

Title: somatropin (Serostim)

Origination: 08/21/97	Revised: 05/25/11	Annual Review: 12/15/11
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Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Background Information:

Medication Summaries

- Serostim is a purified recombinant growth hormone prepared by using either *Escherichia coli* or mammalian cells.
- Serostim has been studied in the treatment of HIV-associated adipose redistribution syndrome (HARS). There is limited short-term data that indicate Serostim decreases visceral adipose tissue; however, the clinical significance with respect to cardiovascular risk profile is unknown.
- Serostim (somatropin) for injection is indicated for the treatment of wasting or cachexia in HIV Members to increase lean body mass and body weight, and to improve physical endurance.

Eligibility Criteria

- Member must be eligible for benefit coverage within the specified date(s) of service.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

Exclusions - Conditions not indicated for Serostim therapy:

• Anorexia	• Fatigue	• Oral/Esophageal Lesions
• Early satiety	• Dysphasia	• Drug/Nutrient Interactions
• Hypermetabolism	• Nausea/Vomiting	• Hypogonadism

Reference Statement

- Guidelines are compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

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Procedure:

- 1.0 Request for *initial therapy* for **HIV-associated adipose redistribution syndrome (HARS)** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying **ALL** of the following:
 - 1.1 The practitioner must be experienced in the diagnosis and management of AIDS and will monitor the Member throughout Serostim therapy; **AND**
 - 1.2 Involuntary weight loss greater than 10% of baseline body weight and one (1) or more of the following:
 - 1.2.1 Chronic diarrhea (at least two [2] loose stools per day for 30 days or more);
 - 1.2.2 Chronic weakness and documented fever (for 30 days or more, intermittent or constant) in the absence of concurrent illness or any condition other than HIV infection that could explain the findings (e.g., cancer, tuberculosis, cryptosporidiosis, or other specific enteritis);
 - 1.3 If Member meets above criteria, Serostim may be approved for a maximum of six (6) weeks of therapy.
- 2.0 Request for *initial therapy* for **failure to thrive with combined treatment modalities** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying **ALL** of the following:
 - 2.1 Exercise (if practical, weight resistant exercises intended for muscle mass development); **AND**
 - 2.2 Adequate dietary intake; **AND**
 - 2.3 Fortified nutritional supplementation; **AND**
 - 2.4 A documented baseline body weight and body cell mass (BCM) by bioelectrical impedance analysis (BIA); **AND**
 - 2.5 A weight chart documenting both body weight and BCM must be included with the Member's medical information provided by the requesting independent practitioner; **AND**

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Procedure, continued:

- 2.0 Request for *initial therapy* with Serostim for **failure to thrive with combined treatment modalities** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying **ALL** of the following, continued:
- 2.6 Concomitant antiretroviral therapy is required; the independent practitioner has previously prescribed antiviral therapy and the Member has demonstrated compliance; **AND**
 - 2.7 Evaluation by a registered dietician. The registered dietician has assessed, intervened, and monitored the Member according to the American Dietetic Association's Nutrition Therapy Protocol for HIV/AIDS (Attachment A); **AND**
 - 2.8 The Member (male) has normal free (>72 ng/mL) and total (>346 ng/dL) testosterone levels;
 - 2.9 If Member meets the criteria, initial therapy may be approved for up to six (6) weeks:
 - 2.9.1 Notify the independent practitioner's office that the Member must be evaluated after four (4) weeks of therapy and both body weight and BCM must be documented to continue therapy beyond the six (6) week initial authorization.
- 3.0 Request for *continuation of therapy* beyond initial authorization period:
- 3.1 Documentation from the Member's medical records maintained by the requesting provider verifying the following must be provided:
 - 3.1.1 Treatment duration is based on analysis of weight and body cell mass (BCM) obtained from a bioelectrical impedance analysis (BIA);
 - 3.1.2 The independent practitioner must evaluate and document the Member's weight and BCM after four (4) weeks of therapy;
 - 3.1.3 Members who show clinical improvement (2% increase in body weight or BCM) after four (4) weeks may have an approval for a total of 12 weeks of therapy;

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Procedure, continued:

- 3.0 Request for *continuation of therapy* beyond initial authorization period, continued:
- 3.2 Members who continue to lose weight during the first four (4) weeks of therapy must be re-evaluated for continued therapy:
- 3.2.1 In Members who experience weight loss after four (4) weeks, Serostim continuation will be re-evaluated based on the intervention of a clinical event (e.g., opportunistic infection), the Member's clinical status, and the measured BCM;
- 3.2.2 Upon treatment of the clinical event and during the sixth week of Serostim therapy, the Member will again be evaluated for continuation of therapy; approval will be based on the stabilization or an increase in BCM;
- 3.2.3 Re-evaluation will be required for maintenance therapy beyond 12 weeks;
- 3.3 If Member meets the criteria, Serostim may be approved for an additional 12 weeks.

References:

1. CDC. 2005 Revised classification system for HIV infection and expanded surveillance case definition for AIDS among adolescents and adults. *MMWR* 2007; 56:634.
2. Nieschlag E, Swerdloff R, Behre HM, et al. Investigation, treatment, and monitoring of late-onset hypogonadism in males: ISA, ISSAM, and EAU recommendations. *J Androl.* 2006 Mar-Apr;27(2):135-7.
3. Polsky B, Kotler D, and Steinhart C. Treatment guidelines for HIV-associated wasting. *HIV Clin Trials.* 2004 Jan-Feb;5(1):50-61.
4. Serono, Inc. Serostim[®] (somatropin) Powder for Injection. Package Insert. Revised August 2007.
5. Nemechek PM, Polsky B, and Gottlieb MS. Treatment guidelines for HIV-associated wasting. *Mayo Clin Proc.* 2000 Apr;75(4):386-94.

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Disclaimer Information:

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.