

Pharmacy Policy Bulletin

Title: Growth Hormones

Policy #: FS.CLIN.26

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, gender or quantity restrictions. Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This pharmacy policy will be reviewed regularly and updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent

Growth hormones are indicated for several disorders including growth failure associated with chronic renal insufficiency, Noonan syndrome, Prader-Willi Syndrome, Turner Syndrome, growth failure in children due to inadequate secretion of endogenous growth hormone, growth hormone deficiency in adults, growth failure in children born small for gestational age, idiopathic short stature, short bowel syndrome, short stature homeobox containing gene deficiency, and HIV wasting.

The use of growth hormones requires prior authorization (i.e. clinical pharmacy and/or Medical Director review).

Description:

Biosynthetic growth hormone is used to replace natural growth hormone and is produced by recombinant DNA technology using either E coli bacteria or mammalian cell lines. Biosynthetic growth hormone goes by the generic name somatotropin and has an amino acid sequence identical to human growth hormone from the pituitary gland. Somatotropin is available under several different brand names.

Policy

Authorizations will be placed for a period of 1 year unless otherwise specified.

Children with idiopathic short stature

(Omnitrope, Norditropin, Humatrope, Genotropin, Saizen, Nutropin/Nutropin AQ, Tev-Tropin)

INITIAL CRITERIA

Growth hormones are approved when all of the following inclusion criteria are met:

- Documentation prescriber is an endocrinologist
- Documentation of a height of less than 2.25 standard deviations from the mean (1.2 percentile)
- Documentation of growth velocity
- Documentation of a trial and failure/contraindication to Norditropin or Humatrope (if requesting any other Growth Hormone)

REAUTHORIZATION CRITERIA

Growth hormones are re-approved when all of the following inclusion criteria are met:

- Documentation of a 50-percent increase in growth velocity from baseline
- Documentation of clinical re-evaluation by the treating endocrinologist at least yearly
- Documentation of a trial and failure/contraindication to Norditropin or Humatrope (if requesting any other Growth Hormone)

Turner Syndrome

(Humatrope, Genotropin, Norditropin, Nutropin/Nutropin AQ and Omnitrope)

INITIAL CRITERIA

Growth hormones are approved when all of the following inclusion criteria are met:

- Diagnosis of Turner syndrome
- Documentation prescriber is an endocrinologist
- Documentation of a trial and failure/contraindication to Norditropin and Humatrope (if requesting Genotropin, Nutropin/Nutropin AQ or Omnitrope)

REAUTHORIZATION CRITERIA

Growth hormones are re-approved when all of the following inclusion criteria are met:

- Growth velocity greater than or equal to 2.5 cm/year
- Documentation of clinical re-evaluation by the treating endocrinologist at least yearly
- Documentation of a trial and failure/contraindication to Norditropin and Humatrope (if requesting a Growth Hormone other than Norditropin or Humatrope)

Growth Hormone deficiency in children

(Omnitrope, Norditropin, Genotropin, Humatrope, Saizen, Nutropin/Nutropin AQ, Tev-Tropin)

INITIAL CRITERIA

Growth hormones are approved when all of the following inclusion criteria are met:

- Documentation of a subnormal serum insulin-like growth factor-1 (IGF-1)
- Documentation prescriber is an endocrinologist
- Documentation of growth velocity less than or equal to 5 cm/year after 2 years of age
- Documentation of bone age determination
- Either of the following responses from provocative testing:
 - Abnormal response on Insulin-induced hypoglycemia test (less than 5 ng/ml)
 - Abnormal response of less than 10 ng/ml to any other two provocative tests (performed sequentially, not simultaneously), such as but not limited to the following:
 - Levadopa
 - Clonidine
- Documentation of a trial and failure/contraindication to Norditropin and Humatrope (if requesting Omnitrope, Genotropin, Saizen, Nutropin/Nutropin AQ, Tev-Tropin)

REAUTHORIZATION CRITERIA

Growth hormones are re-approved when all of the following inclusion criteria are met:

- Growth velocity greater than or equal to 2.5cm/year

- Documentation of clinical re-evaluation by the treating endocrinologist at least yearly
- Documentation of a trial and failure/contraindication to Norditropin and Humatrope (if requesting Omnitrope, Genotropin, Saizen, Nutropin/Nutropin AQ, Tev-Tropin)

Growth hormone deficiency in adults with adult onset hypothalamic pituitary disease

(Omnitrope, Norditropin, Genotropin, Humatrope, Saizen, Nutropin/Nutropin AQ)

INITIAL CRITERIA

Growth hormones are approved when all of the following inclusion criteria are met:

- Documentation prescriber is an endocrinologist
- Clinical history of hypothalamic or pituitary disease of organic origin
- Deficiency in any two of the following:
 - Follicle-stimulating hormone (FSH) and luteinizing hormone (LH) (demonstrated by a low early morning serum testosterone concentration in a man or a low serum estradiol concentration in a woman while FSH and LH concentrations are not elevated)
 - Thyroid-stimulating hormone (TSH) (demonstrated by a low serum T4 concentration and TSH concentration that is not elevated)
 - Adrenocorticotrophic hormone (ACTH) (demonstrated by a low early morning serum cortisol and an ACTH that is not elevated)
- Documentation of one of the following:
 - Serum IGF-1 concentration that is subnormal for age and gender
 - GH response of less than 5 ng/ml to insulin-induced hypoglycemia
- Documentation of a trial and failure/contraindication to Norditropin and Humatrope (if requesting Omnitrope, Genotropin, Saizen, Nutropin/Nutropin AQ)

REAUTHORIZATION CRITERIA

Growth hormones are reapproved when all of the following inclusion criteria are met:

- Normalization of serum IGF-1 concentration for age and gender
- Documentation of clinical re-evaluation by the treating endocrinologist at least yearly
- Documentation of a trial and failure/contraindication to Norditropin and Humatrope (if requesting Omnitrope, Genotropin, Saizen, Nutropin/Nutropin AQ)

Growth Hormone deficiency in adults with childhood onset hypothalamic or pituitary disease

(Omnitrope, Norditropin, Genotropin, Humatrope, Saizen, Nutropin/Nutropin AQ)

INITIAL CRITERIA

Growth hormones are approved when all of the following inclusion criteria are met

- Documentation prescriber is an endocrinologist
- Documentation of a trial and failure/contraindication to Norditropin and Humatrope (if requesting Omnitrope, Genotropin, Saizen, Nutropin/Nutropin AQ)
- One of the following
 - Clinical history of organic or idiopathic panhypopituitarism as a child.
 - History of idiopathic, isolated GH deficiency in childhood requiring documentation of one of the following:
 - Serum IGF-1 concentration that is subnormal for age and gender
 - GH response of less than 5 ng/ml to Insulin-induced hypoglycemia

REAUTHORIZATION CRITERIA

Growth hormones are re-approved when all of the following inclusion criteria are met:

- Normalization of serum IGF-1 concentration for age and gender
- Documentation of clinical re-evaluation by the treating endocrinologist at least yearly
- Documentation of a trial and failure/contraindication to Norditropin and Humatrope (if requesting Omnitrope, Genotropin, Saizen, Nutropin/Nutropin AQ)

Dwarfism-Noonan syndrome

(Norditropin only)

INITIAL CRITERIA

Growth hormones are approved when the following inclusion criteria are met:

- Documentation of Noonan syndrome
- Documentation prescriber is an endocrinologist

REAUTHORIZATION CRITERIA

Growth hormones are re-approved when the following inclusion criteria are met:

- Documentation of clinical re-evaluation by the treating endocrinologist at least yearly
- Documentation of a trial and failure/contraindication to Norditropin (if requesting a growth hormone other than Norditropin)

Dwarfism short stature homeobox containing gene (SHOX) deficiency

(Humatrope only)

INITIAL CRITERIA

Growth hormones are approved when the following inclusion criteria are met:

- Documentation of short stature or growth failure in children with short stature homeobox containing gene(SHOX) deficiency whose epiphyses are not closed
- Documentation prescriber is an endocrinologist

REAUTHORIZATION CRITERIA

Growth hormones are re-approved when the following inclusion criteria are met:

- Documentation of re-evaluation by treating endocrinologist yearly
- Documentation of a trial and failure/contraindication to Humatrope (if requesting a growth hormone other than Humatrope)

Small for gestational age

(Humatrope, Genotropin, Norditropin, Omnitrope)

INITIAL CRITERIA

Growth hormones are approved when all of the following inclusion criteria are met:

- Failure to reach the third percentile for length/height by 2 years of age or older
- Documentation prescriber is an endocrinologist
- Documentation of either of the following:
 - Birth length and/or weight less than the third percentile for gestational age
 - Birth weight less than 2500 grams and gestational age greater than 37 weeks
- Documentation of a trial and failure/contraindication to Norditropin and Humatrope (if requesting Genotropin or Omnitrope)

REAUTHORIZATION CRITERIA

Growth hormones are re-approved when all of the following inclusion criteria are met:

- Growth velocity greater than or equal to 2.5cm/year

- Documentation of clinical re-evaluation by the treating endocrinologist at least yearly
- Documentation of a trial and failure/contraindication to Norditropin and Humatrope (if requesting a growth hormone other than Norditropin or Humatrope)

Hypopituitarism in childhood

(Omnitrope, Norditropin, Genotropin, Humatrope, Saizen, Nutropin/Nutropin AQ, Tev-Tropin)

INITIAL CRITERIA

Growth hormones are approved when all of the following inclusion criteria are met:

- Clinical evidence of a pituitary lesion or midline central nervous system defect
- Documentation prescriber is an endocrinologist
- Growth velocity less than or equal to 5 cm/year after 2 years of age
- Documentation of one of the following:
 - A subnormal serum IGF-1
 - Provocative testing, such as but not limited to the following:
 - Levadopa
 - Clonidine
 - Insulin-induced hypoglycemia
 - Deficiencies in two or more other hypothalamic-pituitary axes
- Documentation of a trial and failure/contraindication to Norditropin and Humatrope (if requesting Omnitrope, Genotropin, Saizen, Nutropin/Nutropin AQ, Tev-Tropin)

REAUTHORIZATION CRITERIA

Growth hormones are reapproved when all of the following inclusion criteria are met :

- Normalization of serum IGF-1 concentration for age and gender
- Documentation of clinical re-evaluation by the treating endocrinologist at least yearly
- Documentation of a trial and failure/contraindication to Norditropin and Humatrope (if requesting Omnitrope, Genotropin, Saizen, Nutropin/Nutropin AQ, Tev-Tropin)

AIDS wasting syndrome

INITIAL CRITERIA

Growth hormones are approved when all of the following inclusion criteria are met:

- Documentation of HIV infection
- Documentation of concomitant antiretroviral therapy
- Current weight less than 90 percent of ideal body weight

REAUTHORIZATION CRITERIA

N/A

Authorizations for AIDS wasting syndrome will be limited to one 12 week course of therapy

Short bowel syndrome

INITIAL CRITERIA

Growth hormones are approved when the following inclusion criteria is met:

- Documentation of short bowel syndrome

REAUTHORIZATION CRITERIA

N/A

Authorizations for short bowel syndrome will be limited to one 6 week course

Prader-Willi syndrome

INITIAL CRITERIA

Growth Hormones are approved when all of the following inclusion criteria are met:

- Documentation of a diagnosis of Prader-Willi syndrome
- Documentation prescriber is an endocrinologist

REAUTHORIZATION CRITERIA

Growth hormones are re-approved when the following inclusion criteria is met:

- Documentation of clinical re-evaluation by the treating endocrinologist at least yearly

Chronic Renal Insufficiency

INITIAL CRITERIA

Growth hormones are approved when all of the following inclusion criteria are met:

- Documentation of growth failure associated with CRI
- Height below the third percentile on standardized growth charts
- No documentation of a renal transplant
- Documentation prescriber is an endocrinologist or nephrologist

REAUTHORIZATION CRITERIA

Growth hormones are re-approved when all of the following inclusion criteria are met:

- No documentation of a renal transplant
- Documentation of clinical re-evaluation by the treating endocrinologist or nephrologist at least yearly
- Growth velocity greater than or equal to 2.5 cm/year

Guidelines

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any products that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References

American Association of Clinical Endocrinologists Medical Guidelines for clinical practice for growth hormone use in adults and children—2003 Update. Endocrine Practice Vol 9. No. 1. January/February 2003.

Facts and Comparisons website.[growth hormone] Available at www.factsandcomparisons.com. Accessed October 27, 2011.

Genotropin [package insert]. New York, NY. Pharmacia & Upjohn; 2008.

Genotropin website. Available at www.genotropin.com. Accessed October 27, 2011.

Humatrope [package insert]. Indianapolis, IN: Eli Lilly and Company; 2008.

Humatrope website. Available at www.humatrope.com. Accessed October 27, 2011.

Mayoclinic website. Available at www.mayoclinic.com. Accessed October 27, 2011.

Merck Manual of Diagnosis and Therapy - 18th Ed. (2006). Available at www.statref.com. Accessed October 27, 2011.

Noonan syndrome website. Available at www.noonansyndrome.org. Accessed October 27, 2011.
Norditropin [package insert]. Princeton, NJ: Novo Nordisk; 2008

Nutropin website. Available at www.nutropin.com. Accessed October 27, 2011.

Nutropin AQ [package insert]. South San Francisco, CA: Genentech Inc 2007.

Omnitrope [package insert]. Princeton, NJ: Sandoz Inc. 2008.
PraderWilli website. Available at www.pwsausa.org/. Accessed October 27, 2011.

Saizen [package insert]. Rockland, MA: Serono Inc. 2007.
Serostim [package insert]. Rockland, MA: Serono Inc. 2006.

Sizonenko PC, Clayton PE, Cohen P, et al. Diagnosis and management of growth hormone deficiency in childhood and adolescence. Growth Hormone & IGF Research. 2001. 11, 137-165.

Tev-Tropin [package insert]. Sellersville, PA: Gate Pharmaceuticals; 2006.

Zorbtive [package insert]. Rockland, MA: Serono Inc. 2003.

Applicable Drugs

i Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Drug Name	Strength and/or formulation
Somatropin (Genotropin)	All
Somatropin (Humatrope)	All
Somatropin (Norditropin)	All
Somatropin (nutropin/Nutropin AQ)	All
Somatropin (Omnitrope)	All
Somtropin (Saizen)	All
Somatropin (Serostim)	All
Somatropin (Tev-Tropin)	All
Somatropin (Zorbtive)	All

▸ Cross References

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