Serostim®
(somatropin) for injection

Statement of Medical Necessity

Get set for submission

To ensure prompt processing, ask yourself the following questions prior to submission:

Did you fill out the entire form?

Did you include the patient's premorbid and current weights?

Did you select a diagnosis?

Did you select a dose?

Did you specify details for injection training?

Select "Register Only" to enroll your patients for services that include a dedicated case manager, assistance programs, 24/7 phone support for product-related questions, and in-home or in-office injection training.

EMD SERONO

EMD Serono is a business of Merck KGaA, Darmstadt, Germany
US/SER/0419/0032

ICD10: R64, B20, B22.2

STATEMENT OF MEDICAL NECESSITY

Phone: 1-877-714-AXIS (2947)

Fax: 866-823-9554

Complete and fax.
Note that some plans may require 3-6 months of clinical notes.
Make sure to complete entire form before submitting.

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☐ ***Register Only***

Pharmacy Name _____
Pharmacy Address _____
Pharmacy Fax _____

1. PATIENT INFORMATION

Patient Name _____
DOB ____/____/____ ☐ Male ☐ Female
Street Address _____
City _____ State _____ Zip _____
Preferred Phone # _____ Email _____
Okay to Leave Detailed Message: Daytime Evening

INSURANCE INFORMATION

Primary Insurance _____
Insurance ID _____ Payer Phone # _____
> **IMPORTANT:** *Attach a copy, front and back, of patient's insurance card*

PATIENT MEDICAL HISTORY

Active malignancy (other than Kaposi's Sarcoma)? ☐ Yes ☐ No
Describe _____ Date ____/____/____
HAART/Antiretroviral therapy ☐ Yes ☐ No
Describe _____ Date ____/____/____
Adequate oral nutritional intake? ☐ Yes ☐ No
Trial with appetite stimulant? ☐ Megace® ☐ Marinol® ☐ Other _____
Describe _____ Date ____/____/____

TREATMENT WITH TESTOSTERONE OR ANABOLIC STEROIDS

Therapy Tried
☐ Testosterone
Therapy Name _____
Response to Therapy _____ Date ____/____/____
☐ Anabolic Steroids
Therapy Name _____
Response to Therapy _____ Date ____/____/____
☐ Other
Therapy Name _____
Response to Therapy _____ Date ____/____/____

IF PATIENT IS NOT A CANDIDATE FOR ANABOLICS, STATE REASON

☐ Elevated liver function enzymes / impaired liver function
☐ Elevated triglycerides or cholesterol
☐ Other _____

2. DIAGNOSIS INFORMATION

This section must be completed in entirety in order for the case to be processed.

☐ Yes ☐ No HIV-associated Wasting
Premorbid Weight _____ Date ____/____/____
Current Weight _____ Date ____/____/____

Weight Loss History

Date						
Weight						

DIAGNOSED BY THE FOLLOWING

☐ **1. Weight Loss**
Unintentional weight loss of ____% in _____ months.

☐ **2. BMI**
Current BMI _____ Date ____/____/____

☐ **3. Other Signs of HIV-associated Wasting**
_____
_____

Include supporting documentation.
Response to previous course of Serostim® therapy *(if applicable)* _____
_____

3. PRESCRIBER INFO

Prescriber Name _____
Office/Clinic/Institution _____
Street Address _____
City _____
State _____ Zip _____
Phone # _____
Fax # _____
Tax ID # _____
Medicaid # _____
NPI # _____

OFFICE CONTACT

Name _____
Phone _____ Email _____

4. Rx AND STATEMENT OF MEDICAL NECESSITY

To be completed and signed by prescriber.

PRESCRIPTION

Serostim®
☐ 4-mg, multi dose 7-vial pack
☐ 5-mg 7-vial pack
☐ 6-mg 7-vial pack

Prescribed dose
_____mg per day for 28 days _____refills
☐ No Substitutions / Dispense as Written

RECONSTITUTION AND ADMINISTRATION

☐ 29G, 1/2″ needles, 3-cc syringe, with 20G, 1″ needles for reconstitution
☐ 30G, 1/2″ needles, 3-cc syringe, with 20G, 1″ needles for reconstitution

Select reconstitution volume
☐ 0.5 mL ☐ 1.0 mL

Injection training to be conducted by EMD Serono
☐ Yes ☐ No

Training location
☐ Prescriber Office ☐ Home / Other ☐ Web-based

PRESCRIBER CERTIFICATION

I certify that the prescribed therapy is medically necessary, that the information in this Statement of Medical Necessity is accurate to the best of my knowledge, and that I am aware of the risks and benefits associated with use of Serostim®. I authorize EMD Serono (1) to provide any information on this form to the insurer of the named patient and (2) to forward the above prescription, by fax or by other mode of delivery, to the chosen pharmacy.

Prescriber's Name: _____

Date: ____/____/____

Prescriber's Signature: _____

Phone: 1-877-714-AXIS (2947)
Fax: 866-823-9554

PATIENT AUTHORIZATION

Serostim®
(somatropin) for injection

Patient Name: _____ **Street Address:** _____

Date of Birth: _____ **City:** _____ **State:** _____

Home Phone #: _____ **Zip:** _____

AUTHORIZATION TO USE AND DISCLOSE HEALTH AND OTHER PERSONAL INFORMATION

I authorize my physician and their staff to disclose my health and other personal information, including, but not limited to, the information on my completed Statement of Medical Necessity form and, if eligible, the application for EMD Serono's Patient Assistance Program and any confidential HIV-related information, if applicable, including HIV test results, to EMD Serono, Inc. and its agents and representatives (collectively "EMD Serono") so that EMD Serono may use and further disclose my information to healthcare providers, pharmacies, insurance companies, prescription drug plans, and other third-party payers (collectively, "Third Parties") in order to:

(1) facilitate the filling of my prescription for and the delivery and administration of Serostim®;
(2) assist me in obtaining insurance coverage for Serostim®;
(3) contact me by mail, e-mail, and/or telephone to enroll me in, and administer, programs that provide Serostim® support services;
(4) including to determine my eligibility to participate in the Patient Assistance Program, and, if eligible, to verify the accuracy of the information I provide in my application for the Patient Assistance Program;
(5) provide me with free educational information and materials;
(6) conduct surveys to measure my satisfaction with patient support services; and
(7) for such other purposes as may be required or permitted by applicable law.

I further authorize the Third Parties to disclose health and other personal information about me in their possession to EMD Serono in order to assist EMD Serono in accomplishing the purposes described above.

I understand that, once my information is disclosed pursuant to this authorization, it may no longer be protected by federal privacy laws (the Health Insurance Portability and Accountability Act). However, I understand that EMD Serono will not release my information to any party, except as provided in this authorization or as permitted by applicable law, without first obtaining my (or my authorized representative's) separate written consent.

I understand that I may refuse to sign this authorization and that such refusal will not affect my ability to receive Serostim®, but, if eligible, it will limit my ability to participate in the Patient Assistance Program.

I understand that this authorization will remain in effect for ten years from the date of my signature, unless I revoke it earlier by contacting EMD Serono in writing at One Technology Place, Rockland, MA 02370.

If I revoke this authorization, EMD Serono will stop using and disclosing my information as soon as possible, but the revocation will not affect prior use or disclosure of my information in reliance on this authorization.

I understand that the services provided by EMD Serono that are described in this authorization can be changed at any time, without prior notification.

I understand that certain Third Parties may receive compensation in exchange for their disclosure of my information to EMD Serono.

I also understand that I have the right to receive a copy of this authorization.

_____

Patient Name *(please print)*

_____

Signature of Patient *(or personal representative)*

Date ____ /____ /____

_____

Authority/Relationship of Personal Representative to Sign on behalf of Patient *(if applicable)*

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The AXIS Center® offers patient support through assistance with prior authorizations, appeals, financial support, injection training, and addressing patient questions.

1. Contact the AXIS Center® at 1-877-714-AXIS (2947).

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2. Fax completed SMN to 866-823-9554.

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3. Receive confirmation of receipt within 24 hours.
If you do not receive confirmation, contact the AXIS Center®.

Select "Register Only" to enroll your patients for services that include a dedicated case manager, assistance programs, 24/7 phone support for product-related questions, and in-home or in-office injection training.

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