

POLICY NAME	Growth Hormone	POLICY #	565P
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Criteria

Preferred Formulary Agents

- ☐ Omnitrope and Norditropin are the preferred short-acting growth hormone (GH) products. Coverage of any non-preferred short-acting agent requires a documented 3-month trial and failure of BOTH Omnitrope and Norditropin, or a documented intolerance or contraindication to BOTH Omnitrope and Norditropin.
- ☐ Coverage of Sogroya requires a documented 3-month trial and failure of BOTH Ngenla and Skytrofa, or a documented intolerance or contraindication to BOTH Ngenla and Skytrofa.

Treatment of Pediatric Growth Hormone Deficiency

- ☐ Applicable products: Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Saizen, Zomacton, Skytrofa, Sogroya, Ngenla
- ☐ Documented failure of two growth hormone stimulation tests
- ☐ Failure is defined as a peak serum growth hormone level <10ng/ml
- ☐ Diagnostic imagery of the brain has excluded the possibility of a tumor
- ☐ The member's medical history exhibits one of the following:
 - >3 standard deviations below the mean height for specific age and sex
 - Between 2 and 3 standard deviations below the mean height for specific age and sex and less than 25th percentile for mean growth velocity (GV) over the previous year
 - Pre-treatment 1 year height velocity >2 SD below the mean
 - Diagnosis of congenital growth hormone deficiency
 - Previously treated cranial radiation therapy or tumor with decreasing growth rate
- ☐ Approval Time
 - Initial: 12 months
 - Re-approval: 12 months provided there is a documented growth velocity 2cm/year following at least one year of GH therapy

Treatment of small for gestational age (SGA) children

- ☐ Applicable products: Genotropin, Humatrope, Norditropin, Omnitrope, Zomacton

- ☐ Documentation of birth weight or length 2 SD below the mean for gestational age

years of age

- ☐ Child remains 2 SD below the median height for their specific age
- ☐ Approval Time:
 - Initial: 12 months
 - Re-approval: 12 months provided there is a documented growth velocity 2cm/year following at least one year of GH therapy

Treatment of Prader-Willi Syndrome

- ☐ Applicable products: Genotropin, Norditropin, Omnitrope
- ☐ Diagnosis of Prader-Willi syndrome
- ☐ Documentation indicates no upper airway obstruction present
- ☐ If less than 30 months of age the member's pretreatment height is >2 SD below the mean and diagnosis of a slow growth velocity, OR
- ☐ If greater than 30 months of age the member's pretreatment height is >2 SD below the mean and 1-year weight velocity is > 1 SD below the mean or a pretreatment 1-year height velocity >2 SD below the mean
- ☐ Approval Time
 - Initial: 12 months
 - Re-approval: 12 months provided there is a documented growth velocity 2cm/year following at least one year of GH therapy, AND
 - Body composition has improved

Treatment of Children with Short Stature Homebox-Containing Gene (SHOX) Deficiency

- ☐ Applicable products: Humatrope, Zomacton
- ☐ Diagnosis of SHOX confirmed by molecular or genetic analysis
- ☐ Member is 3 years of age
- ☐ Pretreatment height is >2 SD below the mean and 1-year height velocity is > 1 SD below the mean or a pretreatment 1-year height velocity >2 SD below the mean
- ☐ Approval Time
 - Initial: 12 months
 - Re-approval: 12 months provided there is a documented growth velocity 2cm/year following at least one year of GH therapy

Treatment of Turner syndrome

- ☐ Applicable products: Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Zomacton
- ☐ Diagnosis of Turner's syndrome confirmed by karyotype study
- ☐ If less than 30 months of age the member's pretreatment height is >2 SD below the mean and diagnosis of a slow growth velocity, OR
- ☐ If greater than 30 months of age the member's pretreatment height is >2 SD below the mean and 1-year height velocity is > 1 SD below the mean or a pretreatment 1-year height velocity >2 SD below the mean
- ☐ Approval Time
 - Initial: 12 months
 - Re-approval: 12 months provided there is a documented growth velocity 2cm/year following at least one year of GH therapy

Treatment of Noonan Syndrome

- ☐ Applicable product: Norditropin
- ☐ Member's 1-year height velocity >2 SD below the mean
- ☐ Member's pretreatment height is >2 SD below the mean and 1-year height velocity is > 1 SD below the mean
- ☐ Approval Time
 - Initial: 12 months
 - Re-approval: 12 months, provided there is a documented growth velocity 2cm/year following at least one year of GH therapy

Treatment of Growth Failure Due to Chronic Renal Insufficiency

- ☐ Applicable product: Nutropin
- ☐ Diagnosis of chronic renal insufficiency
- ☐ If less than 30 months of age the member's pretreatment height is >2 SD below the mean and diagnosis of a slow growth velocity, OR
- ☐ If greater than 30 months of age the member's pretreatment height is >2 SD below the mean and 1-year height velocity is > 1 SD below the mean or a pretreatment 1-year height velocity >2 SD below the mean
- ☐ Documentation that other metabolic, endocrine, and nutritional abnormalities are treated and stabilized
 - Acidosis
 - Malnutrition
 - Secondary hypothyroidism

- ☐ Approval Time
 - Initial: 12 months
 - Re-approval: 12 months, provided there is a documented growth velocity 2cm/year following at least one year of GH therapy

Treatment of Adult Growth Hormone Deficiency Due to Pituitary Damage

- ☐ Applicable products: Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Saizen, Zomacton, Sogroya
- ☐ Documented pituitary disease or brain injury involving pituitary
- ☐ Member has a diagnosis of at least one other pituitary hormone deficiency and each deficiency is optimally treated
- ☐ GH deficiency is confirmed by laboratory analysis
 - Deficiency defined as peak GH response less than 5ng/ml
- ☐ Member's QoL-AGHDA score is 11 points

point = 1 answer in the affirmative

- ☐ Approval Time
 - Initial: 12 months
 - Re-approval: 12 months if the member's QoL-AGHDA score has improved by at least 7 points

Treatment of Adult Growth Hormone Deficiency who were Previously Treated for Pediatric Growth Hormone Deficiency

- ☐ Applicable products: Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Saizen, Zomacton, Sogroya
- ☐ Previous treatment of pediatric growth hormone deficiency
- ☐ Documentation which states the member's growth velocity is <2cm/year and nearing their maximum adult height
- ☐ Discontinuation of previous growth hormone use for at least one month following completion of linear growth
- ☐ Completion of an IGF-1 test which indicates the level is low for the member's pretreatment age and gender
- ☐ Completion of a growth hormone stimulation test with results <5ng/ml
- ☐ Member's QoL-AGHDA score is 11 points

point = 1 answer in the affirmative

- ☐ Approval Time
 - Initial: 12 months
 - Re-approval: 12 months if the member's QoL-AGHDA score has improved by at least 7 points

Treatment of Early Adult-Onset Growth Hormone Deficiency

- ☐ Applicable products: Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Saizen, Zomacton, Sogroya

- ☐ Completion of an IGF-1 test which indicates the level is low for the member's pretreatment age and gender References

- ☐ Completion of a growth hormone stimulation test with results <5ng/ml

- ☐ Member's QoL-AGHDA score is 11 points

point = 1 answer in the affirmative

- ☐ Approval Time
 - Initial: 12 months
 - Re-approval: 12 months if the member's QoL-AGHDA score has improved by at least 7 points

Treatment of HIV-Associated Wasting Algorithm

- ☐ Applicable product: Serostim

- ☐ Diagnosis of HIV/AIDS

- ☐ Active treatment with antiretroviral therapy

- ☐ Documented BMI of 18.5kg/m2

- ☐ Approval Time
 - Initial: 12 months
 - Re-approval: 12 months with documentation that the member's BMI improved or stabilized in response to treatment

Treatment of Short Bowel Syndrome

- ☐ Applicable product: Zorbitive

- ☐ Diagnosis of short bowel syndrome

- ☐ Documented administration of specialized nutritional support

☐ No previous history of growth hormone treatment

☐ Approval Time

- Lifetime: 8 week

Exclusion Criteria – Any of the following prevents coverage

☐ Idiopathic short stature is considered a clinical description and not a diagnosis of an illness, injury or disease. Due to this, coverage of growth hormone for the treatment of idiopathic short stature (ISS) is not considered medically necessary.

☐ ISS is generally considered a normal variant of growth

- Long-term benefits of intervention are unclear
- Predictions of adult height, with or without treatment, are imprecise

☐ Most patients with ISS have normal psychosocial functioning

- Short stature could not be established as the cause of problems with peer relationships
- The effects have not been adequately studied
- Short stature has a minimal impact on peer perceptions of social behavior, friendship, or peer acceptance

☐ Treatment with growth hormone for ISS is controversial

- Majority of children with short stature will experience some catch-up growth during puberty without growth hormone treatment
- Effects of growth hormone are modest and some children with ISS don't respond to treatment
CPT Codes HCPCS Codes J2941 Injection, somatropin, 1 mg