

PEDIATRIC GROWTH HORMONES

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

Preferred product: Norditropin

Pre - PA Allowance

None

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

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Preferred product: Norditropin

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
3. **NO** evidence of tumor activity or active neoplasm
4. **NOT** used in combination with another somatropin agent (such as Serostim, Zorbtive, or any other GH)
5. **NOT** used in combination with Voxzogo (vosoritide)
6. Patient **MUST** have tried the preferred product (Norditropin) unless the patient has a valid medical exception (e.g., inadequate treatment

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Preferred product: Norditropin

response, intolerance, contraindication, reduction of treatment burden with fewer injections)

Prior - Approval Limits

Duration 12 months

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

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Preferred product: Norditropin

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. Weight ≥ 11.5 kg
3. **NO** evidence of tumor activity or active neoplasm
4. Growth velocity $> 2\text{cm/year}$
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)

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Zomacton (aka. Tev-Tropin)

Preferred product: Norditropin

Prior - Approval *Renewal* Limits

Same as above