

Clinical Policy Title:	tesamorelin
Policy Number:	RxA.111
Drug(s) Applied:	Egrifta SV™
Original Policy Date:	02/07/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

Tesamorelin (Egrifta SV™) is a growth hormone releasing factor analog. It is indicated for the reduction of excess abdominal fat in human immunodeficiency virus (HIV)-infected adult patients with lipodystrophy.

Limitation(s) of use:

- Long-term cardiovascular safety of Egrifta SV™ treatment have not been established.
- Not indicated for weight loss management.
- There are no data to support improved compliance with anti-retroviral therapies in HIV- positive patients taking Egrifta SV™.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
tesamorelin (Egrifta SV™)	HIV infection with lipodystrophy	1.4 mg (0.35 mL) SC once daily	1.4 mg/day

Dosage Forms

- Single Dose Vial: 2 mg with a diluent of 10 mL of sterile water for injection.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Human Immunodeficiency Virus Infection with Lipodystrophy (must meet all):

1. Diagnosis of HIV infection with lipodystrophy;
2. Age 18 years of age or older or documentation of closed epiphyses;
3. Member meets clinical indicators for abdominal lipodystrophy (a or b):
 - a. If female, waist circumference \geq 88 cm;
 - b. If male, waist circumference \geq 102 cm;
4. Member is currently receiving and adherent to antiretroviral therapy;
5. Dose does not exceed 2 mg per day.

Approval Duration

Commercial: 6 months

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

Medicaid: 6 months

II. Continued Therapy Approval

A. Human Immunodeficiency Virus Infection with Lipodystrophy (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 2 mg per day.

Approval Duration

Commercial: 12 months

Medicaid: 6 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

HIV: human immunodeficiency virus

APPENDIX B: Therapeutic Alternatives

Not applicable.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
 - Disruption of the hypothalamic-pituitary axis.
 - Active malignancy.
 - Known hypersensitivity to tesamorelin or excipients in Egrifta SV™.
 - Pregnancy.
- Boxed Warning(s):
 - None.

APPENDIX D: General Information

Lipodystrophy refers to changes in body fat that include build-up or loss of fat in certain areas of the body. Hard Belly results when the build-up of extra hard fat in the abdominal (belly) area pushes up against the abdominal wall and stretches the muscles until they become taut.

Regular fat:

- Surrounds organs.
- May be associated with fat accumulation in organs.
- Feels harder and firmer than regular fat.

Hard Belly fat:

- Surrounds organs.
- May be associated with fat accumulation in organs.
- Feels harder and firmer than regular fat.
- May be hard to reduce with diet and exercise alone.

References

1. Egrifta SV prescribing information. Theratechnologies Inc. October 2019. Available at:

https://www.egriftasv.com/include/PDF/HCP/Prescribing_Info_en.pdf. Accessed January 20, 2021.

2. Adrian S, Scherzinger A, Sanyal A, et al. The Growth Hormone Releasing Hormone Analogue, Tesamorelin, Decreases Muscle Fat and Increases Muscle Area in Adults with HIV. *J Frailty Aging* 2019;8(3):154-159. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6766405/#__ffn_sectitle. Accessed January 20, 2021.
3. Lean ME, Han TS, Morrison CE. Waist circumference as a measure for indicating need for weight management. *BMJ* 1995; 311:158. Accessed January 20, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/20/2021	03/09/2021