BlueCross BlueShield
Federal Employee Program
Blue Cross Blue Shield Association
750 9th St NW, Suite 900
Washington, D.C. 20001
1-800-624-5060
Fax 1-877-378-4727

5.30.022

Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	August 1, 2001
Subject:	Serostim	**Page:**	1 of 4

Last Review Date: September 6, 2024

Serostim

Description

Serostim (somatropin)

Background
Serostim (somatropin) is a human growth hormone (hGH) produced by recombinant DNA technology. Serostim is used for the treatment of HIV-associated wasting or cachexia in patients receiving antiretroviral (or HAART) therapy to increase lean body mass and body weight and improve physical endurance (1).

Regulatory Status
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 (1).

Somatropin has the potential for the acceleration of HIV replication; it is recommended that HIV patients be maintained on antiretroviral therapy for the duration of Serostim treatment. Studies have shown no increase in virus production when the antiretroviral agents, zidovudine, didanosine, or lamivudine were added as combined therapy to Serostim (1).

Serostim is contraindicated in patients with acute critical illness, active malignancy, and diabetic retinopathy. Growth hormone therapy should not be initiated in patients with acute critical illness due to complications following open heart or abdominal surgery, multiple accidental trauma or acute respiratory failure. Any preexisting malignancy should be inactive, and its treatment

completed prior to instituting therapy with Serostim. Serostim should be discontinued if there is evidence of recurrent activity (1).

Hyperglycemia may occur in HIV infected individuals. The increases in mean fasting blood glucose concentrations have occurred early in treatment. Serostim has been associated with new onset impaired glucose tolerance, new onset type 2 diabetes mellitus and exacerbation of preexisting diabetes mellitus. Glucose levels should be monitored periodically and dose adjustment of concurrent antihyperglycemic diabetic medications may be required (1).

Intracranial hypertension (IH) with papilledema may develop with Serostim and is usually reversible after discontinuation or dose reduction. Funduscopic examination should be performed routinely before initiating treatment with somatropin to exclude preexisting papilledema, and periodically during somatropin therapy (1).

Cases of pancreatitis have been reported rarely in children and adults receiving Serostim treatment, with some evidence supporting a greater risk in children compared with adults. Pancreatitis should be considered in any somatropin-treated patient, especially a child who develops persistent abdominal pain (1).

Related policies
Growth Hormone Adult, Growth Hormone Pediatric, Zorbtive

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Serostim may be considered **medically necessary** if the conditions indicated below are met.

Serostim may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following:

1. HIV wasting
2. HIV cachexia

AND ALL of the following:

1. Concomitant antiretroviral therapy
2. Absence of acute critical illness due to complications following open heart or abdominal surgery, multiple accidental trauma, or acute respiratory failure
3. Absence of active malignancy
4. Absence of active proliferative or severe non-proliferative diabetic retinopathy
5. **NOT** being used in combination with another somatropin agent

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 3 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

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 to reduce the potential for the acceleration of HIV replication exacerbated by Serostim therapy. Serostim is contraindicated in patients with acute critical illness, active malignancy, and diabetic retinopathy (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Serostim while maintaining optimal therapeutic outcomes.

References

1. Serostim [package insert]. Rockland, MA: EMD Serono, Inc.; June 2019.

Policy History

Date	Action
December 2011	New policy
December 2012	Annual editorial review
September 2013	Annual editorial review and reference update Addition to criteria of absence of acute critical illness due to complications following open heart or abdominal surgery, multiple accidental trauma or acute respiratory failure Addition to criteria of absence of active malignancy Addition to criteria of absence of active proliferative or severe non-proliferative diabetic retinopathy
December 2014	Annual editorial review and reference update Added to criteria: No concurrent use with another somatropin
September 2015	Annual review and reference update
September 2016	Annual review and reference update
December 2017	Annual editorial review and reference update
September 2018	Annual editorial review and reference update
December 2019	Annual review
December 2020	Annual review and reference update
March 2021	Annual editorial review
December 2021	Annual review
September 2022	Annual review
September 2023	Annual review
December 2023	Annual review
September 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.