

# Specialty Guideline Management

## Serostim

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
|------------|--------------|
| Serostim   | somatropin   |

### Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

#### FDA-approved Indications<sup>1</sup>

Serostim is indicated for the treatment of human immunodeficiency virus (HIV) patients with wasting or cachexia to increase lean body mass and body weight, and improve physical endurance. Concomitant antiretroviral therapy is necessary.

All other indications are considered experimental/investigational and not medically necessary.

### Coverage Criteria

#### Treatment of HIV Patients with Wasting or Cachexia to Increase Lean Body Mass and Body Weight, and Improve Physical Endurance<sup>1-6</sup>

Authorization of 12 weeks may be granted for treatment of HIV-associated wasting/cachexia when all of

the following criteria are met:

- Member is currently on antiretroviral therapy.
- Member has had a trial with suboptimal response or intolerance to alternative therapies (see Appendix A) or has a contraindication to alternative therapies.
- Member had a body mass index (BMI) of less than 18.5 kg/m<sup>2</sup> prior to initiating therapy with Serostim (see Appendix B).

## Continuation of Therapy

### Treatment of HIV Patients with Wasting or Cachexia to Increase Lean Body Mass and Body Weight, and Improve Physical Endurance<sup>1</sup>

Authorization of 12 weeks may be granted for continued treatment in members requesting reauthorization for treatment of HIV-associated wasting/cachexia when all of the following criteria are met:

- Member is currently on antiretroviral therapy.
- Member is currently receiving treatment with Serostim excluding obtainment as samples or via manufacturer's patient assistance programs.
- Member's current BMI is less than 27 kg/m<sup>2</sup> (see Appendix B).

## Appendix

### Appendix A – Alternative Therapies for HIV Wasting<sup>3,4,7</sup>

- Cyproheptadine
- Marinol (dronabinol)
- Megace (megestrol acetate)
- Testosterone therapy if hypogonadal

### Appendix B – Calculation of BMI<sup>8</sup>

BMI = [Weight (pounds) x 703] / {[Height (inches)]<sup>2</sup>} OR [Weight (kg)] / {[Height (m)]<sup>2</sup>}

#### BMI Classification

| BMI Classification | BMI Range                     |
|--------------------|-------------------------------|
| Underweight        | < 18.5 kg/m <sup>2</sup>      |
| Normal weight      | 18.5 – 24.9 kg/m <sup>2</sup> |

| BMI Classification        | BMI Range                   |
|---------------------------|-----------------------------|
| Overweight                | 25 – 29.9 kg/m <sup>2</sup> |
| Obesity (class 1)         | 30 – 34.9 kg/m <sup>2</sup> |
| Obesity (class 2)         | 35 – 39.9 kg/m <sup>2</sup> |
| Extreme obesity (class 3) | ≥ 40 kg/m <sup>2</sup>      |

## References

1. Serostim [package insert]. Rockland, MA: EMD Serono, Inc.; June 2019.
2. Mangili A, Murman H, Zampini AM, et al. 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. Clin Infect Dis. 2006;42:836-42.
3. Grinspoon S, Mulligan K for the Department of Health and Human Services Working Group on the Prevention and Treatment of Wasting and Weight Loss. Weight loss and wasting in patients infected with human immunodeficiency virus. Clin Infect Dis. 2003;36(Suppl 2):S69-78.
4. Polsky B, Kotler D, Steinhart C. HIV-associated wasting in the HAART era: guidelines for assessment, diagnosis, and treatment. AIDS Patient Care STDS. 2001;15(8):411-23.
5. Schambelan M, Mulligan K, Grunfeld C, et al. Recombinant human growth hormone in patients with HIV-associated wasting: a randomized placebo-controlled trial. Ann Intern Med. 1996;125:873-882.
6. Evans WJ, Kotler DP, Staszewski S, et al. Effect of recombinant human growth hormone on exercise capacity in patients with HIV-associated wasting on HAART. AIDS Read. 2005;15:301-314.
7. Nemechek PM, Polsky B, Gottlieb MS. Treatment guidelines for HIV-associated wasting. Mayo Clin Proc. 2000;75:386-394.
8. National Heart, Lung, and Blood Institute. Obesity Education Initiative: The practical guide: identification, evaluation, and treatment of overweight and obesity in adults. Bethesda, MD: US Department of Health and Human Services, National Heart, Lung, and Blood Institute; 2000. NIH Publication No. 00-4084.