

Effective date: 06/01/2021
Review date: 03/2021, 02/2022, 3/2023, 12/2023
Pharmacy Scope: Medicaid
Medical Scope: Medicaid, Commercial, MMP

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 medically necessary.

MMP Medical Benefit Requests:

MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements

II. 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 of 12 weeks may be granted when all of the following criteria are met:

- A. Member is diagnosed with HIV-associated wasting/cachexia
- B. Member is currently on antiretroviral therapy
- C. Trial with suboptimal response or contraindication or intolerance to at least three alternative therapies, such as cyproheptadine, dronabinol, megestrol acetate or testosterone therapy if hypogonadal
- D. BMI was less than 18.5 kg/m² prior to initiating therapy with Serostim (See Appendix A)

III. CONTINUATION OF THERAPY

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

Authorization of 12 weeks may be granted when all of the following criteria are met:

- A. Member is diagnosed with HIV-associated wasting/cachexia
- B. Member is currently on antiretroviral therapy
- C. Member is currently receiving treatment with Serostim excluding obtainment as samples or via manufacturer's patient assistance programs

Effective date: 06/01/2021
Review date: 03/2021, 02/2022, 3/2023, 12/2023
Pharmacy Scope: Medicaid
Medical Scope: Medicaid, Commercial, MMP

D. Current BMI is less than 27 kg/m² (See Appendix A)

IV. APPENDIX

Appendix A – 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	≥ 40 kg/m ²

V. DOSING

Weight Range	Dose
>55 kg (>121 lb)	6mg* SC daily
45-55 kg (99-121 lb)	5mg* SC daily
35-45 kg (75-99 lb)	4mg* SC daily
<35 kg (<75 lb)	0.1mg/kg SC daily

*Based on an approximate daily dosage of 0.1 mg/kg

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:

Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

Effective date: 06/01/2021
Review date: 03/2021, 02/2022, 3/2023, 12/2023
Pharmacy Scope: Medicaid
Medical Scope: Medicaid, Commercial, MMP

The following HCPCS/CPT code is:

HCPCS Code	Description
J2941	Injection, somatropin, 1mg

Per §§ 42 CFR 422.101, this clinical medical policy only applies to INTEGRITY in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD).

I. REFERENCES

1. Serostim [package insert]. Rockland, MA: EMD Serono, Inc.; February 2022. Accessed November 2023.
2. Mangili A, Murman H, Zampini AM, et al. Nutrition and HIV infection: review of weight loss and wasting in the era of highly active antiretroviral therapy from the nutrition for healthy living cohort. Clin Infect Dis. 2006;42:836-42.
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.
9. Micromedex Solutions [electronic version]. Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: <http://www.micromedexsolutions.com>. Accessed December 11, 2019.
10. Clinical Pharmacology [database online]. Atlanta, GA: Elsevier, Inc.; 2019. <https://www.clinicalkey.com/pharmacology>. Accessed December 11, 2019.