Newsletter

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TO: Providers of Pharmaceutical Services - **For Action**
Physicians, Dentists, Podiatrists, Certified Nurse Practitioners/Clinical Nurse Specialists, Optometrists, Independent Clinics, and Health Maintenance Organizations - **For Information Only**

SUBJECT: **SOMATROPIN PDUR Standards for HIV-Associated Wasting**

EFFECTIVE: **July 1, 2001**

PURPOSE: To notify providers of pharmaceutical services of enhancements to the State's Prospective Drug Utilization Review (PDUR) program. The New Jersey Drug Utilization Review Board (NJDURB) recommends PDUR standards that are approved by the Commissioners of Human Services and Health and Senior Services. This newsletter provides revised and approved standards for the drug, somatropin [(rDNA origin) for injection].

BACKGROUND: The Division of Medical Assistance and Health Services (DMAHS) and the Department of Health and Senior Services (DHSS),through the State's Point-of-Sale (POS) claims processing system, implemented a PDUR program designed to ensure the cost-effective delivery of quality pharmaceutical services. Currently, Medicaid fee-for-service (FFS), NJ FamilyCare FFS, the Pharmaceutical Assistance to the Aged and Disabled (PAAD), Cystic Fibrosis (CF), Senior Gold Discount Prescription Program and the AIDS Drug Distribution (ADDP) programs monitor duplicate and early refill claim payments, utilization of certain drugs based on State policy, sex and age categories, therapeutic duplication, severe drug-drug conflicts, maximum daily dosage and duration of drug use, as well as provide information to assist pharmacists with their patient consultation responsibilities. Pharmacists should refer to Newsletter Volume 9 No. 67, dated November 1999, for information regarding the Medical Exception Process.

ACTION: **For somatropin [(rDNA origin) for injection] claims with dates of service on or after July 1, 2001,** Error Code 537 may post immediately to these claims indicating a maximum daily dosage standard has been exceeded. Pharmacists should refer to Newsletter Volume 10, No. 34, dated May 2000, for additional information regarding maximum daily dosage standards.

PDUR Standards for Somatropin Powder for Injection, Lyophilized

(1) Initial claims shall require prior authorization from the First Health Services Corporation. First Health Services shall authorize an initial 14-day supply of medication.

Criteria for Approval

Initiation of Therapy:

1. Diagnosis of AIDS; and
2. Concomitant anti-viral therapy; and
3. HIV-associated wasting syndrome with the following characteristics:

    a. 10% unintentional weight loss over 12 months; or
    b. 7.5% unintentional weight loss over 6 months; or
    c. 5% body cell mass (BCM) loss within 6 months; or
    d. males: BCM <35% body weight and BMI <27kg/m^2;*
    females: BCM <23% body weight and BMI <27kg/$m^{2.*}$ or BMI <20kg/m^2

***** As measured by a Bioelectrical Impedance Analysis (BIA) Test

Length of Therapy:

1. First 12-week course of therapy:
    a. 2 weeks upon initial request;
    b. 10 additional weeks if the above criteria (see **Initiation of Therapy**) is met;
2. Treatment after 12 weeks:
    a. **Continuous treatment** beyond the initial 12 weeks shall be approved in 28-day intervals if there has been a positive response to treatment, indicated by a 2% or greater increase in body weight or BCM and clinical evidence of wasting still exists such that patient's weight or body cell mass still poses a health risk.
    b. **Re-treatment** after a lapse in the initial first 12-week course of therapy shall be approved by First Health in three 4-week courses for patients that had a positive response to prior therapy and there is clinical evidence of wasting relapse demonstrated by sustained loss of weight or BCM.

Discontinuation and Re-treatment:

1. BCM is normalized at $\geq$ 40% for men or $\geq$ 30% for women; or
2. 5% increase in body weight without wasting with recommended observation for 8 weeks.

Denial Criteria:

1. Diagnosis other than AIDS; or
2. Absence of anti-viral therapy; or
3. Non-AIDS related weight loss; or
4. BCM > 40% (male) or > 30% (female); or
5. No response to somatropin therapy

(2) After First Health obtains the appropriate information from the prescriber to justify continued use, First Health Services will issue additional prior authorization for somatropin.

(3) These claims will continue to be subject to the 75 percent “early refill rule” that currently applies to pharmacy claims.

The pharmacist must request prior authorization by contacting First Health Services at (877) 888-2939.

If you have any questions regarding this Newsletter, please contact the Chief, Pharmaceutical Services, DMAHS, at (609) 588-2724, or First Health Services Customer Service at (877) 266-3589.

If you have any questions concerning this Newsletter, the PAAD, CF, Senior Gold or ADDP programs, please contact the PAAD Pharmacy Consultant at (609) 631-4887.

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