Dr. Steven Pounders received his medical degree from the University of Texas Medical Branch at Galveston, and he completed his residency in internal medicine at Baylor Medicine of College in Houston. Dr. Pounders is an active member of the HIV education community, and he is the recipient of several honors, including the 2017 Kuchling Humanitarian Award and the 2014 CURE Open Heart Award. An early advocate for patients with HIV, Dr. Pounders has contributed to the Dallas Buyers Club and is currently in private practice in Dallas.

Clinical Conversations in HIV-Associated Wasting
A brief discussion with Steven Pounders, MD

INDICATIONS AND USAGE
Serostim® (somatropin) for injection 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.

IMPORTANT RISK INFORMATION
CONTRAINDICATIONS
Serostim® should not be used in patients with acute critical illness, active malignancy, hypersensitivity to somatropin or any of its excipients, or diabetic retinopathy. Increased mortality has been reported in patients with acute critical illness due to complications following surgery, multiple accidental trauma, or acute respiratory failure. Preexisting malignancies should be inactive and treatment completed prior to instituting therapy. Serostim® should be discontinued if there is evidence of tumor recurrence. Systemic hypersensitivity reactions have been reported with postmarketing use of somatropin products.

Please see additional Important Risk Information throughout and enclosed Full Prescribing Information.
Q: IMPORTANT RISK INFORMATION (CONTINUED)

A: A brief discussion with Steven Pounders, MD

Acute Critical Illnesses: just like the rest of the population, most people think “Thin is in, thin is good.” But for those with HIV-associated wasting, it places them at a higher risk for death. If the physician doesn’t know the patient is experiencing symptoms of HIV-associated wasting, he or she can’t treat it. That’s why it’s important that we ask probing questions during our patient encounters.

Q: Can you tell us about a patient you’ve treated with Serostim® (somatropin) for injection?

A: My patient was a 42-year-old white male with a CD4-cell count of 110–120 cells/mm³ and an RNA viral load of 20 copies/mL. He began to develop problems with his memory and coordination. He could no longer walk and had HIV-associated neurological disorder.

Despite a head CT scan, MRI, and lumbar puncture, we found nothing but HIV. Then in the next year, he started to lose weight and became very fatigued. We checked all of the markers I recommended earlier. He had hypothyroidism, anastolic, and apical systolic. Over the next few months, he continued to lose weight and was really getting more concerned about him. He used to go to the gym regularly and lift weights, and he was not able to do that any longer.

After excluding other reasons for weight loss, I started him on Serostim. I saw him start to gain weight and gain some energy. He could go back to the gym and work out slowly and progressively. I still see him, and he is doing really well.

Q: How do you diagnose HIV-associated wasting?

A: One of the first symptoms I take, especially in men, is to check their hormone profile. Then we look for vitamin deficiencies that can be corrected. They see a decline in that their appetite is good and that they are getting the nutrition they need, and if warranted, try hormone replacement therapy.

IMPORTANT RISK INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS

Acute Critical Illness: InNil mortality in patients with acute critical illness due to complications following open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure has been reported after treatment with somatropin. (Somatropin should be used during pregnancy only if clearly needed and with caution in nursing mothers because it is not known whether it crosses the placenta or is excreted in breast milk.)

Important Risk Information (Continued) 

Patient Case

Clinician’s observation: “We need to monitor any decrease in weight BMI and really listen to patient concerns over time.”

Q: IMPORTANT RISK INFORMATION (CONTINUED)

A: CAUTION: HIV-associated wasting is viewed today as an indicator of HIV-associated disease, just like the rest of the population. Even when we address all these factors, some patients do not regain the weight they have lost or they are still losing weight and lean body mass and have decreased energy for no apparent reason.

Q: What else does it look for?

A: I routinely ask general questions about fatigue and their daily routines. Are they able to do regular exercises? At first, some patients will only mention shortness of breath during fatigue—fatigue meaning they can barely make it through the day. They cannot get their work done and they are not doing interpersonal activities or their regular exercise routines. Patients don’t want to complain because they don’t realize it can be fixed. They say, “Oh, I’m not physics. My workload is down.” But they’re not doing great.

If the physician doesn’t know the patient is experiencing symptoms of HIV-associated wasting, he or she can’t treat it. That’s why it’s important that we ask probing questions during our patient encounters.

Q: How do you think HIV-associated wasting is viewed today?

A: In our society so many people are overweight. People who lose weight unaccountably don’t get a lot of sympathy from others. Most people think “Thin is in, this is good.” But for those with HIV-associated wasting, it places them at a higher risk for mortality. When you are HIV-positive, a lower body mass index is not ideal. BMI should not be evaluated by weight alone. If BMI is not ideal. A person can even have a normal BMI while having a decreased lean body mass. If BMI is not ideal, it may be declining due to a loss of weight that is inevitable. Most people think “Thin is in, thin is good.” But for those with HIV-associated wasting, it places them at a higher risk for death. If the physician doesn’t know the patient is experiencing symptoms of HIV-associated wasting, he or she can’t treat it. That’s why it’s important that we ask probing questions during our patient encounters.

OVERVIEW OF SYMPTOMS AT TIME OF HIV-ASSOCIATED WASTING DIAGNOSIS

- Decreased physical endurance
- No longer able to complete usual exercise routine
- Fatigue
- Poor appetite
- Unintentional weight loss

LABORATORY AND IMAGING RESULTS

- CD4-cell count < 200 cells/mm³
- Viral load: > 100,000 copies/mL
- Testosterone levels: Below normal range
- CT scan, MRI, and lumbar puncture: Normal
- No vitamin deficiencies

TREATMENT HISTORY

- Androgens
- Appetite stimulants
- Testosterone replacement therapy

This case study represents a real patient of Dr. Pounders; however, it may not be a complete representation of the individual’s entire medical case or include his full experience with Serostim®. Certain details such as concurrent medications, dose adjustments, and adverse reactions may not be reflected. For more information obtained from clinical trials and unselected post-marketing reporting of adverse experiences, refer to the Important Risk Information throughout and see enclosed Full Prescribing Information.

Please see additional Important Risk Information continued on the back and enclosed Full Prescribing Information.
A brief discussion with Steven Pounders, MD

Q: Your work in caring for people living with HIV began before HAART was introduced. Can you tell us how the field of HIV care has changed over the past several decades?

A: My early years of working in HIV were intense. Patients were dying every week. Then HAART came around and suddenly things started to change. Treatments were better tolerated, and today medications have become even less toxic. As most of our patients living with HIV are doing well with HAART, it does feel that problems with complications stemming from HIV have diminished. However, some bars have fortunately survived for as long as they have, we still see HIV-related problems. We also see more of our patients getting chronic diseases, just like the rest of the population.

Q: How often do you see HIV-associated wasting among patients in your practice?

A: More than 90% of our patients have undetectable viral loads. While many of my patients struggle to lose weight, as does much of the general US population, I do have patients who need to gain the weight they have lost without trying. We have learned that with HIV, there are attacks on the gut very early on, which cause problems with their immune systems and immune activation. This results in increased inflammation and activation, which interfere with nutrient absorption, resulting in loss of lean body mass and body weight.

Q: What do you think HIV-associated wasting is viewed today?

A: In our society so many people are overweight. People who lose weight unintentionally don’t get a lot of empathy from others. Most people think “ thin is in, this is good.” But for those with HIV-associated wasting, it places them at a higher risk for morbidly and mortality. When you are HIV-positive, a lower body mass index is not ideal. A person can even have a normal BMI, but it may be declining due to a loss of weight that is unexpected or unplanned. That is why we cannot rely only on BMI to determine wasting. We need to monitor any decrease in weight or BMI and really consider it as a sign of wasting syndrome. To those who believe that wasting no longer exists, I would remind them that it continues to impact a range of patients both HIV positive and negative. In fact, I encourage you to work with it on a regular basis. These include patients who have immune reconstitution anorexia, as they have not lost weight but have undetectable viral loads. It also includes those who are newly diagnosed with HIV living with HIV for many years, those who seem to tolerate their medications very well, and those who have no evidence of infections or are recovering from an acute infection.

Q: How do you diagnose HIV-associated wasting?

A: One of the first steps I take, especially in men, is to check their hormone profile. Then we look for vitamin deficiencies that can be corrected. They see a dietitian to ensure that their appetite is good and that they are getting the nutrition they need, and if warranted, try appetite stimulants or anabolic agents. We also screen for active infections.

IMPORTANT RISK INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS (CONTINUED)

Concomitant Antiretroviral Therapy: Somatropin has been shown to potentiate HIV replication in vitro. However, there is no evidence that antiretroviral therapy for the duration of treatment during Somastim® clinical trials and no significant increase in viral burden was observed.

Neoplasms: Patients with preexisting tumors should be monitored for progression or recurrence. Monitor patients on somatropin therapy carefully for preexisting tumors.

Please see additional Important Risk Information continued on the back and enclosed Full Prescribing Information.
Help your patients with HIV-associated wasting keep moving forward with Serostim® (somatropin) for injection

Serostim® is the only FDA-approved treatment to increase lean body mass and weight as well as improve physical endurance—3 key elements of HIV-associated wasting.

In clinical trials, after 12 weeks of treatment with Serostim®, patients with HIV-associated wasting experienced statistically significant increases in lean body mass and weight and clinically and statistically significant improvements in physical endurance.

IMPORTANT RISK INFORMATION (CONTINUED)

WARNING AND PRECAUTIONS (CONTINUED)

Hypoglycemia: Somatropin increases insulin sensitivity. Patients being treated with antidiabetic agents may require dose adjustment. Patients already being treated with insulin should be monitored for the development of hypoglycemia.

Hypersensitivity: Rash, urticaria, or angioedema has been reported rarely with postmarketing use of somatropin products. Patients and caregivers should be informed that such reactions may be fatal and that prompt medical attention should be sought if an allergic reaction occurs.

Hormone-Dependent Neoplasms: Concomitant use of somatropin with hormone-dependent malignancies may increase the risk of tumor progression or recurrence. In some cases, tumors have become hormonally independent and more responsive to somatropin treatment. Pre-existing tumors have also increased in size.

Special Populations: Somatropin is not recommended for use during pregnancy or breastfeeding. Consider the potential benefits of somatropin treatment in pregnant women weighing less than 50 kg (110 lb) and the potential benefits of breastfeeding for the infant after weighing the potential benefits to the mother of continued treatment with somatropin.

ADVERSE REACTIONS

In clinical trials in HIV-associated wasting or cachexia the most common adverse reactions (incidence ≥10%) were: injection site reactions, headache, edema, soft tissue edema, joint pain, musculoskeletal pain, joint swelling, arthralgia, myalgia, fatigue, and back pain. These adverse reactions were generally mild to moderate in severity. Other common adverse reactions (incidence ≥5%) included nausea, arthralgia, myalgia, pain, weakness, headache, edema, injection site reactions, and joint swelling.

SPECIAL POPULATIONS

Somatropin should be used with caution in patients with a history of a hormone-dependent neoplasm or other hormone-responsive malignancies and in patients being treated concomitantly with hormone therapy. In the setting of hormone therapy, somatropin may contribute to the growth of hormone-dependent tumors. In patients with hormone-sensitive malignancies, somatropin therapy should be discontinuing if a hormone-dependent lesion progresses during treatment or if there is evidence of tumor growth.

Before starting therapy, patients with HIV-associated wasting should be evaluated for the presence of a hormone-secreting tumor. If a tumor is found, consideration should be given to its removal before the initiation of somatropin therapy. During somatropin therapy, patients should be monitored for evidence of tumor progression or recurrence. If somatropin treatment is discontinued, patients should be monitored for tumor progression or recurrence for at least 12 months after discontinuation of therapy.

In clinical trials, the safety and efficacy of somatropin for the treatment of HIV-associated wasting in men and women have been established. However, somatropin should be used with caution in patients with a history of hormone-sensitive tumors, hormone-dependent malignancies, or hormone-responsive malignancies. Somatropin should be used with caution in patients with hormone-dependent tumors, and somatropin therapy should be discontinued if there is evidence of tumor progression or recurrence. In patients with hormone-sensitive tumors, somatropin therapy should be discontinued if there is evidence of tumor progression or recurrence and the tumor is unresectable. In patients with hormone-responsive tumors, somatropin therapy should be discontinued if there is evidence of tumor progression or recurrence and the tumor is resectable.

In the event of a tumor progression, somatropin therapy should be discontinued. If tumor progression occurs after somatropin therapy has been discontinued, consideration should be given to other treatment options. In patients with hormone-sensitive tumors who are not candidates for surgical resection, somatropin therapy should not be reinstituted.

In patients with hormone-responsive tumors who are not candidates for surgical resection, somatropin therapy should not be reinstituted. In patients with hormone-resistant tumors who are not candidates for surgical resection, somatropin therapy should be discontinued. In patients with hormone-resistant tumors who are candidates for surgical resection, consideration should be given to surgical resection before the initiation of somatropin therapy.