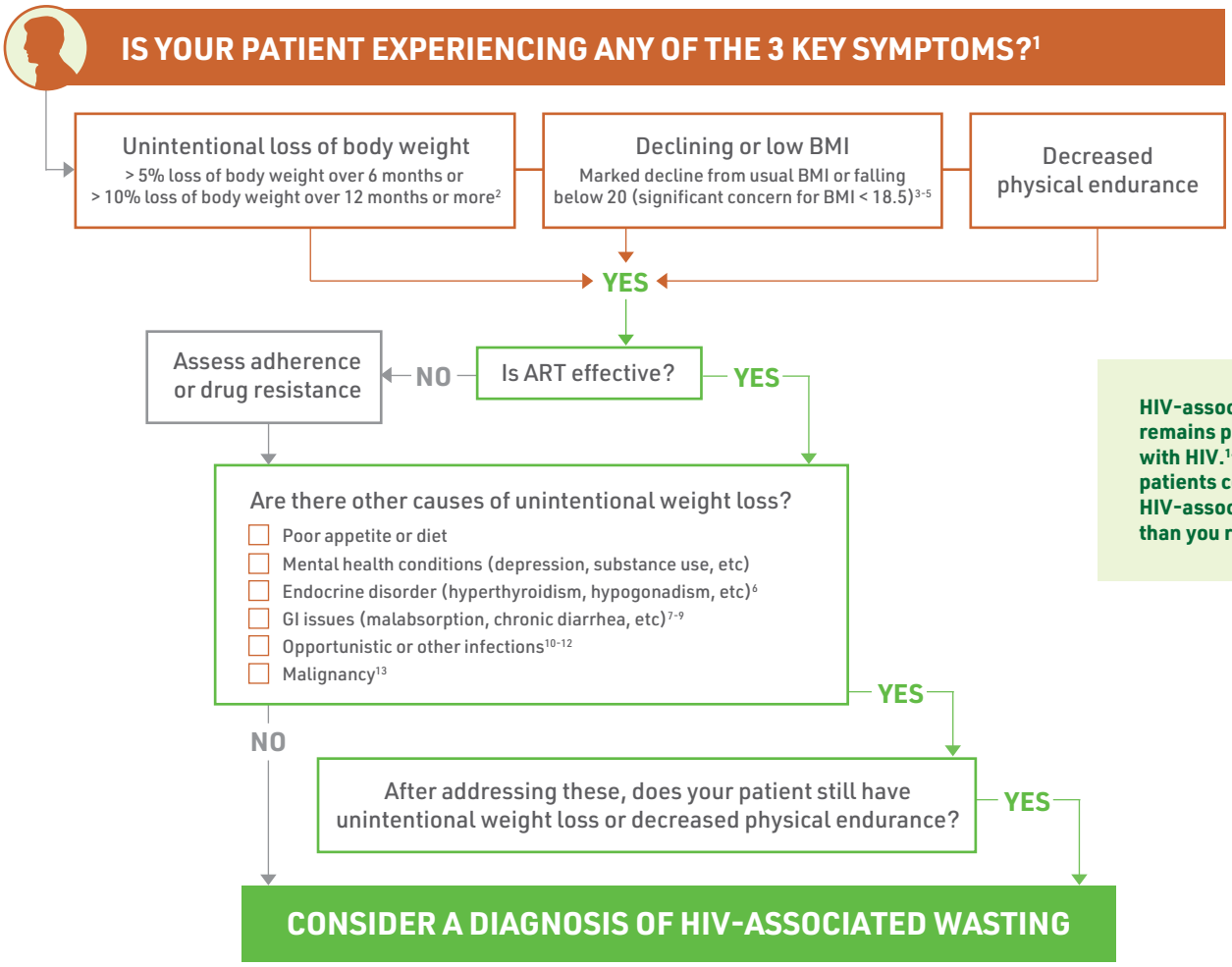
IDENTIFYING PATIENTS WITH **HIV-ASSOCIATED WASTING**

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.

Serostim® 4 mg 5 mg 6 mg
(somatropin) for injection

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 diagnosed[15]
- are long-term survivors[16]
- have their virus well controlled on ART[5,17]
- are on ART and are losing weight without trying[15]
- are on ART and have, or have had, an HIV/AIDS-related infection[17]
- are living with advanced HIV disease[15]
- are on ART, but their viral load has not gone down[17]
- have been prescribed ART but are not taking it as directed[17]

Any of the patient types above may exhibit any or all of the 3 key symptoms of HIV-associated wasting[1]:

- 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**.

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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References:
1. Serostim® (somatropin) for injection. Prescribing information. EMD Serono, Inc: 2021. **2.** Dudgeon WD, Phillips KD, Carson JA, et al. Counteracting muscle wasting in HIV-infected individuals. *HIV Medicine.* 2006;7:299-310. **3.** Mangili A, Murman DH, Zampini AM, Wanke CA, et al. Nutrition and HIV infection: review of weight loss and wasting in the era of highly active antiretroviral therapy from the nutrition for healthy living. *Clin Infect Dis.* 2016;42(6):836-842. **4.** Badowksy ME, Perez SE. Clinical utility of dronabinol in the treatment of weight loss associated with HIV and AIDS. *HIV AIDS (Auckl).* 2016;8:37-45. **5.** Erlandson KM, Li X, Abraham AG, et al. Long-term impact of HIV wasting on physical function in the multicenter AIDS Cohort Study. *AIDS.* 2016;30(3):445-454. **6.** Grinspoon S, Corcoran C, Lee K, et al. Loss of lean body and muscle mass correlates with androgen levels in hypogonadal men with acquired immunodeficiency syndrome and wasting. *J Clin Endocrinol Metab.* 1996;81(11):4051-4058. **7.** Zilberman-Schapira G, Zmora N, Itav S, et al. The gut microbiome in human immunodeficiency virus infection. *BMC Medicine.* 2016;83:14. **8.** Bhaijee F, Subramony C, Tang SJ, et al. Human immunodeficiency virus-associated gastrointestinal disease: common endoscopic biopsy diagnoses. *Path Res Intl.* 2011;2011:247923. **9.** Thompson CG, Gay CL, Kashuba ADM. HIV persistence in gut-associated lymphoid tissues: pharmacological challenges and opportunities. *AIDS Res Hum Retro.* 2017;33(6):512-523. **10.** Jacobson DL, Bica I, Knox TA, et al. Difficulty swallowing and lack of receipt of highly active antiretroviral therapy predict acute weight loss in human immunodeficiency virus disease. *Clin Infect Dis.* 2003;37:1349-56. **11.** Chu C, Selwyn PA. Complications of HIV infection: a systems-based approach. *Am Fam Phys.* 2011;83(4):395-406. **12.** Melchior JC, Raguin G, Boulier A, et al. Resting energy expenditure in human immunodeficiency virus-infected patients: comparison between patients with and without secondary infections. *Am J Clin Nutr.* 1993;57(5):614-9. **13.** Wanke C, Kotler D. Collaborative recommendations: the approach to diagnosis and treatment of HIV wasting. *J Acquir Immune Defic Syndr.* 2004;37:S284-S288. **14.** Siddiqui J, Samuel SK, Hayward B, et al. HIV-associated wasting prevalence in the era of modern antiretroviral therapy. *AIDS.* 2022;36(1):127-135. doi:10.1097/QAD.0000000000003096 **15.** Falutz J. Growth hormone and HIV infection: contribution to disease manifestations and clinical implications. *Best Pract Res Clin Endocrinol Metab.* 2011;25(3):517-529. **16.** Macallan DC. Wasting in HIV infection and AIDS. *J Nutr.* 1999;129(1S suppl):238S-242S. **17.** Wasserman P, Segal-Maurer S, Wehbeh W, Rubin DS. Wasting disease, chronic immune activation, and inflammation in the HIV-infected patient. *Top Clin Nutr.* 2011;26(1):14-28.

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