



STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN - SEROSTIM

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOMATROPIN	SEROSTIM	02824		GPI-10 (3010002010)	BRAND = SEROSTIM

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a patient with a diagnosis of HIV wasting/cachexia who meets **ALL** of the following criteria?
  - The requested medication is NOT prescribed for athletic enhancement or anti-aging purposes
  - Therapy is prescribed by or in consultation with ONE of the following specialists: gastroenterologist, nutritional support specialist, or infectious disease specialist
  - The patient is on HIV anti-retroviral therapy
  - The patient has inadequate response to previous therapy (i.e., exercise training, nutritional supplements, appetite stimulants, or anabolic steroids)
  - The patient has an inadequate response to previous pharmacological therapy including one of the following: cyproheptadine, Marinol (dronabinol), or Megace (megestrol acetate)
  - Alternative causes of wasting have been ruled out; alternative causes include:
    - Altered metabolism (from metabolic and hormonal abnormalities) including testosterone deficiency or peripheral growth hormone resistance
    - Diarrhea
    - Inadequate energy (caloric) intake
    - Malignancies
    - Opportunistic infections
  - The patient meets **ONE** of the following criteria for weight loss:
    - 10% unintentional weight loss over 12 months
    - 7.5% unintentional weight loss over 6 months
    - 5% body cell mass (BCM) loss within 6 months
    - BCM less than 35% (men) AND a body mass index (BMI) less than 27 kg per meter squared
    - BCM less than 23% (women) of total body weight AND a body mass index (BMI) less than 27 kg per meter squared
    - BMI less than 18.5 kg per meter squared

If yes, continue to #2.

If no, do not approve.

**DENIAL TEXT:** See the initial denial text at the end of the guideline.

CONTINUED ON NEXT PAGE



STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN - SEROSTIM

INITIAL CRITERIA (CONTINUED)

2. Is the patient hypogonadal as defined by **ONE** of the following?

- Total serum testosterone level of less than 300ng/dL (10.4 nmol/L)
- A low total serum testosterone level as indicated by a lab result, with a reference range, obtained within 90 days
- A free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)

If yes, continue to #3.

If no, **approve for 12 weeks by GPID or GPI-14 for all strengths.**

3. For patients who are hypogonadal, does the patient meet the following criterion?

- The patient has tried testosterone therapy (e.g., testosterone cypionate, AndroGel, Androderm, Axiron, Delatestryl, Fortesta, Striant, Testim, Testopel, Vogelxo, Natesto)

If yes, **approve for 12 weeks by GPID or GPI-14 for all strengths.**

If no, do not approve.

**INITIAL DENIAL TEXT: \*Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **SOMATROPIN (Serostim)** requires the following rule(s) be met for approval:

- A. You have HIV (human immunodeficiency virus) wasting/cachexia (extreme weight loss and muscle loss)
  - B. The requested medication is NOT prescribed for athletic enhancement or anti-aging purposes
  - C. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions), nutritional support specialist OR infectious disease specialist (doctor who specializes in the treatment of infections)
  - D. You are on HIV (human immunodeficiency virus) anti-retroviral therapy
  - E. You have had an inadequate response to previous therapy such as exercise training, nutritional supplements, appetite stimulants or anabolic steroids
  - F. You have had an inadequate response to previous pharmacological (drug) therapy including one of the following: cyproheptadine, Marinol (dronabinol), or Megace (megestrol acetate)
- (Initial denial text continued on next page)**

CONTINUED ON NEXT PAGE



STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN - SEROSTIM

INITIAL CRITERIA (CONTINUED)

- G. Alternative causes of wasting have been ruled out. Alternative causes may include:
1. Altered metabolism (from metabolic and hormonal abnormalities) including testosterone deficiency or peripheral growth hormone resistance
  2. Diarrhea
  3. Inadequate energy (caloric) intake
  4. Malignancies (tumors)
  5. Opportunistic infections (an infection that can occur because of a weakened immune system)
- H. You meet ONE of the following criteria for weight loss:
1. 10% unintentional weight loss over 12 months
  2. 7.5% unintentional weight loss over 6 months
  3. 5% body cell mass (BCM) loss within 6 months
  4. BCM less than 35% (men) and a body mass index (BMI) less than 27 kg per meter squared
  5. BCM less than 23% (women) of total body weight and a body mass index (BMI) less than 27 kg per meter squared
  6. BMI less than 18.5 kg per meter squared
- I. **If you are hypogonadal (you have low testosterone levels), approval also requires:**
1. You meet one of the following criteria for low testosterone:
    - a. Total serum testosterone level of less than 300ng/dL (10.4nmol/L)
    - b. A low total serum testosterone level as indicated by a lab result, with a reference range, obtained within 90 days
    - c. A free serum testosterone level of less than 5 ng/dL (0.17 nmol/L)
  2. You have tried testosterone therapy (examples include testosterone cypionate, AndroGel, Androderm, Axiron, Delatestryl, Fortesta, Striant, Testim, Testopel, Vogelxo, Natesto)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

CONTINUED ON NEXT PAGE



STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN - SEROSTIM

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Has the patient received more than 24 weeks of therapy within the plan year?

If yes, do not approve.

**DENIAL TEXT:** See the renewal denial text at the end of the guideline.

If no, continue to #2.

2. Is the request for a patient with HIV wasting/cachexia who meets **ALL** of the following criteria?
  - The requested agent is NOT prescribed for athletic enhancement or anti-aging purposes
  - The patient has shown clinical benefit in muscle mass and weight as indicated by a 10% or greater increase in weight or BCM from baseline (**Note:** Current and baseline weight must be documented including dates of measurement)
  - The patient is on HIV anti-retroviral therapy

If yes, **approve for 12 weeks by GPID or GPI-14 for all strengths.**

If no, do not approve.

**RENEWAL DENIAL TEXT:** **\*Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **SOMATROPIN (Serostim)** requires the following rule(s) be met for renewal:

- A. You have HIV (human immunodeficiency virus) wasting/cachexia (severe muscle and weight loss)
- B. You have NOT received more than 24 weeks of therapy within the plan year
- C. The requested agent is NOT prescribed for athletic enhancement or anti-aging purposes
- D. You have shown clinical benefit in muscle mass and weight as indicated by at least a 10 percent increase in weight or BCM (body cell mass) from baseline (Note: current and baseline weight must be documented including dates of measurement)
- E. You are on HIV anti-retroviral therapy

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

**CONTINUED ON NEXT PAGE**



**STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES**

**SOMATROPIN - SEROSTIM**

---

**RATIONALE**

For further information, please refer to the Prescribing Information and/or Drug Monograph for Serostim.

**REFERENCES**

- Serostim [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; June 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/23

Created: 10/22

Client Approval: 11/22

P&T Approval: 04/21