

## PHARMACY POLICY STATEMENT

### North Carolina Marketplace

<b>DRUG NAME</b>	<b>Serostim (somatropin)</b>
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Serostim is an anabolic and anticatabolic agent initially approved by the FDA in 1996. It 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. HIV-associated wasting is a serious condition that may be a concern for patients living with HIV, including those with undetectable viral loads and normal CD4 counts who are well controlled on antiretroviral therapy (ART). The 3 key symptoms of HIV-associated wasting are loss of lean body mass (LBM) and body weight, and decreased physical endurance. Serostim significantly increased LBM and body weight, and improved physical endurance in clinical trials.

Serostim (somatropin) will be considered for coverage when the following criteria are met:

#### HIV-Associated Wasting, Cachexia

For **initial** authorization:

1. Member is at least 18 years or older; AND
2. Medication must be prescribed by or in consultation with an infectious disease specialist; AND
3. Member has documentation of HIV-associated wasting or cachexia, with at least **ONE** of the following:
  - a) Unintentional weight loss of > 10% within the last 12 months;
  - b) Unintentional weight loss of > 7.5% within the last 6 months;
  - c) At least 5% body cell mass (BCM) loss within the last 6 months;
  - d) For Men only: BCM <35% of total body weight and BMI < 27 kg/m<sup>2</sup>;
  - e) For Women only: BCM <23% of total body weight and BMI < 27 kg/m<sup>2</sup>;
  - f) BMI < 20 kg/m<sup>2</sup>; AND
4. Member has tried and had a suboptimal response to nutritional counseling in combination with at least one alternative therapy (e.g., cyproheptadine, dronabinol, megestrol acetate, oxandrolone) unless member has a contraindication or intolerance to all alternative therapies listed; AND
5. Member is currently on antiretroviral therapy; AND
6. Member does **NOT** have a history of active malignancy; AND
7. Member's weight is provided for dose calculation.
8. **Dosage allowed/Quantity limit:** Administer 0.1 mg/kg subcutaneously up to a maximum dose of 6mg once daily. Quantity Limit: 28 vials per 28 days.

Weight Range	Maximum Daily Dose
> 55 kg	6mg SC daily
45-55 kg	5mg SC daily
35-45 kg	4mg SC daily
< 35 kg	0.1 mg/kg SC daily

***If all the above requirements are met, the medication will be approved for 12 weeks.***

For **reauthorization**:

1. Chart notes must show a positive response to therapy, as demonstrated by > 2% increase in body weight and/or BCM; AND

2. Documentation HIV wasting is still present (i.e, demonstrated by BMI < 27 kg/m<sup>2</sup>); AND
3. Duration of treatment has not exceeded 48 weeks.

***If all the above requirements are met, the medication will be approved for an additional 12 weeks.***

**CareSource considers Serostim (somatropin) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.**

DATE	ACTION/DESCRIPTION
10/25/2018	New policy for Serostim created.
11/10/2022	Annual review. Transferred to new format. Updated references. Modified the diagnostic of HIV-associated weight loss. Added quantity limits and weight-based maximum daily dosing guidance. Added note stating Serostim has not been studied longer than 48 weeks.
09/18/2023	Added in consultation with prescribing specialty; added history malignancy exclusion; added documentation of weight; updated references; added reauthorization criteria that duration cannot exceed 48 weeks; removed note that Serostim has not been studied longer than 48 weeks.

References:

1. Serostim [prescribing information]. Rockland, MD: EMD Serono, Inc.; Revised June 2019.
2. Polsky B, Kotler D, Steinhart C. Treatment guidelines for HIV-associated wasting. *HIV Clin Trials*. 2004;5(1):50-61. doi:10.1310/6LAR-CPWA-XEH9-WG3T.
3. Polsky B et al. HIV-associated wasting in the HAART era: guidelines for assessment, diagnosis, and treatment. *AIDS Patient Care STDS*. 2001;15(8):411-423.
4. Mangili A 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(6):836-842.
5. Gelato M et al. Role of recombinant growth hormone in HIV-associated wasting and cachexia: pathophysiology and rationale for treatment. *Clin Ther*. 2007;29(11):2269-2288.
6. Wanke C, Kotler D; HIV Wasting Collaborative Consensus Committee. Collaborative recommendations: the approach to diagnosis and treatment of HIV wasting. *J Acquir Immune Defic Syndr*. 2004;37 Suppl 5:S284-S288. doi:10.1097/01.qai.0000144384.55091.0f

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Revised date: 09/18/2023