



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Serostim

Page: 1 of 3

Effective Date: 4/7/2024

Last Review Date: 4/2024

Applies to:	<input checked="" type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input checked="" type="checkbox"/> New Jersey
	<input checked="" type="checkbox"/> Maryland	<input checked="" type="checkbox"/> Florida Kids	<input checked="" type="checkbox"/> Pennsylvania Kids
	<input type="checkbox"/> Michigan	<input type="checkbox"/> Virginia	<input checked="" type="checkbox"/> Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Serostim under the patient's prescription drug benefit.

Description:

FDA-Approved Indications

Serostim is indicated for the treatment of human immunodeficiency virus (HIV) patients with wasting or cachexia to increase lean body mass and body weight and improve physical endurance. Concomitant antiretroviral therapy is necessary

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Serostim

Policy/Guideline:

I. CRITERIA FOR INITIAL APPROVAL

Treatment of HIV patients with wasting or cachexia to increase lean body mass and body weight, and improve physical endurance

Authorization may be granted for treatment of HIV-associated wasting/cachexia when ALL of the following criteria are met:

- A. Member is currently on antiretroviral therapy
- B. Trial with suboptimal response to alternative therapies (See Appendix A) or contraindication or intolerance to alternative therapies
- C. Body mass index (BMI) was less than 18.5 kg/m² prior to initiating therapy with Serostim (See Appendix B)

II. Criteria for Continuation of Therapy

Treatment of HIV patients with wasting or cachexia to increase lean body mass and body weight, and improve physical endurance

Authorization may be granted for continued treatment of HIV-associated wasting/cachexia when ALL of the following criteria are met:

- A. Member is currently on antiretroviral therapy
- B. Member is currently receiving treatment with Serostim excluding obtainment as samples or via manufacturer's patient assistance programs



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C. Current BMI is less than 27 kg/m² (See Appendix B)

III. APPENDICES

Appendix A – Alternative therapies for HIV Wasting

- Cyproheptadine
- Marinol (dronabinol)
- Megace (megestrol acetate)
- Testosterone therapy if hypogonadal

Appendix B – Calculation of BMI

$$\text{BMI} = \frac{\text{Weight (pounds)} \times 703}{[\text{Height (inches)}]^2} \quad \text{OR} \quad \frac{\text{Weight (kg)}}{[\text{Height (m)}]^2}$$

BMI classification:	Underweight	< 18.5 kg/m ²
	Normal weight	18.5 – 24.9 kg/m ²
	Overweight	25 – 29.9 kg/m ²
	Obesity (class 1)	30 – 34.9 kg/m ²
	Obesity (class 2)	35 – 39.9 kg/m ²
	Extreme obesity (class 3)	≥ 40 kg/m ²

Approval Duration and Quantity Restrictions:

Initial and Renewal Approval: 12 weeks

Quantity Level Limit: Reference Formulary for drug specific quantity level limits

References:

1. Serostim [package insert]. Rockland, MA: EMD Serono, Inc.; June 2019.
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3. Grinspoon S, Mulligan K for the Department of Health and Human Services Working Group on the Prevention and Treatment of Wasting and Weight Loss. Weight loss and wasting in patients infected with human immunodeficiency virus. *Clin Infect Dis.* 2003;36(Suppl 2):S69-78.
4. Polsky B, Kotler D, Steinhart C. HIV-associated wasting in the HAART era: guidelines for assessment, diagnosis, and treatment. *AIDS Patient Care STDS.* 2001;15(8):411-23.
5. Schambelan M, Mulligan K, Grunfeld C, et al. Recombinant human growth hormone in patients with HIV-associated wasting: a randomized placebo-controlled trial. *Ann Intern Med.* 1996;125:873-882.



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6. Evans WJ, Kotler DP, Staszewski S, et al. Effect of recombinant human growth hormone on exercise capacity in patients with HIV-associated wasting on HAART. *AIDS Read.* 2005;15:301-314.
7. Nemechek PM, Polsky B, Gottlieb MS. Treatment guidelines for HIV-associated wasting. *Mayo Clin Proc.* 2000;75:386-394.
8. National Heart, Lung, and Blood Institute. Obesity Education Initiative: The practical guide: identification, evaluation, and treatment of overweight and obesity in adults. Bethesda, MD: US Department of Health and Human Services, National Heart, Lung, and Blood Institute; 2000. NIH Publication No. 00-4084.