Clinical Policy: Somatropin (Serostim)

Reference Number: CP.CPA.151
Effective Date: 11.16.16
Last Review Date: 11.17 Revision Log
Line of Business: Commercial

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Somatropin (Serostim®) is a human growth hormone (hGH) produced by recombinant DNA technology.

FDA approved 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. Concomitant antiretroviral therapy is necessary.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation® that Serostim is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. HIV Infection Wasting or Cachexia (must meet all)**:**

1. Diagnosis of HIV infection;
2. Member is on concomitant anti-viral therapy;
3. Involuntary weight loss of >10% of body weight;
4. One of the following (a or b) unless contraindicated or clinically significant adverse effects are experienced:
   a. If inadequate appetite, failure of megestrol acetate or dronabinol to stimulate appetite;
5. If inadequate intake due to nausea, failure of the preferred agents for nausea; Failure of a therapeutic trial of testosterone in combination with an anabolic steroid in males unless contraindicated or clinically significant adverse effects are experienced;
6. Weight at time of request is provided;
7. Dose does not exceed 6 mg SC/day.

Approval duration: 6 months or to member's renewal period, whichever is longer

B. Other diagnoses/indications

1. Refer to CP.CPA.09 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

II. Continued Therapy

A. HIV Infection Wasting or Cachexia (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Documentation of positive response to therapy (e.g., a 2% increase in body weight and/or body cell mass (BCM). Once BCM is normalized, therapy may be stopped and the patient may be monitored for wasting to reoccur);
3. Dose does not exceed 6 mg SC/day.

Approval duration: 6 months or to member's renewal period, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to CP.CPA.09 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.CPA.09 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

BIA: Bioelectrical impedance analysis
BCM: Body cell mass
hGH: Human growth hormone

Appendix B: General Information

- Micromedex lists the use of Serostim for Fat Maldistribution with HIV Infection as Recommendation IIb.
- For prior authorization guidelines on the use of Serostim in other indications, please refer to the Human Growth Hormone Guidelines.
- Body cell mass (BCM): The total mass of all the cellular elements in the body which constitute all the metabolically active tissue of the body. The preferred method for assessing BCM depletion is bioelectrical impedance analysis (BIA) which can be performed with portable equipment in the office setting.
- Preferred agents for nausea/vomiting include ondansetron, hydroxyzine, promethazine, prochlorperazine, meclizine, trimethobenzamide, or dimenhydranate.
- Contraindicated in patients with active malignancy, diabetic retinopathy, and who are critically ill.

Appendix C: Therapeutic Alternatives

Drug*	Dosing Regimen	Dose Limit/Maximum Dose
Appetite stimulants		

Drug*	Dosing Regimen	Dose Limit/Maximum Dose
Megestrol (Megace®)	400 - 800 mg PO daily (10 – 20 ml/day)	800 mg/day
Dronabinol (Marinol®)	2.5 mg PO bid	20 mg/day
Testosterone replacement products		
Testosterone enanthate or cypionate (Various brands)	50 - 400 mg IM Q2 – 4 wks	400 mg Q 2 wks
Androderm® (testosterone transdermal)	2.5 – 7.5 mg patch applied topically QD	7.5 mg/day
Androgel® (testosterone gel)	5 - 10 gm gel (delivers 50 – 100 mg testosterone) applied topically QD	10 gm/day gel (100 mg/day testosterone)
Testim® (testosterone gel)	5 - 10 gm gel (delivers 50 – 100 mg testosterone) applied topically QD	10 gm/day gel (100 mg/day testosterone)
Anabolic steroid		
Oxandrolone (Oxandrin®)	2.5 – 20 mg PO /day	20 mg/day
Nandrolone decanoate	100 mg IM Q week	100 mg Q wk

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
HIV infection	< 35 kg = 0.1 mg/kg SC daily 35 to 45 kg = 4 mg SC daily 45 kg to 55 kg = 5 mg SC daily > 55 kg = 6 mg SC daily	6 mg/day

VI. Product Availability

Vial (powder for injection): 4 mg multi-use vial; 5, 6 mg single-use vial

VII. References

1. Serostim Prescribing Information Rockland, MA: EMD Serono, Inc; December 2016. Available at www.emdserono.com. Accessed 01.10.17.
2. Clinical Pharmacology Web site. Available at http://clinicalpharmacology-ip.com/. Accessed January 8, 2016.
3. Micromedex Healthcare Series [Internet Database]. Greenwood, Colo: Thomson Healthcare. Updated periodically. Accessed January 8, 2016.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template. Minor changes to verbiage and grammar. References updated.	01.12.17	11.17

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.