SPECIALTY GUIDELINE MANAGEMENT

SEROSTIM (somatropin)

POLICY

A. 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 Indication
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.

B. REQUIRED DOCUMENTATION
The following information is necessary to initiate the prior authorization review:

- Pretreatment height and weight
- Current height and weight
- Documentation of current anti-retroviral therapy regimen

C. EXCLUSIONS
- Active malignancy
- History of active malignancy in the past 12 months

D. PRESCRIBER SPECIALTIES
- Must be prescribed by or in consultation with an infectious disease specialist

E. CRITERIA FOR APPROVAL
Authorization of 12 weeks may be granted to members prescribed Serostim for the 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. Currently on antiretroviral therapy
   c. BMI was less than 18.5 kg/m² prior to initiating therapy with Serostim (See Appendix B)
   d. Unintentional weight loss of more than 5% of body weight in the previous 6 months prior to initiating therapy with Serostim

F. CONTINUATION OF THERAPY
Authorization of 12 weeks may be granted to members currently on Serostim therapy through a CVS Caremark administered benefit for the 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. Currently on antiretroviral therapy
   c. BMI has improved or stabilized in response to Serostim therapy
   d. Current BMI is less than 27 kg/m² (See Appendix B)

G. DOSAGE AND ADMINISTRATION
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.
1. **Dosing Limits**
   The following dosing limits apply:
   - 6 mg subcutaneous injection per day

**H. APPENDICES**

**Appendix A: Alternative therapies for HIV Wasting**
- Cyproheptadine
- Marinol (dronabinol)
- Megace (megestrol acetate)
- Testosterone therapy if hypogonadal

**Appendix B: Calculation of BMI**

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

**BMI classification:**
- Underweight: < 18.5 kg/m²
- Normal weight: 18.5 – 24.9 kg/m²
- Overweight: 25 – 29.9 kg/m²
- Obesity (class 1): 30 – 34.9 kg/m²
- Obesity (class 2): 35 – 39.9 kg/m²
- Extreme obesity: ≥ 40 kg/m²

**REFERENCES**