Indication:
“Serostim is indicated for the treatment of HIV patients with wasting or cachexia to increase lean body mass and body weight, and improve physical endurance.”1

Dosage Form/Strength: 1
- Serostim: 4mg, 5mg, 6mg powder for injection

Criteria for Approval: 1, 2, 3, 4, 5
- The patient has a diagnosis of HIV/AIDS-associated wasting syndrome/cachexia; AND,
- Patient has a Human Immunodeficiency Virus infection; AND,
- The patient is currently receiving antiretroviral therapy; AND,
- Patient has tried and failed, or has a contraindication to either dronabinol (Marinol®) or megestrol (Megace®); AND,
- Causes other than HIV for the patient’s weight loss have been ruled out; AND,
- Patient has unintentionally lost more than 10% of his/her baseline body weight, OR
  - Patient weighs less than 90% of the lower limit of ideal body weight OR
  - Patient has a body mass index (BMI) less than 20 kg/m² OR
  - Patient has lost more than 5% body weight in the past 6 months; AND,
- The patient has chronic diarrhea (defined as 2 or more loose stools daily for at least 30 days), OR
  - The patient has had intermittent or constantly occurring chronic weakness and fever for at least 30 days.

Criteria for Denial: 1, 2, 3, 4, 5, 6, 7, 8
- Patient does not have a diagnosis of HIV or AIDS; OR,
- The patient is not currently receiving antiretroviral therapy; OR,
- Causes other than HIV for the patient’s weight loss have not been ruled out; OR,
- Patient has not tried and failed, or does not have a contraindication to either dronabinol (Marinol) or megestrol (Megace); OR,
- Being used to increase body mass or strength solely for professional, recreational, or social reasons (for example: athletes, bodybuilders); OR,
- Being used to reverse the effects of aging (anti-aging); OR,
- The patient has one or more of the following contraindications or exclusions to the use of GH therapy:
  - An active malignancy or history of malignancy in the past 12 months
  - Active proliferative or severe non-proliferative diabetic retinopathy
  - An acute critical illness.
• Concurrent use with Increlex® (mecasermin), OR,
• Patient has not unintentionally lost more than 10% of his/her baseline body weight, OR
  o Patient weighs greater than or equal to 90% of the lower limit of ideal body weight OR
  o Patient has a body mass index (BMI) greater than or equal to than 20 kg/m² OR
  o Patient has not lost more than 5% body weight in the past 6 months; AND,
• The patient has not had chronic diarrhea (defined as 2 or more loose stools daily for at least 30 days), OR
  o The patient has not had intermittent or constantly occurring chronic weakness and fever for at least 30 days

Criteria for Reauthorization Approval:
• The patient’s lean body mass and body weight have increased, and physical endurance has improved due to treatment with Serostim.

Criteria for Reauthorization Denial
• The rate of the patient’s weight loss was unaffected by Serostim treatment (in other words, treatment with growth hormone did not work and the patient’s weight loss did not slow down, stop, stabilize, or improve).

Length of Authorization:
• Initial coverage may be approved for up to 6 months.
• Subsequent re-authorizations may be approved for 12 months.

Quantity Limit:
• None

Mechanism of Action:
“Serostim® is an anabolic and anticatabolic agent which exerts its influence by interacting with specific receptors on a variety of cell types including myocytes, hepatocytes, adipocytes, lymphocytes, and hematopoietic cells. Some, but not all of its effects, are mediated by insulin-like growth factor-1 (IGF-1).”¹
References / Footnotes:


4. Centers for Disease Control. Revision of the CDC Surveillance Case Definition for Acquired Immunodeficiency Syndrome. MMWR 1987;36(Suppl no. 1S):12S.


