

<b>POLICY NAME</b>	Growth Hormone	<b>POLICY #</b>	565P
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## Criteria

### 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
- ☐ **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
- ☐ **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

### 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
- ☐ **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
- ☐ **4.2** Diagnosis of Prader-Willi syndrome
- ☐ **4.3** Documentation indicates no upper airway obstruction present
- ☐ **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
- ☐ **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
- ☐ **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
- ☐ **5.2** Diagnosis of SHOX confirmed by molecular or genetic analysis
- ☐ **5.3** Member is 3 years of age
- ☐ **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
- ☐ **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  $<2\text{cm/year}$  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  $<5\text{ng/ml}$
- ☐ **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  $<5\text{ng/ml}$
- ☐ **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

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- ☐ **12.2** Diagnosis of HIV/AIDS

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

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- ☐ **12.4** Documented BMI of 18.5kg/m<sup>2</sup>

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- ☐ **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

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

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

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

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- ☐ **13.5** Approval Time
  - Lifetime: 8 week