Serostim

Description

Serostim (somatropin)

Background

Serostim, a human growth hormone, is a treatment for HIV-associated wasting in patients receiving antiretroviral (or HAART) therapy to aid in a better appetite resulting in an increase in the patient’s weight and lean body mass. Serostim improves physical endurance leading to positive changes in the patient’s appearance (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 complete 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 the course of 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 severe 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 for the treatment of HIV-associated wasting or HIV-associated cachexia and if the conditions indicated below are met.

Serostim is 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
Section: Prescription Drugs  Effective Date: January 1, 2020
Subsection: Endocrine and Metabolic Drugs  Original Policy Date: August 1, 2001
Subject: Serostim  Page: 4 of 4

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 2011</td>
<td>New Policy</td>
</tr>
<tr>
<td>December 2012</td>
<td>Annual editorial review</td>
</tr>
<tr>
<td>September 2013</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td></td>
<td>Addition to criteria of absence of acute critical illness</td>
</tr>
<tr>
<td></td>
<td>due to complications following open heart or abdominal</td>
</tr>
<tr>
<td></td>
<td>surgery, multiple accidental trauma or acute respiratory</td>
</tr>
<tr>
<td></td>
<td>failure</td>
</tr>
<tr>
<td></td>
<td>Addition to criteria of absence of active malignancy</td>
</tr>
<tr>
<td></td>
<td>Addition to criteria of absence of active proliferative or</td>
</tr>
<tr>
<td></td>
<td>severe non-proliferative diabetic retinopathy</td>
</tr>
<tr>
<td>December 2014</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td>September 2015</td>
<td>Annual review and reference update</td>
</tr>
<tr>
<td>September 2016</td>
<td>Annual review and reference update</td>
</tr>
<tr>
<td>December 2017</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td>September 2018</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td>December 2019</td>
<td>Annual review</td>
</tr>
</tbody>
</table>

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.