

POLICY NAME	Growth Hormone	POLICY #	565P
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Criteria

Preferred Formulary Agents

- ☐ **1.1** 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.
- ☐ **1.2** 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

- ☐ **2.1** Applicable products: Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Saizen, Zomacton, Skytrofa, Sogroya, Ngenla
- ☐ **2.2** Documented failure of two growth hormone stimulation tests
- ☐ **2.3** Failure is defined as a peak serum growth hormone level <10ng/ml
- ☐ **2.4** Diagnostic imagery of the brain has excluded the possibility of a tumor
- ☐ **2.5** 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
- ☐ **2.6** 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

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

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

years of age

- ☐ **3.4** Child remains 2 SD below the median height for their specific age
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- ☐ **3.5** 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

- ☐ **4.1** Applicable products: Genotropin, Norditropin, Omnitrope
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- ☐ **4.2** Diagnosis of Prader-Willi syndrome
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- ☐ **4.3** Documentation indicates no upper airway obstruction present
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- ☐ **4.4** 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
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- ☐ **4.5** 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
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- ☐ **4.6** 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

- ☐ **5.1** Applicable products: Humatrope, Zomacton
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- ☐ **5.2** Diagnosis of SHOX confirmed by molecular or genetic analysis
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- ☐ **5.3** Member is 3 years of age
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- ☐ **5.4** 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
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- ☐ **5.5** 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

- ☐ 6.1 Applicable products: Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Zomacton
- ☐ 6.2 Diagnosis of Turner's syndrome confirmed by karyotype study
- ☐ 6.3 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
- ☐ 6.4 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
- ☐ 6.5 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

- ☐ 7.1 Applicable product: Norditropin
- ☐ 7.2 Member's 1-year height velocity >2 SD below the mean
- ☐ 7.3 Member's pretreatment height is >2 SD below the mean and 1-year height velocity is > 1 SD below the mean
- ☐ 7.4 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

- ☐ 8.1 Applicable product: Nutropin
- ☐ 8.2 Diagnosis of chronic renal insufficiency
- ☐ 8.3 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
- ☐ 8.4 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
- ☐ 8.5 Documentation that other metabolic, endocrine, and nutritional abnormalities are treated and stabilized
 - Acidosis
 - Malnutrition
 - Secondary hypothyroidism

- ☐ **8.6 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

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

- ☐ **9.2** Documented pituitary disease or brain injury involving pituitary

- ☐ **9.3** Member has a diagnosis of at least one other pituitary hormone deficiency and each deficiency is optimally treated

- ☐ **9.4** GH deficiency is confirmed by laboratory analysis
 - Deficiency defined as peak GH response less than 5ng/ml

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

point = 1 answer in the affirmative

- ☐ **9.6 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

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

- ☐ **10.2** Previous treatment of pediatric growth hormone deficiency

- ☐ **10.3** Documentation which states the member's growth velocity is <2cm/year and nearing their maximum adult height

- ☐ **10.4** Discontinuation of previous growth hormone use for at least one month following completion of linear growth

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

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

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

point = 1 answer in the affirmative

- ☐ **10.8 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

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

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

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

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

point = 1 answer in the affirmative

- ☐ **11.5 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

- ☐ **12.1** Applicable product: Serostim

- ☐ **12.2** Diagnosis of HIV/AIDS

- ☐ **12.3** Active treatment with antiretroviral therapy

- ☐ **12.4** Documented BMI of 18.5kg/m²

- ☐ **12.5 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

- ☐ **13.1** Applicable product: Zorbtive

- ☐ **13.2** Diagnosis of short bowel syndrome

- ☐ **13.3** Documented administration of specialized nutritional support

☐ **13.4** No previous history of growth hormone treatment

☐ **13.5** Approval Time

- Lifetime: 8 week

Exclusion Criteria – Any of the following prevents coverage

☐ **14.1** 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.

☐ **14.2** 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
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☐ **14.3** 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
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☐ **14.4** 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