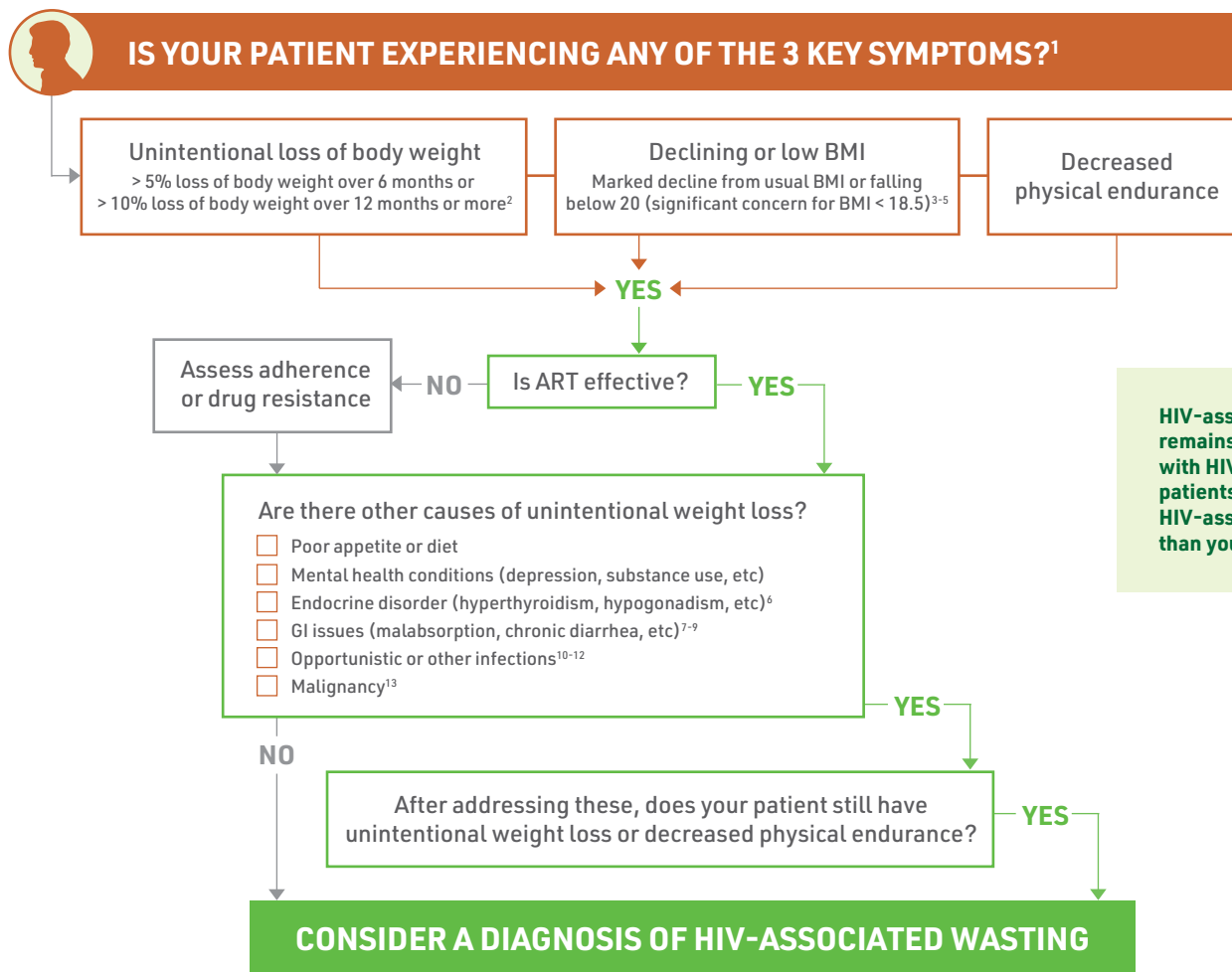


IDENTIFYING PATIENTS WITH HIV-ASSOCIATED WASTING

Assess these common factors when evaluating and diagnosing HIV-associated wasting



HIV-associated wasting remains prevalent in people with HIV.¹⁴ More of your patients could have HIV-associated wasting than you realize.

Serostim[®] (somatropin) for injection is the only FDA approved medication to treat HIV-associated wasting and has more than 25 years of safety and proven efficacy.

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 SAFETY INFORMATION

CONTRAINDICATIONS

Acute Critical Illness: Serostim[®] 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.

Active Malignancy: Somatropin is contraindicated in the presence of active malignancy. Any preexisting malignancy should be inactive and its treatment complete prior to instituting therapy with somatropin. Discontinue somatropin if there is evidence of recurrent activity.

Hypersensitivity: Serostim[®] is contraindicated in patients with a known hypersensitivity to somatropin or any of its excipients. Systemic hypersensitivity reactions have been reported.

Diabetic Retinopathy: Somatropin is contraindicated in patients with active proliferative or severe non-proliferative diabetic retinopathy.

Please see the full Important Safety Information on page 4 and the full Prescribing Information for a complete discussion of Serostim[®] risks.










PATIENT TYPES & SYMPTOMS

A recently published retrospective medical and pharmacy claims study found that, annually, approximately 3.1% of people with HIV receiving medical care met the definition of HIV-associated wasting (approximately 18.3% [7,804/42,587] over 6 years).¹⁴

Being familiar with the key symptoms of HIV-associated wasting and potential patient types can help you identify when to screen for it.

Patient types living with HIV-associated wasting can include those who:

-  are newly diagnosed¹⁵
-  are on ART and have, or have had, an HIV/AIDS-related infection¹⁷
-  are long-term survivors¹⁶
-  are living with advanced HIV disease¹⁵
-  have their virus well controlled on ART^{5,17}
-  are on ART, but their viral load has not gone down¹⁷
-  are on ART and are losing weight without trying¹⁵
-  have been prescribed ART but are not taking it as directed¹⁷

Any of the patient types above may exhibit any or all of the 3 key symptoms of HIV-associated wasting¹:



Loss of Lean Body Mass (LBM)



Loss of Body Weight



Decreased Physical Endurance

IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS

Acute Critical Illness: Increased mortality (42% vs 19% in somatropin compared to placebo treated) 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, and there was no increase in virus production when antiretroviral agents were added to the culture medium. No significant somatropin-associated increase in viral burden was observed. All patients received antiretroviral therapy for the duration of treatment during Serostim[®] clinical trials.

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

Impaired Glucose Tolerance/Diabetes: Patients with other risk factors for glucose intolerance should be monitored closely during Serostim[®] therapy. 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 and, in some, improved when Serostim[®] was discontinued and in others persisted. Some of these patients required initiation or adjustment of antidiabetic treatment.

Intracranial Hypertension: Intracranial hypertension (IH) with papilledema, visual changes, headache, nausea, and/or vomiting has been reported usually within the first 8 weeks of somatropin therapy and rapidly resolved after stopping or reducing the somatropin dose. Funduscopic examination should be performed prior to initiating treatment with somatropin and periodically during 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.

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DIAGNOSIS

Proactively asking patients questions about their energy and weight may reveal problems with decreased physical endurance and loss of LBM that are associated with unintentional loss of weight, which can help drive correct diagnosis.

In addition to patient discussion, you can utilize other screening methods, such as:



Measuring weight and tracking changes compared to previous or pre-morbid measurements



Visually examining physical appearance and changes in habitus



Calculating BMI and determining if it is less than 20 or has dropped suddenly in a short period of time



Evaluating physical endurance



Assessing patient-reported outcomes (lack of physical endurance, clothes not fitting properly, friends or family noticing changes)

To learn more about how to diagnose HIV-associated wasting, the risks and benefits of Serostim[®], dosing and administration, and more, go to [Serostim.com/hcp](https://www.serostim.com/hcp).

IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS (CONTINUED)

Fluid Retention/Carpal Tunnel Syndrome: Increased tissue turgor (swelling, particularly in the hands and feet) and musculoskeletal discomfort (pain, swelling and/or stiffness) may occur during treatment with Serostim[®], but may resolve spontaneously, with analgesic therapy, or after reducing the frequency of dosing. Carpal tunnel syndrome may occur and if the 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 >5%) were arthralgia, myalgia, peripheral edema, arthrosis, nausea, paresthesia, generalized edema, gynecomastia, hypoesthesia and fatigue.

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 pediatric patients with HIV have not been established. Clinical studies did not include sufficient numbers of subjects ≥ 65 to determine a response different from that of younger patients. Studies have not been conducted in patients with hepatic or renal impairment. Gender-based analysis is not available.

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