certain medicines may be more commonly affected. Treatments for HIV that contain zidovudine or stavudine can cause lipodystrophy, especially after long-term use.
- Fat loss occurs in the arms, legs or face while the stomach, back of the neck and chest can gain fat. For people with lipodystrophy, these changes in body shape can be very upsetting and can affect quality of life.
- Several treatments can prevent or improve body shape changes in people with HIV including:
    - Changing HIV medicines
    - Exercising and changing their diet
    - Taking tesamorelin, a medicine that reduces excess stomach fat in people with lipodystrophy associated with HIV medicines.
- Providers who prescribe tesamorelin to a person enrolled in the Oregon Health Plan (OHP) must receive approval from the Oregon Health Authority before OHP will pay for it. This process is called prior authorization (PA).

Purpose of Update: Treatment of HIV-associated lipodystrophy is currently not funded by the Health Evidence Review Commission (HERC) Prioritized List of Health Services.[1] This PA update will evaluate recently published evidence to support revisions of PA criteria and establish specific medical necessity and appropriateness criteria for patients with the Early Periodic Screening Diagnostic and Treatment Benefit.

Background:

Tesamorelin, a growth hormone releasing factor (GRF) analog indicated for reduction of excess abdominal fat in patients with HIV and lipodystrophy, was first reviewed by the Pharmacy and Therapeutics (P & T) committee at the April 2012 meeting.[2] The committee approved PA criteria to limit the use of tesamorelin in OHP-funded conditions. At the September 2015 P & T meeting the PA criteria were re-evaluated and no changes to the PA criteria were recommended at that time (**Appendix 1**). In the third quarter of 2024 there were 9 OHP fee-for-service members with a diagnosis of HIV-associated lipodystrophy. In the first quarter of 2025, there were no pharmacy claims for stavudine or zidovudine.

Lipodystrophy refers to the abnormal distribution of adipose tissue.[3] Human immunodeficiency virus (HIV)-associated lipodystrophy is an undesirable adverse effect of antiretroviral therapy (ART) that occurs due to the redistribution of adipose tissue.[4] HIV-associated lipodystrophy can manifest as two distinct phenotypes: fat accumulation (lipohypertrophy) or fat loss (lipoatrophy).[4] In some patients, the 2 manifestations may coexist as well. The production of

inflammatory cytokines such as interleukins are provoked, which results in adipose cell destruction.[3] In addition, insulin signaling function and glucose transport can be impaired.[3] Lipodystrophy can be inherited or acquired, although inherited lipodystrophic syndromes are very rare.[3] The most prevalent type of lipodystrophy is an acquired form that occurs in individuals with HIV who are receiving highly active antiretroviral therapy (HAART). Up to 40–70% of patients on HAART are reported to have HIV-associated lipodystrophy syndrome (HALS).[3,5]

Lipoatrophy occurs on the face, buttocks, arms, and legs.[4] In contrast, lipohypertrophy occurs in the truncal areas and manifests as abdominal obesity, mammary hypertrophy, accumulation of fat on the neck, or lipomas.[4] These body shape changes, especially facial lipoatrophy, have been linked to depression, decreased self-esteem, sexual dysfunction, and social isolation and can greatly affect the patient's quality of life and adherence to ART.[4] Lipodystrophy also contributes to morbidity via the development of insulin resistance, hyperlipidemia, and endothelial dysfunction, which can increase the risk of cardiovascular disease.[4] Risk factors for HALS include older age, greater severity of HIV-infection, increased viral load, low count of CD4-positive T lymphocytes and coinfection with hepatitis C virus.[3] Modifying the ART regimen so that stavudine or zidovudine is replaced with a different medication, namely tenofovir or abacavir, is the primary medical approach to managing lipodystrophy.[6] This can result in modest gains in limb fat.[6] Tenofovir and abacavir are first-line nucleoside reverse transcriptase inhibitors (NRTIs) because of their efficacy, safety, and convenience, whereas stavudine and zidovudine are associated with many adverse events and inferior virologic potency.[6]

In HIV-associated lipodystrophy, patients have blunted growth hormone (GH) secretion in proportion to the extent of abdominal fat accumulation.[7] Since GH increases lipolysis and suppresses de novo lipogenesis, low GH secretion has been theorized to potentiate abdominal fat accumulation and hepatic steatosis in this patient population.[7] Based on this hypothesis, the GRF analog, tesamorelin was developed as a strategy to restore physiologic GH pulsatility in patients with HIV-associated lipodystrophy.[8]

Two phase 3 clinical randomized controlled trials (RCTs) evaluated the efficacy of tesamorelin compared to placebo over 26 weeks in patients with ART-associated lipodystrophy (n=806).[9] Both RCTs enrolled patients in a 26-week extension phase to evaluate long-term safety.[9] In a pooled analysis of both RCTs, tesamorelin was shown to statistically significantly reduce visceral adipose fat (VAT) compared with placebo (-15.4 vs. -0.6%; $p<0.001$).[9] Secondary efficacy endpoints from the extension phases indicated that the decrease in VAT was not maintained after treatment discontinuation. [9] There was limited reduction in body mass index and waist circumference after 26 weeks of treatment with tesamorelin.[9] This evidence was presented to the P & T Committee at the 2012 meeting.[2]

Adverse events observed with tesamorelin included injection site reactions, arthralgias, limb pain, rash, myalgias, and peripheral edema.[10] Though GH is known to increase insulin resistance, physiology studies have shown no worsening of glycemic control with tesamorelin.[10] However, in a small number of patients, glucose levels may increase, and thus optimization of glycemic control before initiation of therapy and periodic blood glucose monitoring while on treatment may be warranted.[11] Patients receiving tesamorelin should undergo routine assessment of IGF-1; a dose reduction may rarely be needed to maintain levels within the normal range.[11] In addition, patients on tesamorelin should undergo age-appropriate cancer screening before and while on therapy given theoretical concerns that GH may potentiate cancer growth, though tesamorelin specifically has not been shown to increase cancer risk.[11] Tesamorelin is the only medication approved in the United States to treat abdominal fat accumulation in HIV.[11] Tesamorelin has not been studied in the context of other lipodystrophy syndromes characterized by increased visceral adiposity and is not currently approved outside the context of HIV.[11]

Recommendations:

- Revise PA criteria for tesamorelin to define medical necessity and appropriateness for patients with the Early Periodic Screening Diagnostic and Treatment Benefit.
- Maintain tesamorelin as nonpreferred on the Prioritized Drug List (PDL).

References:

1. Prioritized List of Health Services, Health Evidence Review Commission, Oregon Health Plan; January 2025. https://www.oregon.gov/oha/hpa/dsi-herc/pages/prioritized-list.aspx Accessed 2/17/25.
2. Fouts, Brandy. Tesamorelin New Drug Evaluation. April 2012. https://www.orpdl.org/durm/meetings/meetingdocs/2012_04_26/archives/2012_04_26_Tesamorelin_MN.pdf.
3. Fiorenza CG, Chou SH, Mantzoros CS. Lipodystrophy: pathophysiology and advances in treatment. *Nat Rev Endocrinol*. Mar 2011;7(3):137-50. doi:10.1038/nrendo.2010.199
4. Guzman N, Vijayan V. HIV-Associated Lipodystrophy. *StatPearls*. StatPearls Publishing
Copyright © 2025, StatPearls Publishing LLC.; 2025.
5. Heath KV, Hogg RS, Chan KJ, et al. Lipodystrophy-associated morphological, cholesterol and triglyceride abnormalities in a population-based HIV/AIDS treatment database. *Aids*. Jan 26 2001;15(2):231-9. doi:10.1097/00002030-200101260-00013
6. Carr A, Workman C, Smith DE, et al. Abacavir substitution for nucleoside analogs in patients with HIV lipoatrophy: a randomized trial. *Jama*. Jul 10 2002;288(2):207-15. doi:10.1001/jama.288.2.207
7. Fourman LT, Grinspoon SK. Approach to the Patient With Lipodystrophy. *J Clin Endocrinol Metab*. May 17 2022;107(6):1714-1726. doi:10.1210/clinem/dgac079
8. Stanley TL, Chen CY, Branch KL, Makimura H, Grinspoon SK. Effects of a growth hormone-releasing hormone analog on endogenous GH pulsatility and insulin sensitivity in healthy men. *J Clin Endocrinol Metab*. Jan 2011;96(1):150-8. doi:10.1210/jc.2010-1587
9. 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*. Mar 2010;53(3):311-22. doi:10.1097/QAI.0b013e3181cbdaff
10. 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*. Sep 2010;95(9):4291-304. doi:10.1210/jc.2010-0490
11. EGRIFTA (tesamorelin) Subcutanous Injection Prescribing Information. Montreal, Quebec, Canada; Theratechnologies Inc. 02/2024.

Appendix 1: Proposed Prior Authorization Criteria

Tesamorelin (Egrifta®)

Goal(s):
- To ensure appropriate drug use and restrict to indications supported by medical literature.
- Allow case-by-case review for members covered under the EPSDT program.

Length of Authorization:
- Up to 12 months

Requires PA:
- Tesamorelin (Egrifta and Egrifta SV®) subcutaneous injection

Covered Alternatives:
- No preferred alternatives

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the indicated treatment for reduction of excess abdominal fat in HIV-infected patients with lipodystrophy (ICD10 E881)?	**Yes:** If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP If eligible for EPSDT review: Go to #3.	**No:** Pass to RPh. Deny; medical appropriateness.
3. Is there documentation that lipodystrophy has not sufficiently improved or cannot be managed by switching HIV antiretroviral therapy and lifestyle changes (e.g., diet and exercise)?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; medical appropriateness.

Approval Criteria		
4. Is there documentation that the condition is of sufficient severity that it impacts the patient's mental or physical health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc.)?	**Yes:** Approve for 12 months.	**No:** Pass to RPh. Deny; medical necessity.

P&T/DUR Review: *6/25 (DM); 9/15 (AG); 4/12*
Implementation: *8/1/2025; 10/15; 7/12*