

Effective date: 06/01/2021
Review date: 03/2021, 02/2022, 03/2023
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
- 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

VI. HCPCS codes

HCPCS Code	Description
J2941	Injection, somatropin, 1mg

VII. REFERENCES

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