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5.30.012

Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	August 1, 2013
Subject:	Growth Hormone Pediatric	**Page:**	1 of 9

Last Review Date: March 7, 2025

Growth Hormone Pediatric

Description

Genotropin, Humatrope, Ngenla, **Norditropin**, Omnitrope, Saizen, Sogroya, Skytrofa, Zomacton (aka. Tev-Tropin)

Preferred product: Norditropin

Background
Somatropin is a synthetically manufactured genetic copy of natural human growth hormone produced in the pituitary gland. It has the same effect as natural human growth hormone made in the body. Growth hormone (GH) contributes to overall bone, muscle, and organ growth and development in humans. Children with inadequate production of growth hormone, which can be due to various diseases and reasons, require growth hormone replacement in order to complete their development from childhood to adulthood (1-2).

Somatropin, commonly referred to growth hormone, is currently marketed for use in children under the following brands: Genotropin, Humatrope, Norditropin, Omnitrope, Saizen, Skytrofa, and Zomacton (formerly known as Tev-Tropin). Ngenla contains somatrogon, a synthetic growth hormone. Skytrofa is a pegylated version of somatropin allowing for once-weekly subcutaneous dosing (3-11).

Use of any growth hormone in children can cause a number of potentially serious adverse effects; therefore, regular and routine monitoring is required. Sometimes treatment may need to be permanently stopped. These adverse effects include the development of impaired glucose tolerance and diabetes mellitus, upper airway obstruction and sleep apnea in patients with

Prader-Willi syndrome, progression or recurrence of tumors in patients with preexisting tumors, intracranial hypertension, the worsening of hypothyroidism, the worsening of pre-existing scoliosis, and pancreatitis (1-2).

Regulatory Status
FDA-approved indications: Pediatric growth hormone is indicated for: growth hormone deficiency (GHD)/insufficiency; growth failure secondary to chronic renal insufficiency pre-transplantation, Noonan Syndrome, Prader-Willi Syndrome, Turner Syndrome or SHOX (short stature homeobox-containing gene) deficiency; small for gestational age (SGA) for children who have not reached a normal height range by age 2 to 4 years or idiopathic short stature (ISS) (3-9).

Skytrofa is indicated for the treatment of pediatric patients 1 year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormone (10).

Ngenla is indicated for the treatment of pediatric patients 3 years and older who have growth failure due to inadequate secretion of endogenous growth hormone (11).

Although the FDA-labeled indications vary for the growth hormone products, guidelines address all somatropin products collectively with the exception of Skytrofa (1-2).

Related policies
Growth Hormone Adult, Serostim, Zorbtive

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Pediatric growth hormone may be considered **medically necessary** if the conditions indicated below are met.

Pediatric growth hormone may be considered **investigational** for all other indications.

Prior-Approval Requirements

All products except for Ngenla and Skytrofa

Age 17 years of age or under
18 years of age or older **WITH** open epiphyses

Diagnoses

Patient must have **ONE** of the following:

1. Growth failure due to inadequate secretion of endogenous growth hormone as defined by having **ALL** of the following:
    a. Height below 3rd percentile for age or acquired growth hormone deficiency due to CNS lesions
    b. Growth hormone level less than 10 on stimulation test or subnormal IGF-1 level for age or subnormal IGFBP-3 level for age
2. Growth failure in children born small for gestational age who fail to manifest catch-up growth by age 2 to 4 years
3. Growth failure due to chronic renal insufficiency up to the time of renal transplantation
4. Growth failure due to Noonan Syndrome
5. Growth failure due to Prader-Willi Syndrome
6. Growth failure due to SHOX (short stature homeobox-containing gene) deficiency
7. Growth failure due to Turner Syndrome
8. Idiopathic short stature (ISS), also called non-growth hormone-deficient short stature, defined by height standard deviation score (SDS) ≤ -2.25, and associated with growth rates unlikely to permit attainment of adult height in the normal range, and in whom diagnostic evaluation excludes other causes associated with short stature that should be observed or treated by other means

AND ALL of the following for **ALL** products:

1. Open epiphyses (as determined within the last year by radiographic evidence)
2. **NO** evidence of tumor activity or active neoplasm
3. **NOT** used in combination with another somatropin agent (such as Serostim, Zorbtive, or any other GH)
4. **NOT** used in combination with Voxzogo (vosoritide)

5. **Non-preferred medications only:** Patient **MUST** have tried the preferred product (Norditropin) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication, reduction of treatment burden with fewer injections)

Ngenla and Skytrofa only

Age 1 to 17 years of age for Skytrofa
3 to 17 years of age for Ngenla
18 years of age or older **WITH** open epiphyses

Diagnosis

Patient must have the following:

1. Growth failure due to inadequate secretion of endogenous growth hormone as defined by having **ALL** of the following:
   a. Height below 3rd percentile for age or acquired growth hormone deficiency due to CNS lesions
   b. Growth hormone level less than 10 on stimulation test or subnormal IGF-1 level for age or subnormal IGFBP-3 level for age

AND ALL of the following:

1. Open epiphyses (as determined within the last year by radiographic evidence)
2. **Skytrofa only**: weight ≥ 11.5 kg
2. **NO** evidence of tumor activity or active neoplasm
3. **NOT** used in combination with another somatropin agent (such as Serostim, Zorbtive, or any other GH)
4. **NOT** used in combination with Voxzogo (vosoritide)
5. Patient **MUST** have tried the preferred product (Norditropin) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication, reduction of treatment burden with fewer injections)

Prior – Approval *Renewal* Requirements

All products except for Ngenla and Skytrofa

Age 17 years of age or under
18 years of age or older **WITH** open epiphyses

Diagnoses

Patient must have **ONE** of the following:

1. Growth failure due to inadequate secretion of endogenous growth hormone
2. Growth failure in children born small for gestational age who fail to manifest catch-up growth by age 2 to 4 years
3. Growth failure due to chronic renal insufficiency up to the time of renal transplantation
4. Growth failure due to Noonan Syndrome
5. Growth failure due to Prader-Willi Syndrome
6. Growth failure due to SHOX (short stature homeobox-containing gene) deficiency
7. Growth failure due to Turner Syndrome
8. Idiopathic short stature (ISS), also called non-growth hormone-deficient short stature

AND ALL of the following for **ALL** products:

1. Open epiphyses (as determined within the last year by radiographic evidence)
2. **NO** evidence of tumor activity or active neoplasm
3. Growth velocity > 2cm/year
4. Absence of significant side effects
5. Compliance with therapy
6. **NOT** used in combination with another somatropin agent (such as Serostim, Zorbtive, or any other GH)
7. **NOT** used in combination with Voxzogo (vosoritide)
8. **Non-preferred medications only:** Patient **MUST** have tried the preferred product (Norditropin) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication, reduction of treatment burden with fewer injections)

Ngenla and Skytrofa only

Age 1 to 17 years of age for Skytrofa
3 to 17 years of age for Ngenla
18 years of age or older **WITH** open epiphyses

Diagnosis

Patient must have the following:

1. Growth failure due to inadequate secretion of endogenous growth hormone

AND ALL of the following:

1. Open epiphyses (as determined within the last year by radiographic evidence)
2. **Skytrofa only**: weight ≥ 11.5kg
3. **NO** evidence of tumor activity or active neoplasm
4. Growth velocity > 2cm/year
5. Absence of significant side effects
6. Compliance with therapy
7. **NOT** used in combination with another somatropin agent (such as Serostim, Zorbtive, or any other GH)
8. **NOT** used in combination with Voxzogo (vosoritide)
9. Patient **MUST** have tried the preferred product (Norditropin) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication, reduction of treatment burden with fewer injections)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Pituitary growth hormone is a peptide that exerts anabolic effects on target tissues. Growth hormone (GH) secretion is regulated by a balance between growth hormone–releasing hormone (GHRH) and growth hormone-inhibiting (somatostatin) factors. Other growth hormone–releasing peptides (GHRPs) are known to stimulate GH. Receptors for the GHRPs have been identified, and the natural ligand for these receptors has been determined to be ghrelin (1-2).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of pediatric growth hormones while maintaining optimal therapeutic outcomes.

References

1. Cook DM, Yuen KC, Biller BM, Kemp SF, Vance ML. American Association of Clinical Endocrinologists medical guidelines for clinical practice for growth hormone use in growth hormone-deficient adults and transition patients - 2009 update: executive summary of recommendations. Endocr Pract 15:580-586.
2. Wilson TA, Rose SR, Cohen P, et al. Update of guidelines for the use of growth hormone in children: The Lawson Wilkins Pediatric Endocrinology Society Drug and Therapeutics Committee. J Pediatrics. 2003; 143:415-21.
3. Genotropin [package insert]. New York, NY: Pfizer Inc.; April 2019.
4. Humatrope [package insert]. Indianapolis, IN: Eli Lilly and Company; December 2024.
5. Norditropin [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; March 2020.
6. Omnitrope [package insert]. Princeton, NJ: Sandoz Inc., June 2019.
7. Saizen [package insert]. Rockland, MA: EMD Serono Inc.; February 2020.
8. Zomacton [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; April 2024.
9. Sogroya [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; April 2023.
10. Skytrofa [package insert]. Palo Alto, CA: Ascendis Pharma, Inc.; April 2022.
11. Ngenla [package insert]. New York, NY: Pfizer Inc.; June 2023.

Policy History

Date	Action
November 2011	All pediatric growth hormones separated into their own respective individual criteria documents. All diagnoses required to get initial prior authorization to start growth hormone replacement were removed from the renewal sections as these are verified before treatment is started. Criteria rewritten to contain all current FDA labeled indications. All non-FDA labeled indications were

	removed from the criteria. Humatrope is currently FDA indicated for pediatric patients for treatment of the following: growth failure due to an inadequate secretion of endogenous growth hormone, growth failure in children born small for gestational age who fail to manifest catch-up growth by age 2 to 4 years, growth failure associated with Turner syndrome, idiopathic short stature (ISS), and growth failure associated with SHOX (short stature homeobox-containing gene deficiency). Idiopathic short stature, also called non-growth hormone-deficient short Stature, is defined by a height standard deviation score (SDS) ≤ -2.25, and associated with growth rates unlikely to permit attainment of adult height in the normal range, in pediatric patients whose epiphyses are not closed and for whom diagnostic evaluation excludes other causes associated with short stature that should be observed or treated by other means.
December 2012	Annual review-no change in the policy statement and editorial updates
July 2013	Individual child growth hormone criteria merged into one criteria.
December 2014	Annual editorial and reference update Addition of no combination use with another somatropin agent
March 2015	Annual editorial and reference update
June 2015	Tev-Tropin has changed its name to Zomacton
September 2016	Annual editorial review and reference update Policy number change from 5.08.12 to 5.30.12
December 2017	Annual review and reference update
September 2018	Annual review and reference update Updated background section and guidelines reference per SME
December 2019	Annual review and reference update. Addition of requirement to trial preferred product
December 2020	Annual review and reference update
March 2021	Annual editorial review
September 2021	Addition of Skytrofa to policy as non-preferred medication
December 2021	Annual editorial review. Per SME: addition of “reduction of treatment burden with fewer injections” as a valid medical exception.
April 2022	Addition of “not used in combination with Voxzogo” per SME
June 2022	Annual review and reference update
March 2023	Changed policy number to 5.30.012. Added patients aged 18 and older with open epiphyses to age requirement. Addition of Sogroya to policy
September 2023	Annual review. Addition of Ngenla to policy
December 2023	Annual review

June 2024	Annual review and reference update
September 2024	Annual review
February 2025	Removed Nutropin/Nutropin AQ due to being withdrawn from the market
March 2025	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.