RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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).

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