Pharmacy Drug Policy & Procedure

Policy Name:	Growth Hormone	Policy #:	565P

Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of growth hormone products (Genotropin, Humatrope, Ngenla, Norditropin, Nutropin AQ, Omnitrope, Saizen, Serostim, Skytrofa, and Zomacton).

Statement of the Policy

Health Alliance Medical Plans will approve the use of Genotropin, Humatrope, Ngenla, Norditropin, Nutropin AQ, Omnitrope, Saizen, Serostim, Skytrofa, or Zomacton under the specialty pharmacy benefit when the following criteria have been met.

Criteria

1. 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.

2. 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

3. 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

3.3 2 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

4. 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

5. 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

6. 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

7. 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

8. 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

9. 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
- 1 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

10. 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
- 1 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

11. 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

11.3 Completion of a growth hormone stimulation test with results <5ng/ml
11.4 Member's QoL-AGHDA score is 11 points
- 1 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

12. 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

13. 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

14. Exclusion – Idiopathic Short Stature

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

References

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3. Steiger E, DiBaise JK, Messing B, Matarese LE, Blethen S. Indications and recommendations for the use of recombinant human growth hormone in adult short bowel syndrome patients dependent on parenteral nutrition. J Clin Gastroenterol. 2006;40(Suppl 2):S99-S106.
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