Growth Hormone and Stimulating Products

Somatropin (Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Saizen, Zomacton)
Mecasermin (Increlex)
Lonapegsomatropin-tcgd (Skytrofa)
Somapacitan-beco (Sogroya)
Somatrogon-ghla (Ngenla)

Coverage Criteria:
Coverage may not be available in all benefit plans. Check your plan documents for coverage eligibility. All benefit plans with coverage require use of the preferred somatropin product.

Requests for Non-covered Products:
Requests for non-covered/non-preferred growth hormone products will be reviewed for medical necessity, and only granted authorization for coverage if the following criteria are met:

1. Patient has had a documented allergic reaction to a preferred product in the past.

Patients stable on a non-preferred product are required to switch to the preferred somatropin product for coverage. The provision of pharmaceutical samples (from the prescriber or manufacturer assistance/free trial programs) does not guarantee coverage. All criteria must be met in order to obtain coverage. In addition, the use of pharmaceutical samples will not be considered when evaluating the member's medical condition or prior prescription history for medications.

For Pediatric Use:
When growth hormone coverage is available for pediatric use, the following indications will be covered:

1. Panhypopituitarism
2. Prader-Willi Syndrome
3. Turner Syndrome
4. Noonan Syndrome
5. Growth failure due to renal insufficiency

For short stature, coverage is reserved for patients meeting both of these criteria:

A. Short stature as demonstrated by one or more of these growth measurement criteria:
   1. Current height ≤ minus 2.5 standard deviations below normal
   2. Target adult height of ≤ minus 2 standard deviations below their mid-parental height
   3. Height velocity ≤ minus 2 standard deviations for age and Tanner Stage

B. Inadequate growth hormone-IGF axis activity as determined by one or more of these methods:
   1. Growth hormone provocative testing (GH Peak < 10 ng/mL)
   2. Serum IGF levels (IGF-1 or IGFBP-3) < 1 standard deviations below normal
   3. IGF generation test (stimulate level 3x baseline or > 250mg/ml)

Prescriber Restriction:
Coverage is reserved for prescribing by Pediatric Endocrinologists.

Coverage Duration:
Initial treatment will be approved for one year for the following indications:

1. Panhypopituitarism
2. Prader-Willi Syndrome
3. Turner Syndrome
4. Noonan Syndrome

For short stature, initial coverage is approved for six months.

Other Criteria:
Prescribed within the FDA approved dosing regimen.

Renewal Criteria:

Treatment is reviewed annually and covered until the epiphyses are closed for the following indications:
1. Panhypopituitarism
2. Prader-Willi Syndrome
3. Turner Syndrome
4. Noonan Syndrome

For short stature:
After the initial six-month period, continued coverage will be approved for a year when there is an increase in height velocity of more than 50% above baseline.

Reauthorization criteria:
1. Documentation has been provided that show epiphyses/growth plates remain open.
2. Patient continues to respond to therapy, defined as greater than 2 cm of growth per year, calculated over an interval of at least 6 months.

Coverage Duration:
Reauthorizations will be provided for one year.

For Adult Use:
Cases may be reviewed by a second adult endocrinologist, designated by the HealthPartners Pharmacy and Therapeutics Committee, to confirm criteria have been met.

Initial coverage is generally approved when all the following criteria are met:

1. Patients must have documented childhood onset GHD or adult onset GHD secondary to hypothalamic or pituitary disease or history of cranial irradiation. GHD is defined as:
    a. Low IGF 1 levels based on age-adjusted values and
    b. Serum growth hormone peak concentration of less than 5ng/ml following stimulation testing with one of the following tests.
        i. Insulin tolerance test (ITT)
        ii. Arginine, alone or in combination with GHRH
        iii. Glucagon stimulation test
        iv. Macrilen stimulation test

2. Complete pituitary hormone function has been tested and replaced when appropriate.

3. The individual demonstrates at least three of the following clinical features of GHD.
    a. Altered body composition with increased body fat mass with abdominal preponderance and decreased lean body mass.
    b. Decreased muscle strength and exercise capacity.
    c. Reduced bone density or presence of a fragility fracture.
    d. Poor sleep;
    e. Impaired sense of well-being.

4. Secondary medical illnesses that affect GH have been ruled out, such as liver disease, kidney disease, and malnutrition.

5. Prescribed product must have FDA labeling for use in adult patients, products not meeting this requirement (e.g., Zomacton) will be denied as not medically necessary.

Prescriber Restriction:
Coverage is reserved for prescribing by Endocrinologists

Coverage Duration:
Initial approvals will be provided for one year.

Other Criteria:
Prescribed within the FDA approved dosing regimen.

Renewal Criteria:
Reauthorization for growth hormone therapy is reviewed annually.
IGF-1 levels are reviewed, and thyroid function tests, lipids, regular body weight, and waist/hip ratio measurements are also recommended. If the patient perceives no benefit, then a trial of GH withdrawal should be considered.