

Policies Repository



Policy Title Growth Hormones

Policy Number FS.CLIN.26

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

Policy

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 (ie, clinical pharmacy and/or Medical Director review).

Policy 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 Guideline Inclusion

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 and Nutropin/Nutropin AQ)

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 or Nutropin/Nutropin AQ)

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

Policy Guideline Exclusion

Children with idiopathic short stature

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

INITIAL CRITERIA

Growth hormones are denied when any of the following exclusion criteria are present:

- No documentation prescriber is an endocrinologist
- No documentation of a height of less than 2.25 standard deviations from the mean (1.2 percentile)
- No documentation of growth velocity
- No documentation of a trial and failure/contraindication to Norditropin or Humatrope (if requesting any other Growth Hormone)

REAUTHORIZATION CRITERIA

Growth hormones are denied when any of the following exclusion criteria are present:

- No documentation of a 50-percent increase in growth velocity from baseline
- No documentation of clinical re-evaluation by the treating endocrinologist at least yearly
- No documentation of a trial and failure/contraindication to Norditropin or Humatrope (if requesting any other Growth Hormone)

Turner Syndrome

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

INITIAL CRITERIA

Growth hormones are denied when any of the following exclusion

criteria are present:

- No diagnosis of Turner syndrome
- No documentation prescriber is an endocrinologist
- No documentation of a trial and failure/contraindication to Norditropin and Humatrope (if requesting Genotropin or Nutropin/Nutropin AQ)

REAUTHORIZATION CRITERIA

Growth hormones are denied when any of the following exclusion criteria are present:

- No documentation of growth velocity greater than or equal to 2.5 cm/year
- No documentation of clinical re-evaluation by the treating endocrinologist at least yearly
- No 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 denied when any of the following exclusion criteria are present:

- No documentation of a subnormal serum insulin-like growth factor-1 (IGF-1)
- No documentation prescriber is an endocrinologist
- No documentation of growth velocity less than or equal to 5 cm/year after 2 years of age
- No documentation of bone age determination
- No documentation of 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:

§ Clonidine

- No 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 denied when any of the following exclusion criteria are present:

- No documentation of growth velocity greater than or equal to 2.5cm/year
- No documentation of clinical re-evaluation by the treating endocrinologist at least yearly
- No 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 denied when any of the following exclusion criteria are present:

- No documentation prescriber is an endocrinologist
- No Clinical history of hypothalamic or pituitary disease of organic origin
- No 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)
- No 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

- No documentation of a trial and failure/contraindication to Norditropin and Humatrope (if requesting Omnitrope, Genotropin, Saizen, Nutropin/Nutropin AQ)

REAUTHORIZATION CRITERIA

Growth hormones are denied when any of the following exclusion criteria are present:

- No normalization of serum IGF-1 concentration for age and gender
- No documentation of clinical re-evaluation by the treating endocrinologist at least yearly
- No 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 denied when any of the following exclusion criteria are present:

- No Documentation prescriber is an endocrinologist
- NO Documentation of a trial and failure/contraindication to Norditropin and Humatrope (if requesting Omnitrope, Genotropin, Saizen, Nutropin/Nutropin AQ)
- No documentation of One of the following
 - o Clinical history of organic or idiopathic panhypopituitarism as a child.
 - o 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 denied when any of the following exclusion criteria are present:

- No normalization of serum IGF-1 concentration for age and gender

- No documentation of clinical re-evaluation by the treating endocrinologist at least yearly
- No 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 denied when any of the following exclusion criteria are present:

- No documentation of Noonan syndrome
- No documentation prescriber is an endocrinologist

REAUTHORIZATION CRITERIA

Growth hormones are denied when any of the following exclusion criteria are present:

- No documentation of clinical re-evaluation by the treating endocrinologist at least yearly
- No 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 denied when any of the following exclusion criteria are present:

- No documentation of short stature or growth failure in children with short stature homeobox containing gene(SHOX) deficiency whose epiphyses are not closed
- No documentation prescriber is an endocrinologist

REAUTHORIZATION CRITERIA

Growth hormones are denied when any of the following exclusion criteria are present:

- No documentation of re-evaluation by treating endocrinologist yearly

- No 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 denied when any of the following exclusion criteria are present:

- No documentation of Failure to reach the third percentile for length/height by 2 years of age or older
- No documentation prescriber is an endocrinologist
- No 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
- No Documentation of a trial and failure/contraindication to Norditropin and Humatrope (if requesting Genotropin or Omnitrope)

REAUTHORIZATION CRITERIA

Growth hormones are denied when any of the following exclusion criteria are present:

- No documentation of Growth velocity greater than or equal to 2.5cm/year
- No documentation of clinical re-evaluation by the treating endocrinologist at least yearly
- No documentation of a trial and failure/contraindication to Norditropin and Humatrope (if requesting a growth hormone other then Norditropin or Humatrope)

Hypopituitarism in childhood

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

INITIAL CRITERIA

Growth hormones are denied when any of the following exclusion criteria are present:

- No clinical evidence of a pituitary lesion or midline central nervous system defect

- No documentation prescriber is an endocrinologist
- No documentation of growth velocity less than or equal to 5 cm/year after 2 years of age
- No 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
- No 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 denied when any of the following exclusion criteria are present :

- No normalization of serum IGF-1 concentration for age and gender
- No documentation of clinical re-evaluation by the treating endocrinologist at least yearly
- No 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 denied when any of the following exclusion criteria are present:

- No documentation of HIV infection
- No documentation of concomitant antiretroviral therapy
- No documentation of 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 denied when the following exclusion criteria is present:

- No 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 denied when any of the following exclusion criteria are present:

- No documentation of a diagnosis of Prader-Willi syndrome
- No documentation prescriber is an endocrinologist

REAUTHORIZATION CRITERIA

Growth hormones are denied when the following exclusion criteria is present:

- No documentation of clinical re-evaluation by the treating endocrinologist at least yearly

Chronic Renal Insufficiency

INITIAL CRITERIA

Growth hormones are denied when any of the following exclusion criteria are present:

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

REAUTHORIZATION CRITERIA

Growth hormones are denied when any of the following exclusion criteria are present:

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

Policy List of Applicable Drugs

Brand Name	Generic Name
Genotropin	Somatropin
Humatrope	Somatropin
Norditropin	Somatropin
Nutropin/Nutropin AQ	Somatropin
Omnitrope	Somatropin
Saizen	Somatropin
Serostim	Somatropin
Tev-Tropin	Somatropin
Zorbtive	Somatropin

Dosing and Administration

Refer to the specific manufacturer's prescribing information for administration and dosage details for each specific agent.

Policy References

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Policy Link to Related Policies

Printed

11/15/2010 09:17:57

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