Health Alliance™ Health Alliance NORTHWEST™

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 and Health Alliance Northwest 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 Drug

1.1 Omnitrope is the preferred formulary growth hormone (GH) product. Coverage of any non-preferred agent requires a documented 3-month trial and failure of Omnitrope, or a documented intolerance to Omnitrope, or a documented contraindication to Omnitrope.

2. Treatment of Pediatric Growth Hormone Deficiency

2.1 Labs showing failure of two growth hormone stimulation tests
- Failure is defined as a peak serum growth hormone level <10ng/ml

2.2 Possibility of a tumor has been excluded

2.3 The member's medical history exhibits ONE of the following:
- Height is greater than 3 standard deviations (SD) below the mean for member’s age and sex
- Height is 2 to 3 SD below the mean for member’s age/sex AND growth velocity (GV) is below the 25th percentile over the previous year
- Pre-treatment 1 year height velocity more than 2 SD below the mean
- Diagnosis of congenital growth hormone deficiency (deficiency is present at birth)
- Member has had radiation treatment to the brain or previous brain tumor with decreasing growth rate

2.4 Approval Time
- Initial: 12 months
- Re-approval: 12 months with a documented growth velocity of at least 2cm per year following one year of GH therapy

3. Treatment of Pediatric Growth Hormone Deficiency in the Neonate with Hypoglycemia

3.1 Diagnosis of neonatal hypoglycemia (low blood sugar)

3.2 Prescriber notes that other causes of hypoglycemia were ruled out or other treatments were ineffective

3.3 Pretreatment random GH level which is less than the lab reference range

3.4 Approval Time
- Initial: 12 months
- Re-approval: 12 months if member’s blood sugar remains normal or notes indicate the member's GH therapy will be adjusted to obtain normal blood sugars.

4. Treatment of small for gestational age (SGA) children

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

4.2 2 years of age

4.3 Child remains 2 SD below the median height for their specific age

4.4 Approval Time:

- Initial: 12 months
- Re-approval: 12 months with a documented growth velocity of at least 2cm per year following at least one year of GH therapy

5. Treatment of Prader-Willi Syndrome

5.1 Diagnosis of Prader-Willi syndrome

5.2 Documentation indicates no upper airway obstruction present

5.3 For members less than 30 months of age:

- pretreatment height is more than 2 SD below the mean, AND documented slow growth velocity

5.4 For members more than 30 months of age:

- pretreatment height is more than 2 SD below the mean AND weight velocity is more than 1 SD below the mean, OR
- pretreatment 1-year height velocity is more than 2 SD below the mean

5.5 Approval Time

- Initial: 12 months
- Re-approval: 12 months with a documented growth velocity of at least 2cm per year following at least one year of GH therapy and body composition has improved

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

6.1 Diagnosis of SHOX confirmed by molecular or genetic analysis

6.2 Member is 3 years of age

6.3 Pretreatment height is >2 SD below the mean AND 1-year height velocity is > 1 SD below the mean, OR

6.4 Pretreatment 1-year height velocity >2 SD below the mean

6.5 Approval Time

- Initial: 12 months
- Re-approval: 12 months with a documented growth velocity of at least 2cm per year following at least one year of GH therapy

7. Treatment of Turner syndrome

7.1 Diagnosis of Turner's syndrome confirmed by chromosomal study

7.2 If less than 30 months of age:

- Pretreatment height is >2 SD below the mean AND a diagnosis of slow growth velocity

7.3 If greater than 30 months of age:

- Pretreatment height is >2 SD below the mean AND 1-year height velocity is > 1 SD below the mean, OR
- Pretreatment 1-year height velocity is more than 2 SD below the mean

7.4 Approval Time

- Initial: 12 months
- Re-approval: 12 months with a documented growth velocity of 2cm per year following at least one year of GH therapy

8. Treatment of Noonan Syndrome

8.1 Member's 1-year height velocity more than 2 SD below the mean, OR

8.2 Pretreatment height is more than 2 SD below the mean AND 1-year height velocity is > 1 SD below the mean

8.3 Approval Time

- Initial: 12 months
- Re-approval: 12 months with a documented growth velocity of 2cm per year following at least one year of GH therapy

9. Treatment of Growth Failure Due to Chronic Renal Insufficiency

9.1 Diagnosis of chronic renal insufficiency

9.2 If less than 30 months of age:

- Pretreatment height is >2 SD below the mean AND diagnosis of a slow growth velocity

9.3 If more than 30 months of age:

- Pretreatment height is >2 SD below the mean AND 1-year height velocity is > 1 SD below the mean, OR
- Pretreatment 1-year height velocity >2 SD below the mean

9.4 Documentation that other metabolic, endocrine, and nutritional abnormalities are treated and stabilized

- Acidosis (body fluids contain too much acid)
- Malnutrition (imbalances in a person's intake of nutrients)
- Secondary hypothyroidism (low activity of the thyroid gland.

9.5 Approval Time

- Initial: 12 months
- Re-approval: 12 months, with a documented growth velocity of 2cm per year following at least one year of GH therapy

10. Treatment of Adult Growth Hormone Deficiency Due to Pituitary Damage

10.1 Documented pituitary disease or brain injury involving pituitary

10.2 Member has a diagnosis of at least one other pituitary hormone deficiency and each deficiency is optimally treated

10.3 GH deficiency is confirmed by laboratory analysis

- Deficiency defined as peak GH response less than 5ng/ml

10.4 Member's [QoL-AGHDA](#) score is 11 points

- 1 point = 1 answer in the affirmative

10.5 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 Adult Growth Hormone Deficiency who were Previously Treated for Pediatric Growth Hormone Deficiency

11.1 Previous treatment of pediatric growth hormone deficiency

11.2 Documentation which states the member's growth velocity is less than 2cm per year and nearing their maximum adult height

11.3 Discontinuation of previous growth hormone use for at least one month following completion of linear growth

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

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

11.6 Member's [QoL-AGHDA](#) score is 11 points

- 1 point = 1 answer in the affirmative

11.7 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 Early Adult-Onset Growth Hormone Deficiency

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

12.2 Completion of a growth hormone stimulation test with results <5ng/ml
12.3 Member's QoL-AGHDA score is 11 points
- 1 point = 1 answer in the affirmative

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

13. Treatment of HIV-Associated Wasting Algorithm

13.1 Diagnosis of HIV/AIDS
13.2 Active treatment with antiretroviral therapy
13.3 Documented BMI of 18.5kg/m^2
13.4 Approval Time
- Initial: 12 months
- Re-approval: 12 months with documentation that the member's BMI improved or stabilized in response to treatment

14. Treatment of Short Bowel Syndrome

14.1 Diagnosis of short bowel syndrome
14.2 Documented administration of specialized nutritional support
14.3 No previous history of growth hormone treatment
14.4 Approval Time
- Lifetime: 8 weeks

15. Exclusion – Idiopathic Short Stature

15.1 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.
15.2 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

15.3 Most patients with ISS have normal psychological and social 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

15.4 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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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.