

The following policy is for medication that falls under the Medicare Part D benefit only.

Prior Authorization Group: Growth Hormone Therapy

Drug(s): INCRELEX (mecasermin), IPLEX (mecasermin), GENOTROPIN (somatropin), HUMATROPE (somatropin), NORDITROPIN (somatropin), NUTROPIN (somatropin), OMNITROPE (somatropin), SAIZEN (somatropin), SEROSTIM (somatropin), TEV-TROPIN (somatropin), ZORBTIVE (somatropin)

Covered Uses: All FDA-approved indications not otherwise excluded from Part D.

Required Medical Information: Height and growth charts, bone age, parental heights, GH testing and growth plate status/x-rays as requested, chart notes and other medical documentation as requested.

Age Restrictions: Insulin growth factors should not be used in children under age 2 or in adults. For the diagnosis of AIDS wasting/Cachexia member must be 18 yrs or older.

Prescriber Restrictions: Restricted to endocrinologists, nephrologists, or physicians treating HIV members.

Other Criteria:

A. Growth Hormone Deficiency (GHD):

- height must be beneath the 3rd percentile of normal and/or 2 standard deviations (SD) below the 50th percentile **AND**
- growth velocity must be less than the 10th percentile of normal and/or greater than 2 SD below the mean **AND**
- lack of response to two separate GH provocative tests defined as a serum GH level of less than 10 ng/ml in children and adolescents or less than 2.5ng/ml in adults for GHRH/arginine and 5ng/ml for all other tests in adults.

B. Children with Turners Syndrome or Growth Retardation due to Chronic Renal Insufficiency (CRI):

- present height must be below the 5th percentile of normal **OR**
- height greater than 2 SD below the mid-parental height prediction or growth velocity less than 25% for bone age and bone age less than 14 years.
- GH testing is not required for using GH to treat children with CRI.

C. Children w/ Prader-Willi Syndrome (PWS):

- Severe hypotonia in neonates, followed by hyperphagia and obesity.
- Short stature, hypogonadism, cognitive disabilities and small hands and feet are common features.
- GH testing is not required for using GH to treat children with PWS.

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D. Adults with AIDS Wasting/Cachexia (Serostim):

- Documented HIV infection; unintentional weight loss of at least 10% from baseline pre-morbid weight, or significant weight loss (BMI less than 20kg/m²) and wasting not the result of an active, HIV-related opportunistic infection, TB or cancers or other preventable causes of weight loss.
- Member should be free from infection for 4-8 weeks before initiation of therapy
- Member should be receiving at least 100% of estimated caloric requirement on current nutritional regimen.
- Individuals receiving assisted enteral/parenteral nutrition must be weight stable for at least 2 months or have persistent weight loss despite such interventions;
- Previous therapy with megestrol acetate and/or dronabinol where the attending physician has determined:
 - the response to be poor,
 - continued treatment with these agents is likely to be of doubtful promise,
 - or treatment with either agent is contraindicated on medical grounds;
- Currently receiving HAART for at least 1 month with viral load reduced to less than 10k copies/ml.

E. Children with severe primary Insulin Growth Factor Deficiency (IGFD):

- open growth plates,
- Height standard deviation score ≤ -3.0 **AND** Basal IGF-1 standard deviation score ≤ -3.0 **AND** Normal or elevated growth hormone.

F. Idiopathic Short Stature is covered when all of the following are met:

- in the presence of growth hormone deficiency **AND**
- with open growth plates **AND**
- height less than the 3rd percentile **AND**
- growth velocity less than the 10th percentile.

Exclusion Criteria: GH will not be covered for the following:

- Doses exceeding FDA approved dosing;
- An active malignant condition.
- If GHD results from an intracranial tumor, absence of tumor growth or tumor recurrence must be documented for at least 6 months prior to therapy initiation;
- Small for Gestational Age (SGA);
- GH is not indicated for treatment of wounds or burns;

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- PWS with 1 or more risk factors including severe obesity, history of respiratory impairment or sleep apnea, or unidentified respiratory infection;
- Catabolic illnesses (other than AIDS use with Serostim) or to improve muscle strength or exercise tolerability;
- Members w/ proliferative or pre-proliferative diabetic retinopathy;
- Current or predicted height without GH therapy greater than or equal to mid-parental height;
- Non-euthyroid state
- GH therapy for AIDS Wasting is approved for one month and is renewable upon confirmation that the patient's weight has stabilized or there has been no further weight loss. In addition, members must have been able to tolerate at least 80% of the prescribed dose;
- IGF is not covered for secondary forms of IGF-1 deficiency such as GHD, malnutrition, hypothyroidism or chronic treatment w/ pharmacologic doses of anti-inflammatory steroids;
- IGF-1 in combo with GH is not covered;
- GH will not be covered for adults with AIDS Wasting/Cachexia for the following:
 - evidence of GI bleeding, obstruction or malabsorption;
 - active malignancy except for Kaposi's sarcoma (KS);
 - had systemic chemo, interferon, anabolic steroids (except for documented hypogonadism and on treatment for at least 2 months prior) or investigational agents within 30 days;
 - Diabetes mellitus or history of fasting blood glucose greater than 200 mg/dl;
 - unstable or untreated hypertension;
 - evidence of angina, CHF, CAD, CRF or serious chronic edema
 - Karnofsky performance score (QoL) > 50%.

Extension of therapy for children for GHD will not be covered if no further growth or mid-parental ht is achieved OR epiphyseal fusion is complete OR bone age indicates growth is complete OR renal transplant has occurred (for CRI) OR growth rate of 2cm/yr has not occurred.

Coverage Duration: 12 months for GHD, 12 weeks for AIDS wasting/Cachexia