

Initial approval period is for a total of ninety (90) days; 30 days for retreatment.
Note: Form must be completed in full. An incomplete form may be returned.

Serostim® Criteria:

1. The physician must first complete, sign, and date the Serostim PA form.
2. For initial therapy, or request for additional therapy, the physician must submit official medical records to support or answer all the questions addressed on the PA form, in addition to a six-month weight chronical indicating the most recent weights.
3. Recipient must 18 years of age or older.
4. Recipient must have a diagnosis of HIV associated wasting or cachexia.
5. Recipient must be on anti-retroviral therapy.
6. Recipient must have experienced at least a 7.5% unintentional weight loss within the last 6 months, 10% involuntary weight loss in last 12 months, or have a Body Mass Index (BMI) < 20 for initial approval.
7. Alternatively, recipient may have a Body Cell Mass (BCM) < 35% (male) or <23% (female) of total body weight and a Body Mass Index less than 27. Another qualifier would be a greater than or equal to 5% BCM loss over 6 months. **(ATTACH A SERIES OF BIOELECTRIC IMPEDANCE ANALYSIS [BIA] RESULTS IF APPLICABLE.)**
8. Treatment must also include nutritional assessment and counseling. Total parenteral nutrition is sometimes of benefit in patients with damaged gastrointestinal tracts. Appetite stimulants such as megestrol may promote weight gain; however, most gain with megestrol acetate is in fat rather than BCM.
9. Serostim is contraindicated in patient's with active neoplasia.
10. Testosterone replacement therapy (minimum of 4 weeks) in hypogonadal men may increase lean body mass and muscle strength.
11. Oxandrolone has been found to produce significant increases in weight gain and BCM.
12. Dosage must be adjusted according to recipient's weight.

Weight Range	Dose
>55kg (121 lb)	6 mg SC daily
45-55kg (99-121 lb)	5 mg SC daily
35-45kg (75-99 lb)	4 mg SC daily
<35 kg(<75 lb)	0.1 mg/kg SC daily

13. Length of therapy is 12 weeks; however, if a positive response to therapy (a 2% or greater increase in body weight and/or BCM) occurs but wasting is still evident, treatment may be continued and response reevaluated on a month-by-month basis. **THEREFORE, RETREATMENT WILL BE APPROVED FOR A MAXIMUM OF 30 DAYS AT A TIME.**
14. Physician must submit a new PA form for additional therapy.