The ADAP Medical Advisory Committee has determined the criteria for use of growth hormone. Growth hormone (SEROSTIM only) is restricted to use in the treatment of AIDS WASTING SYNDROME. It is not covered by ADAP for treatment of lipodystrophy or HIV Adipose Redistribution Syndrome (HARS) in the absence of HIV-wasting. Treatment can be approved for a 12-week course of therapy only and must be dispensed in 4-week increments. The patient must be notified of Serostim dispensing restrictions at the time of initial dispensing: 1) maximum dispensing quantity of 4-week supply; 2) required re-evaluation of weight loss at specified refills to confirm that weight loss has stopped.

Complete the appropriate section listed below for determination of treatment authorization. CD4, Viral load, BCM, BMI, weight and supporting lab documents are required. The committee also recommends the following:

1. Proper antiretroviral therapy to control viral load.
2. Nutrition consultation to assure adequate caloric intake and rule out malabsorption.

FORM “A” (INITIAL FILL)

Section 1 – Medical Justification - Completion of all questions 1-7 with documentation are REQUIRED for Approval

Indicate diagnosis for use of Serostim:

1. Document one of the following criteria for use (ATTACH COPIES OF BIA RESULTS IF APPLICABLE*):
   a. Body Cell Mass (BCM) loss of ≥ 5% over 6 months
      Current BCM/date recorded* / Previous BCM/date recorded* ______________ / __________
   b. In males, BCM < 35% of total body weight and Body Mass Index (BMI) < 27kg/m2
      Current BCM/date recorded* / BMI/date determined ______________ / __________
   c. In females, BCM < 23% of total body weight and BMI < 27 kg/m2
      Current BCM/date recorded* / BMI/date determined ______________ / __________
   d. BMI < 20 kg/m2
      Current BMI/date recorded* ______________ / __________
   e. BMI ≥ 20 kg/m2 and < 25 kg/m2 AND
      1) Unintentional weight loss of ≥ 10% within the preceding 12 months OR
      2) Unintentional weight loss of > 7.5% within the preceding 6 months
         Current BMI/date determined ______________ / __________
         Current weight/date / Previous weight/date ______________ / __________

2. Documentation of a CD4 < 50
   Yes ☐ No ☐ (ATTACH COPIES OF CD4 LAB RESULTS):
   4. Has it been confirmed that there are no active malignancies, excluding Kaposi’s sarcoma? Yes ☐ No ☐
   5. Is the patient hypogonadal? Yes ☐ No ☐ If yes, is testosterone replacement therapy being administered? Yes ☐ No ☐
   6. Has the patient already failed an 8-week trial of anabolic steroids? Yes ☐ No ☐
      Document dates and dosage of anabolic steroid use: Drug / directions ______________ / __________
      Dates: __________________ to __________________
      If no trial of anabolic steroids, why not? ________________________________
   7. Is the Serostim dosing within the recommended guidelines for weight? Yes ☐ No ☐ Dose: ______________

Refill Documentation – Medical Justification Required for Fill #2 (after 4 weeks), and Fill #3 (after 8 weeks).

1. Patient’s current weight / date recorded: ______________ / ______________
California ADAP Supplemental Form for Serostim Use

TELEPHONE: 888-311-7632  FAX: 800-848-4241

The ADAP Medical Advisory Committee has determined the criteria for use of growth hormone. Growth hormone (SEROSTIM only) is restricted to use in the treatment of AIDS WASTING SYNDROME. It is NOT covered by ADAP for treatment of lipodystrophy or HIV Adipose Redistribution Syndrome (HARS) in the absence of HIV-wasting. Treatment can be approved for a **12-week course of therapy only** and must be dispensed in 4-week increments. The patient must be notified of Serostim dispensing restrictions at the time of initial dispensing: 1) maximum dispensing quantity of 4-week supply; 2) required re-evaluation of weight loss at specified refills to confirm that weight loss has stopped.

Complete the appropriate section listed below for determination of treatment authorization. The committee also recommends the following:
1. Proper antiretroviral therapy to control viral load.
2. Nutrition consultation to assure adequate caloric intake and rule out malabsorption.

### FORM “B” (REFILLS ONLY)

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<th>Physician Fax #</th>
<th>Pharmacy Name</th>
<th>NABP #</th>
<th>Contact Person</th>
<th>Phone</th>
<th>Fax</th>
</tr>
</thead>
</table>

**Section 3 – Medical Justification Required for use WITHIN 6 months after completion of initial therapy (one of the following with supporting documentation provided):**

1. Document unintentional 5% loss of body weight, or BCM loss of ≥5%
   - Current weight/date recorded _______________/__________
   - Previous weight/date recorded _______________/__________
   - Current BCM results/date recorded _______________/__________
   - Previous BCM results/date recorded _______________/__________
   (Attach copies of chart note documentation of weight loss or BIA results)

2. In males, BCM <35% of total body weight and Body Mass Index (BMI) <27 kg/m2 (Attach BIA results)
3. In females, BCM <23% of total body weight and BMI <27 kg/m2 (Attach BIA results)
4. BMI <20 kg/m2
   - Current BCM/date _______________/__________
   - Current BMI/date _______________/__________

**Section 4 – Medical Justification Required for Repeating Therapy AFTER 6 Months of Completion of the Initial 12 Week Course**

1. Confirm that patient has not reinitiated therapy within 6 months. When did patient complete last treatment course?
   - Date: _______________

2. Complete Section 1 of Form “A”.

**Refill Documentation – Medical Justification Required for Fill #2 (after 4 weeks), and Fill #3 (after 8 weeks).**

Patient’s current weight / date recorded: _______________/__________

**RPHRx USE ONLY:**

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<tr>
<th>Approved</th>
<th>Denied</th>
<th>By:</th>
<th>Date:</th>
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