



STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN - NORDITROPIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOMATROPIN	NORDITROPIN FLEXPRO	02824		GPI-10 (3010002000)	BRAND = NORDITROPIN FLEXPRO

**GUIDELINES FOR USE**

**INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)**

1. Is the request for treatment of **ANY** of the following?

- Athletic enhancement
- Anti-aging purposes
- Idiopathic short stature

If yes, do not approve.

**DENIAL TEXT:** See the initial denial text at the end of the guideline.

If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses and meet the associated criteria?

**For pediatric growth hormone deficiency (GHD), approval requires ALL of the following:**

- Therapy is prescribed by or in consultation with an endocrinologist
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- The patient meets at least ONE of the following criteria for short stature:
  - Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
  - Height velocity less than the 25th percentile for age
  - Documented low peak growth hormone (less than 10ng/mL) on two GH stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 SD below the mean for age and gender

**For short stature associated with Turner syndrome, approval requires ALL of the following:**

- Therapy is prescribed by or in consultation with an endocrinologist
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- The patient's height is greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender

**For short stature associated with Noonan syndrome, approval requires ALL of the following:**

- Therapy is prescribed by or in consultation with an endocrinologist
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- The patient's height is greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender

***(Initial criteria continued on next page)***

**CONTINUED ON NEXT PAGE**



STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN - NORDITROPIN

INITIAL CRITERIA (CONTINUED)

**For short stature in pediatric patients born small for gestational age (SGA), approval requires ALL of the following:**

- Therapy is prescribed by or in consultation with an endocrinologist
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- Patient with no catch-up growth by age 2 to 4 years
- The patient's height is greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender

**For adult growth hormone deficiency, approval requires ALL of the following:**

- Therapy is prescribed by or in consultation with an endocrinologist
- The patient has growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, Surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

**For growth failure due to Prader-Willi syndrome (PWS), approval requires ALL of the following:**

- Confirmed genetic diagnosis of PWS
- Therapy is prescribed by or in consultation with an endocrinologist

If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**

If no, do not approve.

**INITIAL DENIAL TEXT: \*Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **SOMATROPIN (Norditropin Flexpro)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:

1. Pediatric growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)
2. Short stature associated with Turner syndrome (TS: a type of gene condition)
3. Short stature associated with Noonan syndrome (a type of gene condition)
4. Short stature born small for gestational age (SGA) in a pediatric patient
5. Adult growth hormone deficiency
6. Growth failure due to Prader-Willi syndrome (PWS: a type of gene condition)

This medication will not be approved for treatment of ANY of the following conditions:

1. Athletic enhancement
2. Anti-aging purposes
3. Idiopathic short stature (short height due to unknown cause)

***(Initial denial text continued on next page)***

**CONTINUED ON NEXT PAGE**



STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN - NORDITROPIN

INITIAL CRITERIA (CONTINUED)

- B. If you have pediatric growth hormone deficiency, approval also requires:**
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
  2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
  3. You meet at least ONE of the following criteria for short stature:
    - a. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender
    - b. Your height velocity is less than the 25th percentile for your age
    - c. You have documented low peak growth hormone (less than 10ng/mL) on two GH (growth hormone) stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 standard deviations below the mean for your age and gender
- C. If you have short stature associated with Turner syndrome, approval also requires:**
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
  2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
  3. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender
- D. If you have short stature associated with Noonan syndrome, approval also requires:**
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
  2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
  3. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender
- E. If you are a child with short stature born small for gestational age, approval also requires:**
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
  2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
  3. You had no catch-up growth by age 2 to 4 years
  4. Your height is greater than or equal to 2 standard deviations (SD) below the mean (average) height for normal children of the same age and gender
- F. If you have adult growth hormone deficiency, approval also requires:**
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
  2. You have growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases (disease of a major hormone producing gland), hypothalamic disease (disease of a small area of the brain important for hormone production and body processes), surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency
- (Initial denial text continued on next page)***

CONTINUED ON NEXT PAGE



STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN - NORDITROPIN

INITIAL CRITERIA (CONTINUED)

**G. If you have growth failure due to Prader-Willi syndrome, approval also requires:**

1. You have confirmed genetic diagnosis of Prader-Willi syndrome
2. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Is the request for treatment of **ANY** of the following?

- Athletic enhancement
- Anti-aging purposes
- Idiopathic short stature

If yes, do not approve.

**DENIAL TEXT:** See the renewal denial text at the end of the guideline.

If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses and meet the associated criteria?

**For pediatric growth hormone deficiency (GHD), renewal requires ALL of the following:**

- Therapy is prescribed by or in consultation with an endocrinologist
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand or the patient has not completed prepubertal growth)
- The patient meets ONE of the following:
  - Annual growth velocity of 2 cm or more compared with what was observed from the previous year
  - Annual growth velocity of 1 cm or more compared with what was observed from the previous year for patients who are near the terminal phase of puberty

**For short stature associated with Noonan syndrome, renewal requires ALL of the following:**

- Therapy is prescribed by or in consultation with an endocrinologist
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height

***(Renewal criteria continued on next page)***

CONTINUED ON NEXT PAGE



STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN - NORDITROPIN

RENEWAL CRITERIA (CONTINUED)

**For short stature associated with Turner syndrome, renewal requires ALL of the following:**

- Therapy is prescribed by or in consultation with an endocrinologist
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height

**For short stature in pediatric patients born small for gestational age (SGA), renewal requires ALL of the following:**

- Therapy is prescribed by or in consultation with an endocrinologist
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height

**For adult growth hormone deficiency, renewal requires:**

- Therapy is prescribed by or in consultation with an endocrinologist

**For growth failure due to Prader-Willi syndrome (PWS), renewal requires ALL of the following:**

- Therapy is prescribed by or in consultation with an endocrinologist
- Improvement in body composition

If yes, **approve for 12 months by GPID or GPI-14 for all strengths.**

If no, do not approve.

**RENEWAL DENIAL TEXT: \*Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **SOMATROPIN (Norditropin Flexpro)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:

1. Pediatric growth hormone deficiency (GHD)
2. Short stature associated with Turner syndrome (type of genetic disorder where you are missing a X chromosome)
3. Short stature associated with Noonan syndrome (a type of genetic disorder causing abnormal body development)
4. Short stature born small for gestational age (SGA) in a pediatric patient
5. Adult growth hormone deficiency
6. Growth failure due to Prader-Willi syndrome (PWS: genetic disorder that causes obesity, intellectual disability, and short height)

This medication will not be approved for treatment of **ANY** of the following conditions:

1. Athletic enhancement
2. Anti-aging purposes
3. Idiopathic short stature (unknown cause for short height)

***(Renewal denial text continued on next page)***

**CONTINUED ON NEXT PAGE**



STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN - NORDITROPIN

RENEWAL CRITERIA (CONTINUED)

- B. If you have pediatric growth hormone deficiency, renewal also requires:**
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
  2. Your epiphyses (end part of long bone) are NOT closed (confirmed by radiograph [type of imaging test] of the wrist and hand or you have not completed prepubertal growth
  3. You meet ONE of the following:
    - a. Your annual growth velocity is 2 cm or more compared with what was observed from the previous year
    - b. Your annual growth velocity is 1 cm or more compared with what was observed from the previous year if you are near the terminal (end) phase of puberty
- C. If you have short stature associated with Noonan syndrome, renewal also requires:**
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
  2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
  3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height
- D. If you have short stature associated with Turner syndrome, renewal also requires:**
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
  2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
  3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height
- E. If you are a child with short stature born small for gestational age, renewal also requires:**
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
  2. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
  3. Your growth velocity is 2 cm or more compared with what was observed from the previous year and/or you have not reached 50th percentile for your predicted adult height
- F. If you have adult growth hormone deficiency, renewal also requires:**
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
- G. If you have growth failure due to Prader-Willi syndrome, renewal also requires:**
1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
  2. You had improvement in body composition

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

CONTINUED ON NEXT PAGE



**STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES**

**SOMATROPIN - NORDITROPIN**

---

**RATIONALE**

For further information, please refer to the Prescribing Information and/or Drug Monograph for Norditropin.

**REFERENCES**

- Norditropin [Prescribing Information]. Plainsboro, NJ: Novo Nordisk; March 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 11/01/22

Created: 10/22

Client Approval: 10/22

P&T Approval: 04/21