

Policy Name:	Egrifta SV (tesamorelin acetate)	Policy #:	1943P
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Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Egrifta SV.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Egrifta SV under the specialty pharmacy benefit when the following criteria have been met.

Criteria

1. Coverage Criteria

- 1.1 Diagnosis of human immunodeficiency virus (HIV)
- 1.2 Documented presence of abdominal lipodystrophy (abnormal fat distribution)
- 1.3 Documentation which indicates the sole purpose of treatment is **not** weight loss
- 1.4 Documented compliance with antiretroviral therapy (ART; such as Biktarvy, Complera, etc)

2. Approval Criteria

- 2.1 Initial: 12 months
- 2.2 Renewal: 12 months with demonstrated a clear clinical improvement from baseline that is supported by a waist circumference or CT scan

CPT Codes

HCPCS Codes

References

1. Egrifta SV [package insert]. Montreal, Quebec, Canada: Theratechnologies Inc.; October 2019.
2. Brown TT. Approach to the human immunodeficiency virus-infected patient with lipodystrophy. *J Clin Endocrinol Metab.* 2008;93(8):2937–2945.
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; 95:4291.
4. Kumar NS, Malappa, Venugopal K, et al. Lipodystrophy in Human Immunodeficiency Virus (HIV) Patients on Highly Active Antiretroviral Therapy (HAART). *J Clin Diagn Res.* 2015 Jul;9(7):OC05-8.
5. 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. Year. Available at <http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf>.

Created Date: 09/15/11
Effective Date: 09/15/11
Posted to Website: 01/01/22
Revision Date: 06/05/24

DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.