





Provider Certification Prior Authorization Form – Serostim®

Patient's Last Name:

Grid for Patient's Last Name

Patient's First Name:

Grid for Patient's First Name

Prescription Information:

Please fill out all questions completely and submit required clinical documentation where noted.

Dosing Recommendations: 0.1 mg/kg subcutaneous (SC) QD or QOD up to 6 mg per day

- 1. Drug Name: Serostim® (somatropin)
2. Drug Strength:
[ ] 4.0 mg vial
[ ] 5.0 mg vial
[ ] 6.0 mg vial

3. Directions:

Blank lines for Directions

Clinical Requirements:

4. Please document if this a request for initial therapy or continuation of therapy:

Blank line for documentation

5. Has the patient been diagnosed with acquired immunodeficiency syndrome (AIDS) and AIDS wasting syndrome (see chart on last page for reference)? [ ] Yes [ ] No

6. Has the patient tried and failed preferred CADAP formulary regimens of megestrol and dronabinol? [ ] Yes [ ] No

If Yes, please provide prescribed date(s) for each trial and submit clinical documentation of failures with fax:

7. Is the patient continuing to use their prescribed anti-viral therapy? [ ] Yes [ ] No

List current anti-viral therapy: \_\_\_\_\_

8. Has the patient been evaluated for and diagnosed with inadequate nutritional intake, malabsorption, and/or hypogonadism? [ ] Yes [ ] No

9. If the patient is hypogonadal, has the patient been administered testosterone? [ ] Yes [ ] No

If Yes, please attach documentation of administration.

(Form continued on next page.)



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Patient's Last Name:

Grid for Patient's Last Name (13 columns)

Patient's First Name:

Grid for Patient's First Name (13 columns)

10. Has the patient had progressive weight loss greater than or equal to 10% of their body weight?

Yes  No

If Yes, please document the patient's two most recent body mass indexes (BMI) obtained within the last year:

BMI 1 and date taken: \_\_\_\_\_

BMI 2 and date taken: \_\_\_\_\_

11. Does the patient have a known hypersensitivity to growth hormone?

Yes  No

12. Are you requesting greater than 48 weeks of Serostim® therapy?

Yes  No

Note: If requesting greater than 48 weeks of Serostim therapy, you must supply sufficient clinical justification which will be forwarded to the ADAP Coordinator at the CT Department of Public Health.

Healthcare Provider Certification: I certify that I am a licensed healthcare provider with prescriptive authority and the information provided on this form is true, accurate, and complete. The issuance of the prescription is in compliance with the utilization criteria outlined on the back of this prior authorization form. I understand that if I provide false, fraudulent, and misleading information, that I face fines and penalties under State law.

Healthcare Provider's Signature

NPI Number

Date of Request

Time of Request



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Clinical Requirements for Serostim®\* under the CADAP [Somatropin (rDNA origin) for injection]

**FOR REFERENCE ONLY\* PLEASE DO NOT FAX THIS PAGE**

**Diagnostic Indications:**

- Serostim® is indicated for the treatment of AIDS and AIDS wasting syndrome to increase lean body mass and body weight, and improve physical endurance.

**Note: The package insert for Serostim indicates that there is no safety or efficacy data for continuous use of this medication beyond 48 weeks.**

**Patient MUST meet one of the following definitions of AIDS and AIDS wasting syndrome:**

- 10% unintentional weight loss over 6 months;
- 7.5% unintentional weight loss over 3 months;
- 5% Body cell mass (BCM) loss within 30 days; **OR**
- BMI < 20 kg/m<sup>2</sup>.

**Contraindications:**

- Serostim® should not be used in patients with acute critical illness due to complications following open heart or abdominal surgery, multiple accidental trauma, or acute respiratory failure.
- Serostim® is contraindicated in patients with active neoplasia (either newly diagnosed or recurrent). Any anti-tumor therapy should be completed prior to starting therapy with Serostim®.

**Other:**

- Optimal nutrition is essential to keep up with the increased caloric demands and to decrease the rate of catabolism.
- Patient must be on proper antiretroviral therapy to control viral load.

**Dosage:**

Weight Range	Dose
> 55kg (> 121 lb.)	6.0 mg* SC daily
45–55 kg (99–121 lb.)	5.0 mg* SC daily
35–45 kg (75–99 lb.)	4.0 mg* SC daily; 8.8 mg* SC daily
< 35 kg (< 75 lb.)	0.1 mg/kg SC daily

\*Based on an approximate daily dosage of 0.1 mg/kg.

**UPON COMPLETION, PLEASE RETURN VIA FAX TO: 855-461-2759**

The fax machine is in a secured location as required by HIPAA regulations.

For any questions, please call Magellan Rx Management Pharmacy Unit at: 800-424-3310