Effective date: 06/01/2021
Review date: 03/2021, 02/2022, 3/2023, 12/2023, 01/2024 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. SUMMARY OF EVIDENCE

Serostim was approved for the treatment of HIV patients with wasting or cachexia to increase lean body mass, overall body weight, and improve physical endurance. Common side effects include fatigue, nausea, arthralgia, myalgia, gynecomastia, arthrosis, paresthesia, peripheral edema, and generalized edema. A 12-week, randomized, double-blind, placebo-controlled study followed by an open-label extension phase was responsible for the approval of this drug. This study included 178 patients with severe HIV wasting taking nucleoside analogue therapy (pre-HAART era). The patients were treated with Serostim 0.1 mg/kg daily or placebo. The results from one hundred forty (140) evaluable patients were analyzed (those completing the 12-week course of treatment and who were at least 80% compliant with study drug). The average difference in lean body mass (LBM) change between the Serostim-treated group and the placebo-treated group was 3.1 kg (6.8 lbs). The average increase in weight, LBM, and average decrease in body fat, were significantly greater in the Serostim-treated group than in the placebo group after 12 weeks of treatment. There were no significant changes with continued treatment beyond 12 weeks suggesting that the original gains of weight and LBM were maintained. The study also showed that the median treadmill work output increased 13% after 12 weeks of treatment of Serostim and did not occur with placebo.

III. 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/m^2 prior to initiating therapy with Serostim (See Appendix A)

IV. 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/m^2 (See Appendix A)

V. APPENDIX

Appendix A – Calculation of BMI

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

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

VI. 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.

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).

Policy Rationale:
Serostim was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Serostim according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

I. REFERENCES

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