

ALASKA MEDICAID
Prior Authorization Criteria

Serostim® (somatropin)

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.

Serostim criteria

Version 2

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Effective for Dates of Service: 10/3/2016 and thereafter

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- Concurrent use with Increlex® (mecasermin), **OR**,
- Patient has not unintentionally lost more than 10% of his/her baseline body weight,
OR
 - Patient weighs greater than or equal to 90% of the lower limit of ideal body weight
OR
 - Patient has a body mass index (BMI) greater than or equal to than 20 kg/m²
OR
 - 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
 - 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

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References / Footnotes:

- ¹ Serostim Prescribing Information. EMD Serono, Inc. Rockland, MA. October 2015. http://www.emdserono.com/ms.country.us/en/images/Serostim_PI_tcm115_140011.pdf. Accessed 4/13/2016.
- ² Gelato M, McNurlan M, Freedland E. "Role of recombinant human growth hormone in HIV-associated wasting and cachexia: pathophysiology and rationale for treatment." *Clin Ther*. 2007 Nov;29(11):2269-88.
- ³ Schambelan M, Mulligan K, Grunfeld C, Daar ES, LaMarca A, Kotler DP, Wang J, Bozzette SA, Breitmeyer JB. "Recombinant human growth hormone in patients with HIV-associated wasting. A randomized, placebo-controlled trial. Serostim Study Group." *Ann Intern Med*. 1996 Dec 1;125(11):873-82.
- ⁴ Centers for Disease Control. Revision of the CDC Surveillance Case Definition for Acquired Immunodeficiency Syndrome. *MMWR* 1987;36(Suppl no. 1S):12S.
- ⁵ Mangili A, Murman DH, Zampini AM, Wanke CA. Nutrition and HIV Infection: Review of Weight Loss and Wasting in the Era of Highly Active Antiretroviral Therapy from the Nutrition for Healthy Living Cohort. *Clinical Infectious Diseases*. 2006;42:836-42.
- ⁶ Cook DM, Yuen KCJ, Biller BMK, Kemp SF, Vance ML. "American Association of Clinical Endocrinologists medical guidelines for clinical practice for growth hormone use in growth hormone-deficient adults and transition patients – 2009 Update." *Endocrine Practice*, Vol 15 (Suppl 2) September/October 2009.
- ⁷ Drug Enforcement Administration: Office of Diversion Control. "Human Growth Hormone." August, 2013. http://www.deadiversion.usdoj.gov/drug_chem_info/hgh.pdf. Accessed 4/13/2016.
- ⁸ Bichell DP, Kikuchi K, Rotwein P. Growth hormone rapidly activates insulin-like growth factor I gene transcription in vivo. *Molecular Endocrinology*. 1992;6:11, 1899-1908.

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Page 3 of 3