

Specialty Guideline Management

Serostim

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Serostim	somatropin

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹

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.

Coverage Criteria

Treatment of HIV Patients with Wasting or Cachexia to Increase Lean Body Mass and Body Weight, and Improve Physical Endurance¹⁻⁸

Authorization of 12 weeks may be granted for treatment of HIV-associated wasting or cachexia when all of

the following criteria are met:

- Member is currently receiving antiretroviral therapy.
- Member has had a trial with suboptimal response or intolerance to alternative therapies (see Appendix A) or has a contraindication to alternative therapies.
- Member meets any of the following criteria:
 - Member has documented unintentional weight loss of $\geq 5\%$ over 6 months.
 - Member has documented unintentional weight loss of $\geq 10\%$ over 12 months.
 - Member has a body mass index (BMI) of $< 20 \text{ kg/m}^2$ prior to initiating therapy with Serostim (see Appendix B).

Continuation of Therapy

Authorization of 12 weeks may be granted for continued treatment in members requesting reauthorization for treatment of HIV-associated wasting or cachexia when all of the following criteria are met:

- Member is currently receiving antiretroviral therapy.
- Member is currently receiving treatment with Serostim excluding when it is obtained as samples or via manufacturer’s patient assistance programs.
- Member has achieved or maintained a documented positive clinical response (e.g. increase in body weight, weight stabilization, or slowing of disease progression).

Appendix

Appendix A – Alternative Therapies for HIV Wasting^{3,4,7,8}

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

Appendix B – Calculation of BMI⁹

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

BMI Classification

BMI Classification	BMI Range
Underweight	$< 18.5 \text{ kg/m}^2$
Normal weight	$18.5 - 24.9 \text{ kg/m}^2$

Reference number(s)
1870-A

BMI Classification	BMI Range
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

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.
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. Bedimo R, Hardy D, Lee D, Palella F, Wohl D. Expert Consensus Statement on an Updated Definition of Unintended Weight Loss Among Persons With Human Immunodeficiency Virus in the Modern Treatment Era. *Clin Infect Dis.* 2024;79(Suppl 2):S63-S75.
9. National Heart, Lung, and Blood Institute (NHLBI) 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, Public Health Service, National Institutes of Health, NHLBI; 2000. NIH Publication No. 00-4084.