

PHARMACY POLICY STATEMENT

Ohio Medicaid

DRUG NAME	Serostim (somatropin)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product)
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Serostim (somatropin) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

HIV-ASSOCIATED WASTING, CACHEXIA

For **initial** authorization:

1. Member is age 18 years or older; AND
2. Medication must be prescribed by an infectious disease specialist; AND
3. Member is currently on antiretroviral therapy; AND
4. Member has tried and had a suboptimal response to at least one alternative therapy (e.g., cyproheptadine, dronabinol, megestrol acetate) unless member has a contraindication or intolerance to all alternative therapies listed; AND
5. Member has a pre-treatment BMI < 18.5 kg/m²; AND
6. Member has had unintentional weight loss of > 10% body weight in the previous 6 months before initiating therapy.
7. **Dosage allowed:** 0.1 mg/kg up to 6 mg.

If member meets all the requirements listed above, the medication will be approved for 12 weeks.

For **reauthorization**:

1. Member must be in compliance with all of the initial criteria; AND
2. BMI has improved in response to therapy with Serostim; AND
3. Current BMI is < 27 kg/m².

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 weeks.

CareSource considers Serostim (somatropin) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Adult growth hormone deficiency
- Constitutional growth delay
- Corticosteroid-induced growth failure
- Cystic fibrosis



- Idiopathic, or non-growth hormone dependent, short stature
- Juvenile idiopathic, or chronic, arthritis
- Noonan Syndrome
- Obesity
- Partial growth hormone deficiency
- Pediatric growth failure due to chronic kidney disease
- Pediatric growth hormone deficiency
- Prader-Willi Syndrome
- SHOX deficiency
- Small for Gestational Age
- Turner Syndrome
- Wound healing in burns patients

DATE	ACTION/DESCRIPTION
10/25/2018	New policy for Serostim created.

References:

1. Serostim [prescribing information]. Rockland, MD: EMD Serono, Inc.; Revised June 2014.
2. Nemecheck PM, Polsky B, Gottlieb MS. Treatment Guidelines for HIV-associated wasting. *May Clin Proc.* 2000; 27: 386-394.

Effective date: 02/01/2019

Revised date: 10/25/2018