Somatropin (Serostim) Clinical Guideline

Somatropin (Serostim) is a self-injected medication used in the treatment of AIDS wasting syndrome. Although depletion of body weight and lean body mass has been associated with increased morbidity and mortality in AIDS, the clinical significance of treatment-induced weight gain and increased lean body mass has yet to be established.

Because somatropin has minimal efficacy in many patients (average weight gain of 1.6 kg and no significant changes with continued treatment beyond 12 weeks), has a limited indication, as well as being extremely costly, prior authorization (PA) requests for somatropin must meet strict approval criteria.

The following information will be required with somatropin PA requests:
1. All prescriptions for somatropin must be written by a physician specializing in HIV.
2. PAs for somatropin will be evaluated only if written for a patient meeting the Center for Disease Control and Prevention’s (CDC) definition of AIDS wasting syndrome:
   a. Profound involuntary weight loss of >10% of baseline body weight, plus either chronic diarrhea (≥2 loose stools per day) for ≥30 days or chronic weakness and documented fever (intermittent or constant), for ≥30 days, in the absence of a concurrent illness or condition other than HIV infection that could explain these symptoms (e.g., cancer, tuberculosis, cryptosporidiosis or other specific enteritis).
3. PAs for somatropin will require documentation that other causes have been ruled out that may potentially cause weight loss. These other causes include, but are not limited to, malignancy, inadequate nutritional intake (anorexia, diarrhea, stomatitis, depression) and opportunistic infections (Mycobacterium avium, Pneumocystis carinii, esophageal candidiasis, cryptosporidiosis, microsporidiosis, Salmonella, Shigella, cytomegalovirus, tuberculosis).
4. Somatropin should be reserved for patients who have had an inadequate response to all first-line agents used in the treatment of AIDS wasting syndrome. These agents include, but are not limited to, megestrol, dronabinol, oxandrolone and testosterone.
5. To be effective, patients receiving somatropin must have adequate caloric intake. Therefore, a written evaluation by a registered dietitian that documents adequate nutrition is required.
6. In vitro data suggests that treatment with somatropin may potentially accelerate replication of HIV. Therefore, appropriate antiretroviral therapy is essential for approval of somatropin. Somatropin PAs may be denied for patients not receiving three or more antiretrovirals and/or for patients not adherent with antiretroviral regimens.
7. The recommended dose of somatropin is 0.1mg/kg/day up to 6 mg subcutaneously at bedtime daily. The maximum approved dosage is 6 mg subcutaneously daily for 12 weeks.

FDA-Approved Indication:
Serostim (somatropin [rDNA origin] for injection) 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.
**Evaluation Criteria for Somatropin:**

**Initial four weeks of treatment:**
- Documentation in the medical record of complete history and physical examination including:
  - History of nutritional status including appetite, estimation of caloric intake, gastrointestinal function including presence of diarrhea and number of daily stools, and history of endoscopic procedures
  - Psychosocial evaluation, including presence of significant anxiety and/or depression affecting food intake
- Record of the following measurements:
  - Height, weight, ideal body weight, body mass index (BMI)
  - Body cell mass (BCM) by bioelectrical impedance analysis (BIA)
  - Serial measurements — weekly
- Patients must meet one of the following criteria for HIV-associated wasting:
  - BCM loss of 5% within the preceding six months
  - In men: BCM less than 35% of total body weight and BMI less than 27 kg/m²
  - In women: BCM less than 23% of total body weight and BMI less than 27 kg/m²
  - BMI less than 20 kg/m²
  - BMI greater than 20 kg/m² and less than 25 kg/m², and
  - Unintentional weight loss of 10% within the preceding 12 months or 7.5% unintentional weight loss within the preceding six months
- Patients should have an evaluation of gastrointestinal function with attention to the presence of malabsorption, a review of food intake, number of daily calories and estimate of physical activity level.
- An active malignancy other than Kaposi’s sarcoma has been excluded clinically, through diagnostic laboratory examination, and/or radiographically.
- Male patients should have a serum testosterone level and, if low, a trial of testosterone replacement therapy.
- Patients must have a viral load assay and a CD4 count and must be undergoing treatment with an appropriate antiretroviral therapy regimen.
- Patients should have a trial with an appetite stimulant if the recipient has inadequate caloric intake and anorexia.
- For male patients, an initial trial of androgen is recommended for HIV-associated wasting. If this is omitted, a statement should be provided documenting the clinical decision to proceed directly with somatropin therapy.
- Patients must receive somatropin within recommended dosing guidelines for body weight.

**Criteria for reassessment of therapy through 12 weeks:**
- Treatment must be re-evaluated after four weeks and eight weeks of therapy. Repeat weight assessment and documentation is required at four weeks and eight weeks of therapy to assure weight stabilization.
- Therapy must be discontinued in recipients who continue to lose weight in the first four weeks of treatment.
- If, after four weeks of therapy, weight loss has stopped or if the recipient is gaining weight, somatropin may be continued for another 28 days.
- If, after eight weeks of therapy, the patient is losing or has failed to gain weight from the original measurement, somatropin must be stopped.
- If the patient had initially gained weight at four weeks but has neither gained nor lost weight at the eight-week re-evaluation, somatropin may be continued for another 28 days.
• A maximum of 12 weeks of treatment is allowed with prior authorization. Claims without prior authorization will be denied.
• Prior authorization is limited to four-week intervals.

Continuation beyond the initial 12 weeks:
• All patients must stop somatropin following the initial 12-week treatment for an eight-week period of observation unless there is documentation that HIV-associated wasting is still present. During the eight-week observation period, body weight, BMI and BCM should be monitored on a weekly basis.
• Therapy beyond 12 weeks may be continued with a patient who has demonstrated a beneficial response to somatropin during the initial 12 weeks of therapy (defined as a 2% or greater increase in body weight or BCM), and
  ○ Still exhibits evidence of wasting (BMI less than 20 kg/m2) or has a BCM not yet normalized (BCM less than 40% in non-obese men or less than 28% in non-obese women).
• As long as the patient continues to gain weight or BCM, somatropin may be extended every 28 days with prior authorization, until BCM and/or weight are normalized.
• Once BCM and/or weight have normalized, somatropin should be stopped.

Criteria for reinitiating therapy within six months:
• Patients may resume somatropin therapy within six months of initial therapy if there is documentation of an unintentional 5% loss of body weight or BCM loss of greater than 5% or any of the criteria for HIV-associated wasting within six months after completion of an uninterrupted 12-week course of somatropin therapy.
• Reinitiating somatropin is allowed for up to an additional 12 weeks, with reassessments required at the same four- and eight-week intervals during the second 12-week course of therapy. A recent copy of the recipient’s BIA documenting the BCM loss is required with prior authorization submission.

Criteria for repeat somatropin therapy six months after cessation of treatment:
• If the patient has not re-initiated somatropin six months after completing an uninterrupted 12-week course of therapy, somatropin may be repeated, provided the criteria for the initial 28 days of therapy are met. Reinitiating somatropin is allowed for up to an additional 12 weeks, with reassessments required at the same four- and eight-week intervals during the second 12-week course of therapy. A recent copy of the recipient’s BIA is required with prior authorization submission.
• Trials of alternate treatment may be omitted if previous use in the recipient was unsuccessful. The use of somatropin beyond the initial 12-week course must meet the criteria stated above for continued treatment.

**Dosing:**

*Initial 12 weeks:* 4 to 6mg subcutaneously (SC) daily based upon weight:
- >55 kg: 6 mg SC daily at bedtime
- 45–55 kg: 5 mg SC daily at bedtime
- 35–45 kg: 4 mg SC daily at bedtime
- <35 kg: 0.1 mg/kg SC daily at bedtime

*Therapy approved beyond 12 weeks:* 4 mg subcutaneously daily at bedtime.

**AWP Cost Information** as of April 2020
- 4 mg vial = $460
- 5 mg vial = $580

April 2020
6 mg vial = $695
Estimated cost per month = $12,880 to $19,460

References