



## POLICY AND PROCEDURE

POLICY NUMBER: *RX.PA.007.E*

REVISION DATE: *4/13*

PAGE NUMBER: 1 of 3

**POLICY TITLE:** Somatropin (Serostim)  
**DEPARTMENT:** Clinical Pharmacy Services- Utilization Management  
**ORIGINAL DATE:** November 2001 (as adopted from UPMC Health Plan)

**Last P & T Committee Approval Date:** February 2017

**Product Applicability:** mark all applicable products below:

<b>COMMERCIAL</b>	<input type="checkbox"/> HMO <input type="checkbox"/> PPO   Products: <input type="checkbox"/> Small   Exchange: <input type="checkbox"/> Shop <input checked="" type="checkbox"/> All <input type="checkbox"/> Indiv. <input type="checkbox"/> Indiv. <input type="checkbox"/> Large
<b>OTHER</b>	<input checked="" type="checkbox"/> Self-funded/ASO

### PURPOSE

The purpose of this policy is to define the prior authorization process for somatropin (Serostim).

Somatropin (Serostim) is indicated for HIV-associated wasting/cachexia.

### DEFINITIONS

N/A

### POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

The drug, somatropin (Serostim), is subject to the prior authorization process.

### PROCEDURE

#### Initial Authorization Criteria:

*Must meet all of the criteria listed under the respective diagnosis:*

**For All Diagnoses:**



- Must have clear documentation of HIV infection with serum antibodies to HIV
- Must have failed treatment with at least one other medication used for HIV-wasting [*i.e.*, dronabinol (Marinol®), megestrol (Megace®)] as documented by the treating provider unless contraindications exist
- Must be compliant with antiretroviral medications
- Must have a documented involuntary weight loss of at least 10% from baseline pre-morbid weight or to a BMI <20 in the absence of a concurrent illness or medical condition other than HIV infection that would explain these findings
- Must be receiving adequate caloric intake and nutritional counseling
- Must not have active malignancy other than Kaposi's Sarcoma
- Must follow somatropin (Serostim) dosing guidelines of 4 – 6mg/day (based on approximate 0.1mg/kg/day)
- If needed, cases may be reviewed with a health care specialist from an AIDS clinic to assist in making a decision to provide therapy.

**Reauthorization Criteria:**

All prior authorization renewals are reviewed on a case-by-case basis to determine the Medical Necessity for continuation of therapy. One additional authorization may be given for therapy continuation for up to 36 additional weeks with documentation from the prescriber of weight stabilization or weight gain. There are no safety or efficacy data for continuous somatropin (Serostim) use beyond 48 weeks.

**Limitations:**

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 12 weeks
Reauthorization	Case-by-case basis

If the established criteria are not met, the request is referred to a Medical Director for review.

**REFERENCES**

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4. Mulligan K, Grunfeld C, Hellerstein MK, et al. Anabolic effects of recombinant human growth hormone in patients with wasting associated with human immunodeficiency virus infection. *J Clin Endocrinol Metab*. 1993;77:956-962.
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7. Revision of the CDC surveillance case definition for acquired immunodeficiency syndrome. *MMWR Morbid Mortal Wkly Rep.* 1987;36:3S-15S.
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13. Weinroth SE, Parenti DM, Simon GL. Wasting syndrome in AIDS pathophysiologic mechanisms and therapeutic approaches. *Infect Agents Dis.* 1995;4:76-94.

#### **RECORD RETENTION**

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

#### **REVIEW HISTORY**

<b>DESCRIPTION OF REVIEW / REVISION</b>	<b>DATE APPROVED</b>
<i>Annual Review</i>	<i>02/17</i>

