STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN - NUTROPIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SOMATROPIN	NUTROPIN AQ NUSPIN	02824		GPI-10 (3010002000)	FDB: BRAND = NUTROPIN AQ NUSPIN. MEDI-SPAN: BRAND = NUTROPIN AQ NUSPIN 5, NUTROPIN AQ NUSPIN 10, NUTROPIN AQ NUSPIN 20

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 had a trial of or contraindication to the preferred agent: Norditropin
   - 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:
     - 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
     - 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 growth failure secondary to chronic kidney disease (CKD), approval requires ALL of the following:
   - Therapy is prescribed by or in consultation with a nephrologist
   - The patient has NOT undergone a renal transplantation
   - The patient's height or growth velocity is greater than or equal to 2 standard deviations (SD) below the mean for normal children of the same age and gender

   (Initial criteria continued on next page)

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SOMATROPIN - NUTROPIN

INITIAL CRITERIA CONTINUED)

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 had a trial of or contraindication to the preferred agent: Norditropin
- 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 adult growth hormone deficiency, approval requires ALL of the following:

- Therapy is prescribed by or in consultation with an endocrinologist
- The patient had a trial of or contraindication to the preferred agent: Norditropin
- 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

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 (Nutropin AQ Nuspin)** 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. Growth failure secondary to chronic kidney disease (CKD)
3. Short stature associated with Turner syndrome (TS: a type of gene condition)
4. Adult growth hormone deficiency

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)

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SOMATROPIN - NUTROPIN

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. You had a trial of or contraindication (harmful for) to the preferred medication: Norditropin
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   4. 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 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 growth failure secondary to chronic kidney disease, approval also requires:**
   1. You have NOT undergone a renal (kidney) transplantation
   2. Therapy is prescribed by or in consultation with a nephrologist (kidney doctor)
   3. Your height or growth velocity 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 Turner syndrome, approval also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)
   2. You had a trial of or contraindication (harmful for) to the preferred medication: Norditropin
   3. Your epiphyses (end part of long bone) are NOT closed as confirmed by radiograph (type of imaging test) of the wrist and hand
   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

E. **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 had a trial of or contraindication (harmful for) to the preferred medication: Norditropin
   3. 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

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.

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SOMATROPIN - NUTROPIN

GUIDELINES FOR USE (CONTINUED)

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.
   DENIALTEXT: 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 growth failure secondary to chronic kidney disease (CKD), renewal requires ALL of the following:
   - The patient has not undergone a renal transplantation
   - 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 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 adult growth hormone deficiency, renewal requires:
   - 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.
   DENIAL TEXT: See the denial text at the end of the guideline.

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SOMATROPIN - NUTROPIN

RENEWAL CRITERIA (CONTINUED)

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 (Nutropin AQ Nuspin)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Pediatric growth hormone deficiency (GHD: a type of hormone disorder with low growth hormone)
   2. Growth failure secondary to chronic kidney disease (CKD)
   3. Short stature associated with Turner syndrome (TS: a type of gene condition)
   4. Adult growth hormone deficiency

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)

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 growth failure secondary to chronic kidney disease, renewal also requires:**
   1. You have not had a renal (kidney) transplantation
   2. Your growth velocity is 2 cm or more compared with what was observed from the previous year 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 have adult growth hormone deficiency, renewal also requires:**
   1. Therapy is prescribed by or in consultation with an endocrinologist (hormone doctor)

(Renewal denial text continued on next page)

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RENEWAL CRITERIA (CONTINUED)

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.

RATIONALE

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

REFERENCES

- Nutropin [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; December 2016.

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