STATEMENT OF MEDICAL NECESSITY

Serostim®

[somatropin (rDNA origin) for injection]

EMD Serono

EMD Serono, Inc. is a subsidiary of Merck KGaA, Darmstadt, Germany

EMD

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

STATEMENT OF MEDICAL NECESSITY

Complete and fax. Note some plans may require 3-6 months of clinical notes.

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Pharmacy Name _____
Pharmacy Address _____
Pharmacy Fax _____

NDC # : 4 mg, 44087-0004-7
NDC # : 5 mg, 44087-0005-7
NDC # : 6 mg, 44087-0006-7

J2941
ICD9: 799.4 and 042
ICD10: R64, B20, B22.2

☐ **Register Only** (for Injection Training or Device Order)

Information to be Completed by Physician

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

Office Contact:

Name _____ Phone _____

Diagnosis Information:

Height _____
Premorbid Weight _____ Date _____
Current Weight _____ Date _____

HIV Wasting ☐ YES ☐ NO

Diagnosed per one of the following:

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

☐ 2. BMI
Current BMI _____ Date _____

☐ 3. Other Signs of HIV Wasting

Weight Loss History	
Date	Weight

_____
_____

Include supporting documentation
Response to previous course of Serostim® therapy (if applicable):

_____
_____

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®
Describe: _____ Date _____

_____
_____

Trial of testosterone or anabolic steroids :

☐ Testosterone Date _____ Response _____
☐ Anadrol® Date _____ Response _____
☐ Deca-Durabolin® Date _____ Response _____
☐ Oxandrolone Date _____ Response _____
☐ (other)_____ Date _____ Response _____

_____
_____

If patient is not a candidate for anabolics, state reason:

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

Information to be Completed by Patient

Patient Name _____
DOB _____ ☐ Male ☐ Female
Street Address _____
City _____ State _____ Zip _____
Daytime # _____ Evening # _____
Cell Phone # _____ Email _____

☐ OKAY TO CALL: ☐ Daytime ☐ Evening ☐ Cell
☐ OKAY TO LEAVE DETAILED MESSAGE: ☐ Daytime ☐ Evening ☐ Cell

Insurance Information:

Primary Insurance _____
Insurance ID _____
Payor Phone # _____

Important: Attach a copy, front and back, of patient's insurance card

Rx and Statement of Medical Necessity to be Completed and Signed by Physician

Prescription:

☐ **Serostim® [somatropin (rDNA origin) for injection]**
☐ **4 mg multi dose 7-vial pack** ☐ **5 mg 7-vial pack** ☐ **6 mg 7-vial pack**

Prescribed Dose: _____ milligrams per day for 28 days with _____ refills
☐ **NO SUBSTITUTION / DISPENSE AS WRITTEN**

Reconstitution and Administration:

☐ **Needle and Syringe**
Choose one: ☐ **27G, 1/2″ needles** ☐ **29G, 1/2″ needles** ☐ **30G, 1/2″ needles**
Check here: ☐ **3 cc syringe, with 20G, 1″ needles for reconstitution**

OR

☐ **cool.click®2 needle-free device (for 4 mg, 5 mg and 6 mg vials)**

Refills for cool.click®2: Device 3
Needles, syringes, pistons, nozzles and vial connectors 12

Injection Training to be completed by EMD Serono: ☐ YES ☐ NO

Training Location: ☐ **MD Office** ☐ **Home / Other**

Physician 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) forward the above prescription, by fax or by other mode of delivery, to the chosen pharmacy.

Physician's Name _____

Date _____

X _____
(Physician's Signature)

PATIENT AUTHORIZATION

AXIS™ CENTER

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

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Information to be Completed by Patient

Patient's Name _____

Address _____

_____

Home Phone # _____

DOB _____ / _____ / _____

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 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, text, and/or telephone to enroll me in, and administer, programs that provide Serostim® support services;
(4) provide me with free educational information and materials; and / or
(5) conduct surveys to measure my satisfaction with Serostim® and Serostim® support services.

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 descibed 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) or state privacy laws and may be further disclosed to others. 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 such refusal will not affect my ability to receive Serostim®, my treatment, payment for treatment, eligibility for or enrollment in health benefits, but it will limit my ability to receive support services for Serostim®.

I understand that this authorization will remain in effect for ten years, or such shorter period as may be required by state law, 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 and any Third Parties who are notified of my revocation 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 I have agreed to and that are described in this authorization may be reduced at any time, without prior notification. However, if any services are added, EMD Serono will obtain my authorization to receive any such additional services.

I understand that 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. Contact the AXIS Center at: 1-877-714-AXIS (2947). Your office should receive a confirmation of receipt of SMN within 24 hours. If you have not received confirmation, contact the AXIS center.

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