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. 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)

Patient Name_____
Last Name **First Name**

ADAP ID Code_____

DOB_____ **Height** _____

Latest CD4 count &Viral Load _____/_____

Date of results: _____

_____
Signature of pharmacist or physician ***Date***

Prescribing Physician _____

Physician DEA # _____

Physician Telephone # _____

Physician Fax # _____

Pharmacy Name _____

NABP # _____**Contact Person** _____

Phone (_____**)**_____**Fax (**___**)**_____

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: _____ / _____

RPHRx USE ONLY: **Approved** ____ **Denied** ____ **By:** **Date:**
Fill # **1** **2** **3**

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)

Patient Name_____
Last Name **First Name**

ADAP ID Code_____

DOB_____ **Height** _____

Latest CD4 count &Viral Load _____/_____

Date of results: _____

Prescribing Physician _____

Physician DEA # _____

Physician Telephone # _____

Physician Fax # _____

Pharmacy Name _____

NABP # _____**Contact Person** _____

Phone (_____)_____**Fax** (___)_____

_____
Signature of pharmacist or physician ***Date***

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: **Approved** ____ **Denied** ____ **By:** **Date:**

Fill # **1** **2** **3**