

SPECIALTY GUIDELINE MANAGEMENT

SEROSTIM (somatropin)

POLICY

I. 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 Indications

Serostim is indicated for the treatment of 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 are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

Authorization of 12 weeks may be granted for treatment of HIV-associated wasting/cachexia when all of the following criteria are met:

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

III. CONTINUATION OF THERAPY

Authorization of 12 weeks may be granted for the treatment of HIV-associated wasting/cachexia when all of the following criteria are met:

- A. Member is currently receiving treatment with Serostim through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs)
- B. Member is currently on antiretroviral therapy
- C. Current BMI is less than 27 kg/m² (See Appendix B)

IV. APPENDICES

Appendix A – Alternative therapies for HIV Wasting

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

Appendix B – Calculation of BMI and IBW

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

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	≥ 40 kg/m ²

V. REFERENCES

1. Serostim [package insert]. Rockland, MA: EMD Serono, Inc.; December 2016.
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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. 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.