



Dr. Brian J. Beesley earned his DO from the Ohio University Heritage College of Osteopathic Medicine and completed his internship and residency at OhioHealth Doctors Hospital in Columbus. He is board certified in Osteopathic Family Medicine and is certified as an HIV Specialist by the American Academy of HIV Medicine. Dr. Beesley's clinical practice in Columbus is one of the largest comprehensive primary care centers for HIV/AIDS treatment and prevention in Ohio. He speaks regionally and nationally on HIV disease treatment and prevention, as well as holding faculty positions with both The Ohio State University College of Medicine and Ohio University.

Clinical Conversations in HIV-Associated Wasting

A brief discussion with Brian Beesley, DO, AAHIVS

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.

Serostim[®]
(somatropin) for injection

A brief discussion with Brian Beesley, DO, AAHIVS

Q: How has the field of HIV care changed in the years you have been practicing?

A: Initially HIV couldn't be treated. But now it's an infection that can be better controlled. The treatment options that we have are more encouraging and people can tolerate them much better. But we still see ongoing issues around weight-related changes despite patients having undetectable viral loads.

We may not see HIV-associated wasting as much as we did in the 1990s. But even with today's HIV treatments, we still do see patients with unintentional weight loss and decreased energy due to HIV. We have to remember that HIV is a catabolic disease because your body is constantly using energy to try to fight a disease that it can't cure. So it creates a chronic catabolic state, which means despite suppressing viral load with antiretroviral therapies, wasting can still occur.

Q: Has awareness or concern about wasting changed during this time?

A: Patients are very concerned about the potential for wasting because they don't want someone to know their HIV status from their appearance.

Q: Is there a specific patient type you would assess for HIV-associated wasting?

A: Generally, the patients I diagnose with HIV-associated wasting have decreased physical endurance and a drop in weight from their pre-HIV weight, or an involuntary change in weight at any point. If they are unintentionally losing weight without dieting or over-exercising, I'll ask about their physical endurance, which is an important factor to consider. Once we get these initial answers, we can start ruling out causes.

Q: What is your treatment strategy for HIV-associated wasting?

A: Whether a patient is newly diagnosed or has been living with controlled HIV for years, I prescribe Serostim[®] (somatropin) for injection if they meet these criteria: If they are eugonadal, they have optimized their ARV therapy, they are experiencing decreased physical endurance, and they have had an unintentional drop in their body weight or BMI. I don't prescribe any other growth hormone brands, even if Serostim[®] is not preferred or covered by insurance, because Serostim[®] is the only one that's FDA approved for HIV-associated wasting and indicated to increase lean body mass and weight, and improve physical endurance—the 3 elements of HIV-associated wasting.

Q: Can you tell us about a patient you've treated with Serostim[®]?

A: I treated a 50-year-old male who was originally diagnosed with HIV in 1999 and then later diagnosed with AIDS in 2003. He had been having some symptoms such as decreased physical endurance, a drop in BMI, some memory loss, weight loss, decreased cognitive function, fatigue, headaches and peripheral neuropathy, occasional heartburn, and diarrhea.

He was inactive and avoided working out because he was gradually losing weight. His previous physician prescribed appetite stimulants and nutrition supplements, and testosterone replacement.

I began seeing him after his AIDS diagnosis. At that point his wasting was substantial enough for his friends to notice as well. He was distraught but he didn't think there was anything we could do about it. So although he was concerned about his appearance, the goal at that time was to get his virus controlled. Once we got him on a new regimen, I prescribed Serostim[®] to help with his weight loss and decreased energy.

Q: What led you to the diagnosis?

A: This patient actually carried a picture of himself in his wallet from before he was HIV-positive. He needed to remind himself of what he looked like before his "new normal." After listening to him and evaluating him based on his medical history and physical exam, I came to the conclusion that he was wasting.

Q: How did this patient respond?

A: After taking Serostim[®], this patient felt noticeably different. I remember he smiled for the first time and he never smiled before. One of the specific things he said was that he previously didn't have enough strength to take the trash to the end of the driveway. It was a basic, everyday thing for him, and it meant a lot to him that he was able to do it again.

Since treatment with Serostim[®] he has maintained a normal BMI. He really feels strongly that this medication has helped him in a way that he thought nothing else could.

Q: What can physicians do to better screen patients for wasting?

A: Today, with most EMR systems, a BMI is automatically calculated. It's right there in the medical record. This helps us look at BMI at every single visit so it's easy to quickly spot patients who are at risk.

But remember, it's more than BMI. Some people in the normal range can have wasting happen. A patient who has a BMI of 19 or 20 might be wondering why they are losing weight, even with an undetectable viral load. This is especially true if their "normal" BMI was 24. In these cases, it might be that the catabolic state of the disease is persisting.

Q: Overall, how would you describe your experience treating with Serostim[®]?

A: So far, I've had a majority of positive experiences with it. This drug is something that really should be discussed with all HIV-positive patients with decreased physical endurance, unintentional weight loss or a declining BMI after ruling out other potential causes.

Prescribing Serostim[®] for HIV-associated wasting has been a very positive experience. Whether my patients are male or female, this is really what I think fits the need.

Patient Case

Clinician's observation: "A patient might wonder why they are losing weight, even with an undetectable viral load. In these cases, it might be that the catabolic state of the disease is persisting."

PATIENT PROFILE

50-year-old male with a 17-year history of HIV+ and 14-year history of AIDS, presented with asthenia and general malaise. Laboratory tests noted below-normal testosterone levels, white matter changes on MRI, and BMI classification of underweight. Testosterone replacement therapy was initiated, followed by nutritional supplements and appetite stimulants. Upon consideration of potential factors associated with reduced caloric intake and altered metabolism, Serostim® (somatropin) for injection was initiated for treatment of HIV-associated wasting.

RELEVANT MEDICAL HISTORY

- HIV+ (1999)
- AIDS (2003)

SOCIAL HISTORY

- Unemployed on disability
- Inactive; avoided working out due to weight loss
- In a long-term, stable relationship

OVERVIEW OF SYMPTOMS AT TIME OF HIV-ASSOCIATED WASTING DIAGNOSIS

- Decreased physical endurance
- Weight loss
- Fatigue
- Difficulty completing daily tasks
- Concerns about appearance
- Diarrhea
- Occasional heartburn
- Decreased cognitive function/memory loss
- Headaches
- Peripheral neuropathy

WEIGHT HISTORY

- Height: 5'6"
- Premorbid weight: 130 lb
- Premorbid BMI: 21
- Weight at HIV-associated wasting diagnosis: 113 lb
- BMI at HIV-associated wasting diagnosis: 18.2

PHYSICAL EXAMINATION

- Neurology: Decreased gross light touch and pinprick sensation and vibratory sense

LABORATORY AND IMAGING RESULTS

- Testosterone levels: Below normal limits
- MRI results: Decreased white matter changes and atrophy most likely associated w/dementia

TREATMENT HISTORY

- Testosterone replacement therapy
- Nutritional supplements
- Appetite stimulants

This case study represents a real patient of Dr. Beesley, 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 concomitant medications, dose adjustments, and adverse reactions may not be reflected. For more information obtained from clinical trials and unsolicited post-marketing reporting of adverse experiences, refer to the Important Risk Information throughout and see enclosed Full Prescribing Information.

IMPORTANT RISK INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS

Acute Critical Illness: Increased 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 [pharmacologic amounts of] somatropin.

Concomitant Antiretroviral Therapy: Somatropin has been shown to potentiate HIV replication in vitro, however there was no increase in virus production when antiretroviral agents were added to the culture medium. All patients received antiretroviral therapy for the duration of treatment during Serostim® clinical trials and no significant increase in viral burden was observed.

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

Please see additional Important Risk Information continued on the back and enclosed Full Prescribing Information.

Only Serostim® (somatropin) for injection treats HIV-associated wasting in 2 unique ways

Serostim® has anabolic and anticatabolic properties, which:

- Promote growth of new lean body mass (LBM)
- Preserve existing LBM



Serostim® is an anabolic and anticatabolic agent in HIV-associated wasting

	Anabolic (Builds up LBM)	Anticatabolic (Protects LBM from breaking down)
Changes in metabolism	<ul style="list-style-type: none"> • Increases protein synthesis 	<ul style="list-style-type: none"> • Decreases fat production and increases fat burning for energy
How changes in metabolism affect LBM	<ul style="list-style-type: none"> • Promotes growth of LBM, much of which is protein 	<ul style="list-style-type: none"> • Burns fat for energy rather than protein (protein-sparing lipid oxidation)
End result	<ul style="list-style-type: none"> • Produces new LBM 	<ul style="list-style-type: none"> • Preserves existing LBM

IMPORTANT RISK INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS

Impaired Glucose Tolerance/Diabetes: Cases of new onset impaired glucose tolerance, new onset type 2 diabetes, and exacerbation of preexisting diabetes have been reported in patients receiving Serostim®. Some patients developed diabetic ketoacidosis and diabetic coma. Patients with risk factors for hyperglycemia and glucose intolerance should be monitored closely and those using antidiabetic agents may require dose adjustment.

Intracranial Hypertension: Intracranial hypertension (IH) with papilledema, visual changes, headache, nausea, and/or vomiting has been reported. Funduscopic examination should be performed prior to initiating treatment with Serostim® and periodically during the course of treatment. If papilledema is observed, treatment should be stopped and restarted at a lower dose after IH-associated symptoms have resolved.

Severe Hypersensitivity: Serious systemic hypersensitivity reactions including anaphylactic reactions and angioedema have been reported with postmarketing use of somatropin products. Patients and caregivers should be informed that such reactions are possible and that prompt medical attention should be sought if an allergic reaction occurs.

Fluid Retention/Carpal Tunnel Syndrome: Swelling (particularly in the hands and feet), musculoskeletal discomfort, or carpal tunnel syndrome may occur during treatment with Serostim®. Symptoms may resolve spontaneously, with analgesic therapy, or after reducing the frequency of dosing. If symptoms of carpal tunnel do not resolve by decreasing the weekly number of doses, it is recommended that Serostim® treatment be discontinued.

Skin Atrophy: Rotate the injection site to avoid tissue atrophy.

Pancreatitis: Cases of pancreatitis have been reported rarely. Consider pancreatitis in patients who develop persistent severe abdominal pain.

ADVERSE REACTIONS

In clinical trials in HIV-associated wasting or cachexia the most common adverse reactions (incidence >10%) were increased tissue turgor, arthralgia, myalgia, and arthrosis, which may be responsive to dose reduction. Other common adverse reactions (incidence >5%) included nausea, fatigue, gynecomastia, paresthesia, generalized edema and hypoesthesia.

SPECIAL POPULATIONS:

Somatropin should be used during pregnancy only if clearly needed and with caution in nursing mothers because it is not known whether somatropin is excreted in human milk. The safety and effectiveness of somatropin in patients with hepatic or renal impairment or in patients aged 65 years and over have not been evaluated in clinical studies.

Please see the enclosed Prescribing Information for full disclosure.



EMD Serono is a business of Merck KGaA, Darmstadt, Germany
©2017 EMD Serono, Inc. US/SER/0217/0007a(2). All rights reserved.

