



## **RATIONALE FOR INCLUSION IN PA PROGRAM**

### **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. Fundoscopic examination should be performed routinely



**BlueCross  
BlueShield**

Federal Employee Program.

## **SEROSTIM** (somatropin)

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).

### **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.