SOMATROPIN

Generic	Brand	HICL	GCN	Exception/Other
SOMATROPIN	GENOTROPIN, HUMATROPE, NORDITROPIN FLEXPRO, NUTROPIN AQ NUSPIN, OMNITROPE, SAIZEN, SEROSTIM, ZOMACTON, ZORBTIVE	02824		
SYRINGE ACCESSORY	OMNITROPE PEN	07933		

GUIDELINES FOR USE

**** Please use the criteria for the specific drug requested. ****

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

SEROSTIM

1. Is the request for Serostim for a patient with a diagnosis of HIV wasting/cachexia and meet **ALL** of the following criteria?
   - The requested agent is **NOT** prescribed for athletic enhancement or anti-aging purposes
   - The medication is prescribed by or given in consultation with one of the following specialist: Gastroenterologist, Nutritional Support Specialist, or Infectious Disease Specialist
   - The patient is on HIV anti-retroviral therapy
   - The patient has inadequate response to previous therapy (i.e., exercise training, nutritional supplements, appetite stimulants, or anabolic steroids)
   - The patient has an inadequate response to previous pharmacological therapy including one of the following: cyproheptadine, Marinol (dronabinol), or Megace (megestrol acetate)
   - Alternative causes of wasting has been ruled out; alternative causes include:
     - Altered metabolism (from metabolic and hormonal abnormalities) including testosterone deficiency or peripheral growth hormone resistance
     - Diarrhea
     - Inadequate energy (caloric) intake
     - Malignancies
     - Opportunistic infections

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INITIAL CRITERIA - SEROSTIM (CONTINUED)

- The patient meets **ONE** of the following criteria for weight loss:
  - 10% unintentional weight loss over 12 months
  - 7.5% unintentional weight loss over 6 months
  - 5% body cell mass (BCM) loss within 6 months
  - BCM less than 35% (men) **AND** a body mass index (BMI) less than 27 kg per meter squared
  - BCM less than 23% (women) of total body weight **AND** a body mass index (BMI) less than 27 kg per meter squared
  - BMI less than 18.5 kg per meter squared

  If yes, continue to #2.
  If no, do not approve.
  DENIAL TEXT: See the initial denial text at the end of the **SEROSTIM** guideline.

2. Is the patient hypogonadal as defined by **ONE** of the following?
   - Total serum testosterone level of less than 300ng/dL (10.4 nmol/L)
   - A low total serum testosterone level as indicated by a lab result, with a reference range, obtained within 90 days
   - A free serum testosterone level of less than 5 pg/mL (0.17 nmol/L)

   If yes, continue to #3.
   If no, **approve Serostim for 12 weeks by GPID.**

3. For patients who are hypogonadal, does the patient meet the following criteria?
   - Patient has tried testosterone therapy (e.g., testosterone cypionate, AndroGel, Androderm, Axiron, Delatestryl, Fortesta, Striant, Testim, Testopel, Vogelxo, Natesto)

   If yes, **approve Serostim for 12 weeks by GPID.**
   If no, do not approve.
   INITIAL DENIAL TEXT: The guideline named **SOMATROPIN (Serostim)** requires a diagnosis of HIV wasting/cachexia. The following criteria must also be met.
   - The requested agent is **NOT** prescribed for athletic enhancement or anti-aging purposes.
   - The medication is prescribed by or given in consultation with one of the following specialist: Gastroenterologist, Nutritional Support Specialist, or Infectious Disease Specialist.
   - The patient is on HIV anti-retroviral therapy
   - The patient has inadequate response to previous therapy (i.e., exercise training, nutritional supplements, appetite stimulants, or anabolic steroids)

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SOMATROPIN

INITIAL CRITERIA - SEROSTIM (CONTINUED)

- The patient has an inadequate response to previous pharmacological therapy including one of the following: cyproheptadine, Marinol (dronabinol), or Megace (megestrol acetate).
- Alternative causes of wasting has been ruled out; alternative causes include:
  - Altered metabolism (from metabolic and hormonal abnormalities) including testosterone deficiency or peripheral growth hormone resistance
  - Diarrhea
  - Inadequate energy (caloric) intake
  - Malignancies
  - Opportunistic infections
- The patient meets **ONE** of the following criteria for weight loss:
  - 10% unintentional weight loss over 12 months
  - 7.5% unintentional weight loss over 6 months
  - 5% body cell mass (BCM) loss within 6 months
  - BCM less than 35% (men) and a body mass index (BMI) less than 27 kg per meter squared
  - BCM less than 23% (women) of total body weight and a body mass index (BMI) less than 27 kg per meter squared
  - BMI less than 18.5 kg per meter squared

For patients who are hypogonadal (patients with low testosterone levels), approval requires the following:

- The patient has tried testosterone therapy (e.g., testosterone cypionate, AndroGel, Androderm, Axiron, Delatestryl, Fortesta, Striant, Testim, Testopel, Vogelxo, Natesto)
- The patient meets one of the following criteria for low testosterone:
  - Total serum testosterone level of less than 300ng/dL (10.4 nmol/L).
  - A low total serum testosterone level as indicated by a lab result, with a reference range, obtained within 90 days
  - A free serum testosterone level of less than 5 pg/mL (0.17 nmol/L).

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SOMATROPIN

INITIAL CRITERIA (CONTINUED)

ZORBTIVE

1. Is the request for Zorbtive for a patient with a diagnosis of short bowel syndrome and meet **ALL** of the following criteria?
   - The requested agent is **NOT** prescribed for athletic enhancement or anti-aging purposes
   - The patient is currently on specialized nutritional support (such as high carbohydrate, low-fat diet, adjusted for individual requirements and preferences)
   - The medication is prescribed by or given in consultation with a gastroenterologist

   If yes, **approve Zorbtive for 4 weeks by GPID for #1 vial per day (max dose not to exceed 8mg per day).**
   If no, do not approve.
   INITIAL DENIAL TEXT: The guideline named **SOMATROPIN (Zorbtive)** requires a diagnosis of short bowel syndrome. The following criteria must also be met.
   - The requested agent is **NOT** prescribed for athletic enhancement or anti-aging purposes
   - The patient is currently on specialized nutritional support (such as high carbohydrate, low-fat diet, adjusted for individual requirements and preferences)
   - The medication is prescribed by or given in consultation with a gastroenterologist

GENOTROPIN

1. Is the request for Genotropin for the 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 **GENOTROPIN** guideline.
   If no, continue to #2.

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SOMATROPIN

INITIAL CRITERIA - GENOTROPIN (CONTINUED)

2. Does the patient have **ONE** of the following diagnoses and meet **ALL** of the following criteria?
   For the diagnosis of pediatric growth hormone deficiency (GHD), approval requires:
   - The medication is prescribed by or given in consultation with an endocrinologist
   - The patient had a previous trial of or contraindication to Norditropin
   - The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
   - 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 the diagnosis of growth failure associated with Turner Syndrome, approval requires:
   - The medication is prescribed by or given in consultation with an endocrinologist
   - The patient had a previous trial of or contraindication to Norditropin
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - 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

   For the diagnosis of growth failure due to Prader-Willi Syndrome (PWS), approval requires:
   - Confirmed genetic diagnosis of PWS
   - The medication is prescribed by or given in consultation with an endocrinologist
   - The patient had a previous trial of or contraindication to Norditropin

   For the diagnosis of growth failure in children born small for gestational age (SGA), approval requires:
   - The medication is prescribed by or given in consultation with an endocrinologist
   - The patient had a previous trial of or contraindication to Norditropin
   - 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 years
   - 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

   For the diagnosis of adult growth hormone deficiency, approval requires:
   - The medication is prescribed by or given in consultation with an endocrinologist
   - The patient had a previous trial of or contraindication to 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, continued on next page.

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INITIAL CRITERIA - GENOTROPIN (CONTINUED)

If yes, **approve Genotropin for 12 months by GPID.**
If no, do not approve.
INITIAL DENIAL TEXT: The guideline named **SOMATROPIN (Genotropin)** requires **ONE** of the following diagnoses:

- Pediatric growth hormone deficiency
- Growth failure associated with Turner Syndrome
- Growth failure due to Prader-Willi Syndrome (PWS)
- Growth failure in children born small for gestational age (SGA)
- Adult growth hormone deficiency

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

- Athletic enhancement
- Anti-aging purposes
- Idiopathic Short Stature

The following criteria must also be met:
For the diagnosis of pediatric growth hormone deficiency (GHD), approval requires:

- The medication is prescribed by or given in consultation with an endocrinologist
- The patient had a previous trial of or contraindication to Norditropin
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- 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 the diagnosis of growth failure associated with Turner Syndrome, approval requires:

- The medication is prescribed by or given in consultation with an endocrinologist
- The patient had a previous trial of or contraindication to Norditropin
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- 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

For the diagnosis of growth failure due to Prader-Willi Syndrome (PWS), approval requires:

- Confirmed genetic diagnosis of PWS
- The medication is prescribed by or given in consultation with an endocrinologist
- The patient has had a previous trial of or contraindication to Norditropin

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SOMATROPIN

INITIAL CRITERIA - GENOTROPIN (CONTINUED)

For the diagnosis of growth failure in children born small for gestational age (SGA), approval requires:

- The medication is prescribed by or given in consultation with an endocrinologist
- The patient had a previous trial of or contraindication to Norditropin
- 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 years
- 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

For the diagnosis of adult growth hormone deficiency, approval requires:

- The medication is prescribed by or given in consultation with an endocrinologist
- The patient had a previous trial of or contraindication to 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

HUMATROPE

1. Is the request for Humatrope for the 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 **HUMATROPE** guideline.
   If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses and meet the following criteria?
   For the diagnosis of pediatric growth hormone deficiency (GHD), approval requires:
   - The medication is prescribed by or given in consultation with an endocrinologist
   - The patient had a previous trial of or contraindication to Norditropin
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - 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 25^{th} 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

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SOMATROPIN

INITIAL CRITERIA - HUMATROPE (CONTINUED)

For the diagnosis of short stature associated with Turner Syndrome, approval requires:

- The medication is prescribed by or given in consultation with an endocrinologist
- The patient had a previous trial of or contraindication to Norditropin
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- 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

For the diagnosis of short stature or growth failure in children with SHOX deficiency, approval requires:

- The medication is prescribed by or given in consultation with an endocrinologist
- The patient had a previous trial of or contraindication to Norditropin
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- 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

For the diagnosis of growth failure in children born small for gestational age (SGA), approval requires:

- The medication is prescribed by or given in consultation with an endocrinologist
- The patient had a previous trial of or contraindication to Norditropin
- 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
- 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

For the diagnosis of adult growth hormone deficiency, approval requires:

- The medication is prescribed by or given in consultation with an endocrinologist
- The patient had a previous trial of or contraindication to 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 Humatrope for 12 months by GPID.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the **HUMATROPE** guideline.

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SOMATROPIN

INITIAL CRITERIA - HUMATROPE (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **SOMATROPIN (Humatrope)** requires **ONE** of the following diagnoses:

- Pediatric growth hormone deficiency
- Short stature associated with Turner Syndrome
- Short stature or growth failure in children with SHOX Deficiency
- Growth failure in children born small for gestational age (SGA)
- Adult growth hormone deficiency

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

- Athletic enhancement
- Anti-aging purposes
- Idiopathic Short Stature

The following criteria must also be met:

For the diagnosis of pediatric growth hormone deficiency (GHD), approval requires:

- The medication is prescribed by or given in consultation with an endocrinologist
- The patient had a previous trial of or contraindication to Norditropin
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- 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 the diagnosis of short stature associated with Turner Syndrome, approval requires:

- The medication is prescribed by or given in consultation with an endocrinologist
- The patient had a previous trial of or contraindication to Norditropin
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- 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

For the diagnosis of short stature or growth failure in children with SHOX deficiency, approval requires:

- The medication is prescribed by or given in consultation with an endocrinologist
- The patient had a previous trial of or contraindication to Norditropin
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- 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

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SOMATROPIN

INITIAL CRITERIA - HUMATROPE (CONTINUED)

For the diagnosis of growth failure in children born small for gestational age (SGA), approval requires:
- The medication is prescribed by or given in consultation with an endocrinologist
- The patient had a previous trial of or contraindication to Norditropin
- 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 4years
- 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

For the diagnosis of adult growth hormone deficiency, approval requires:
- The medication is prescribed by or given in consultation with an endocrinologist
- The patient had a previous trial of or contraindication to 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

NORDITROPIN FLEXPRO

1. Is the request for Norditropin FlexPro for the 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 **NORDITROPIN FLEXPRO** guideline.
   If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses and meet the following criteria?
   For the diagnosis of pediatric growth hormone deficiency (GHD), approval requires:
   - The medication is prescribed by or given 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

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SOMATROPIN

INITIAL CRITERIA - NORDITROPIN FLEXPRO (CONTINUED)

For the diagnosis of short stature associated with Turner Syndrome, approval requires:
- The medication is prescribed by or given 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 greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender

For the diagnosis of short stature associated with Noonan Syndrome, approval requires:
- The medication is prescribed by or given in consultation with an endocrinologist
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- 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

For the diagnosis of short stature born small for gestational age (SGA) in a pediatric patient, approval requires:
- The medication is prescribed by or given 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
- 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

For the diagnosis of adult growth hormone deficiency, approval requires:
- The medication is prescribed by or given 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 the diagnosis of growth failure due to Prader-Willi syndrome (PWS), approval requires
- Confirmed genetic diagnosis of PWS
- The medication is prescribed by or given in consultation with an endocrinologist

If yes, **approve Norditropin Flexpro for 12 months by GPID.**
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the **NORDITROPIN FLEXPRO** guideline.

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SOMATROPIN

INITIAL CRITERIA - NORDITROPIN FLEXPRO (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **SOMATROPIN (Norditropin Flexpro)**, requires **ONE** of the following diagnoses:

- Pediatric growth hormone deficiency
- Short stature associated with Turner Syndrome
- Short stature associated with Noonan Syndrome
- Short stature born small for gestational age (SGA) in a pediatric patient
- Adult growth hormone deficiency
- Growth failure due to Prader-Willi syndrome (PWS)

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

- Athletic enhancement
- Anti-aging purposes
- Idiopathic Short Stature

The following criteria must also be met:

For the diagnosis of pediatric growth hormone deficiency (GHD), approval requires:

- The medication is prescribed by or given in consultation with an endocrinologist
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- 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 the diagnosis of short stature associated with Turner Syndrome, approval requires:

- The medication is prescribed by or given in consultation with an endocrinologist
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- 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

For the diagnosis of short stature associated with Noonan Syndrome, approval requires:

- The medication is prescribed by or given in consultation with an endocrinologist
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- 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

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SOMATROPIN

INITIAL CRITERIA - NORDITROPIN FLEXPRO (CONTINUED)

For the diagnosis of short stature born small for gestational age (SGA) in a pediatric patient, approval requires:

- The medication is prescribed by or given 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
- 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

For the diagnosis of adult growth hormone deficiency, approval requires:

- The medication is prescribed by or given 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 the diagnosis of growth failure due to Prader-Willi syndrome (PWS), approval requires:

- Confirmed genetic diagnosis of PWS
- The medication is prescribed by or given in consultation with an endocrinologist

NUTROPIN AQ NUSPIN

1. Is the request for Nutropin AQ NuSpin for the 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 **NUTROPINAQ NUSPIN** guideline.
   If no, continue to #2.

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SOMATROPIN

INITIAL CRITERIA - NUTROPIN AQ NUSPIN (CONTINUED)

2. Does the patient have **ONE** of the following diagnoses and meet the following criteria?
   For the diagnosis of pediatric growth hormone deficiency (GHD), approval requires:
   - The medication is prescribed by or given in consultation with an endocrinologist
   - The patient had a previous trial of or contraindication to Norditropin
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - 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 the diagnosis of growth failure secondary to chronic kidney disease (CKD), approval requires:
   - The medication is prescribed by or given in consultation with a nephrologist
   - Patient has NOT undergone a renal transplantation
   - Patient's height or growth velocity greater than or equal to 2 standard deviations (SD) below the mean for normal children of the same age and gender
   - The patient had a previous trial of or contraindication to Norditropin

   For the diagnosis of short stature associated with Turner Syndrome, approval requires:
   - The medication is prescribed by or given in consultation with an endocrinologist
   - The patient had a previous trial of or contraindication to Norditropin
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - 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

   For the diagnosis of adult growth hormone deficiency, approval requires:
   - The medication is prescribed by or given in consultation with an endocrinologist
   - The patient had a previous trial of or contraindication to 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.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the **NUTROPIN AQ NUSPIN** guideline.

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SOMATROPIN

INITIAL CRITERIA - NUTROPIN AQ NUSPIN (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **SOMATROPIN (Nutropin AQ Nuspin)**, requires **ONE** of the following diagnoses:

- Pediatric growth hormone deficiency (GHD)
- Growth failure secondary to chronic kidney disease (CKD)
- Short stature associated with Turner Syndrome
- Adult growth hormone deficiency

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

- Athletic enhancement
- Anti-aging purposes
- Idiopathic Short Stature

The following criteria must also be met:

For the diagnosis of pediatric growth hormone deficiency (GHD), approval requires:

- The medication is prescribed by or given in consultation with an endocrinologist
- The patient had a previous trial of or contraindication to Norditropin
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- 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 the diagnosis of growth failure secondary to chronic kidney disease (CKD), approval requires:

- The medication is prescribed by or given in consultation with a nephrologist
- Patient has not undergone a renal transplantation
- Patient's height or growth velocity greater than or equal to 2 standard deviations (SD) below the mean for normal children of the same age and gender
- The patient had a previous trial of or contraindication to Norditropin

For the diagnosis of short stature associated with Turner Syndrome, approval requires:

- The medication is prescribed by or given in consultation with an endocrinologist
- The patient had a previous trial of or contraindication to Norditropin
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- 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

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SOMATROPIN

INITIAL CRITERIA - NUTROPIN AQ NUSPIN (CONTINUED)

For the diagnosis of adult growth hormone deficiency, approval requires:
- The medication is prescribed by or given in consultation with an endocrinologist
- The patient had a previous trial of or contraindication to 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

OMNITROPE

1. Is the request for Omnitrope for the 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 **OMNITROPE** guideline
   If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses and meet the following criteria?
   For the diagnosis of pediatric growth hormone deficiency (GHD), approval requires:
   - The medication is prescribed by or given in consultation with an endocrinologist
   - The patient had a previous trial of or contraindication to Norditropin
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - 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 the diagnosis of growth failure due to Prader-Willi Syndrome (PWS), approval requires:
   - Confirmed genetic diagnosis of PWS
   - The medication is prescribed by or given in consultation with an endocrinologist
   - The patient had a previous trial of or contraindication to Norditropin

   (Initial criteria continued on next page)

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SOMATROPIN

INITIAL CRITERIA - OMNITROPE (CONTINUED)

For the diagnosis of growth failure in children born small for gestational age (SGA), approval requires:

- Patient with no catch-up growth by age 2 years
- The medication is prescribed by or given in consultation with an endocrinologist
- The patient had a previous trial of or contraindication to Norditropin
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- 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

For the diagnosis of growth failure associated with Turner Syndrome, approval requires:

- The medication is prescribed by or given in consultation with an endocrinologist
- The patient had a previous trial of or contraindication to Norditropin
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- 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

For the diagnosis of adult growth hormone deficiency, approval requires:

- The medication is prescribed by or given in consultation with an endocrinologist
- The patient had a previous trial of or contraindication to 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 Omnitrope for 12 months by GPID.**
If no, do not approve.
INITIAL DENIAL TEXT: The guideline named **SOMATROPIN (Omnitrope)** requires **ONE** of the following diagnoses:

- Pediatric growth hormone deficiency (GHD)
- Growth failure due to Prader-Willi Syndrome (PWS)
- Growth failure in children born small for gestational age (SGA)
- Growth failure associated with Turner Syndrome
- Adult growth hormone deficiency

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

- Athletic enhancement
- Anti-aging purposes
- Idiopathic Short Stature

(Initial denial text continued on next page)

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SOMATROPIN

INITIAL CRITERIA - OMNITROPE (CONTINUED)

The following criteria must also be met:

For the diagnosis of pediatric growth hormone deficiency (GHD), approval requires:

- The medication is prescribed by or given in consultation with an endocrinologist
- The patient had a previous trial of or contraindication to Norditropin
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- 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 the diagnosis of growth failure due to Prader-Willi Syndrome (PWS), approval requires:

- Confirmed genetic diagnosis of PWS
- The medication is prescribed by or given in consultation with an endocrinologist
- The patient had a previous trial of or contraindication to Norditropin

For the diagnosis of growth failure in children born small for gestational age (SGA), approval requires:

- The medication is prescribed by or given in consultation with an endocrinologist
- The patient had a previous trial of or contraindication to Norditropin
- 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 years
- 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

For the diagnosis of growth failure associated with Turner Syndrome, approval requires:

- The medication is prescribed by or given in consultation with an endocrinologist
- The patient had a previous trial of or contraindication to Norditropin
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- 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

For the diagnosis of adult growth hormone deficiency, approval requires:

- 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
- The medication is prescribed by or given in consultation with an endocrinologist
- The patient had a previous trial of or contraindication to Norditropin

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SOMATROPIN

INITIAL CRITERIA (CONTINUED)

SAIZEN

1. Is the request for Saizen for the 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 **SAIZEN** guideline.
   If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses and meet the following criteria?
   For the diagnosis of pediatric growth hormone deficiency (GHD), approval requires:
   - The medication is prescribed by or given in consultation with an endocrinologist
   - The patient had a previous trial of or contraindication to Norditropin
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - 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 the diagnosis of adult growth hormone deficiency, approval requires:
   - The medication is prescribed by or given in consultation with an endocrinologist
   - The patient had a previous trial of or contraindication to 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 Saizen for 12 months by GPID.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the **SAIZEN** guideline.

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SOMATROPIN

INITIAL CRITERIA - SAIZEN (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **SOMATROPIN (Saizen)** requires **ONE** of the following diagnoses and meet the following criteria:

- Pediatric Growth Hormone Deficiency (GHD)
- Adult Growth Hormone Deficiency

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

- Athletic enhancement
- Anti-aging purposes
- Idiopathic Short Stature

The following criteria must also be met:

For the diagnosis of pediatric growth hormone deficiency (GHD), approval requires:

- The medication is prescribed by or given in consultation with an endocrinologist
- The patient had a previous trial of or contraindication to Norditropin
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- 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 the diagnosis of adult growth hormone deficiency, approval requires:

- The medication is prescribed by or given in consultation with an endocrinologist
- The patient had a previous trial of or contraindication to 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

ZOMACTON

1. Is the request for Zomacton for the 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 **ZOMACTON** guideline.
   If no, continue to #2.

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SOMATROPIN

INITIAL CRITERIA - ZOMACTON (CONTINUED)

2. Does the patient have **ONE** of the following diagnoses and meet **ALL** of the following criteria?
   For the diagnosis of pediatric growth hormone deficiency (GHD) approval requires:
   - The medication is prescribed by or given in consultation with an endocrinologist
   - The patient had a previous trial of or contraindication to Norditropin
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - 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 the diagnosis of short stature associated with Turner Syndrome, approval requires:
   - The medication is prescribed by or given in consultation with an endocrinologist
   - The patient had a previous trial of or contraindication to Norditropin
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - 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

   For the diagnosis of short stature in children born small for gestational age (SGA), approval requires:
   - The medication is prescribed by or given in consultation with an endocrinologist
   - The patient had a previous trial of or contraindication to Norditropin
   - 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
   - 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

   For the diagnosis of short stature or growth failure in children with SHOX deficiency, approval requires:
   - The medication is prescribed by or given in consultation with an endocrinologist
   - The patient had a previous trial of or contraindication to Norditropin
   - The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
   - 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

   For the diagnosis of adult growth hormone deficiency, approval requires:
   - The medication is prescribed by or given in consultation with an endocrinologist
   - The patient had a previous trial of or contraindication to 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

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INITIAL CRITERIA - ZOMACTON (CONTINUED)

If yes, **approve Zomacton for 12 months by GPID.**
If no, do not approve.
INITIAL DENIAL TEXT: The guideline named **SOMATROPIN (Zomacton)** requires **ONE** of the following diagnoses:

- Pediatric Growth Hormone Deficiency (GHD)
- Short stature associated with Turner Syndrome
- Short stature in children born small for gestational age (SGA)
- Short stature or growth failure in children with SHOX deficiency
- Adult Growth Hormone Deficiency

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

- Athletic enhancement
- Anti-aging purposes
- Idiopathic Short Stature

The following criteria must also be met:
For the diagnosis of pediatric growth hormone deficiency (GHD), approval requires:

- The medication is prescribed by or given in consultation with an endocrinologist
- The patient had a previous trial of or contraindication toNorditropin
- 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 the diagnosis of short stature associated with Turner Syndrome, approval requires:

- The medication is prescribed by or given in consultation with an endocrinologist
- The patient had a previous trial of or contraindication to Norditropin
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- 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

For the diagnosis of short stature in children born small for gestational age (SGA), approval requires:

- The medication is prescribed by or given in consultation with an endocrinologist
- The patient had a previous trial of or contraindication to Norditropin
- 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
- 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

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SOMATROPIN

INITIAL CRITERIA - ZOMACTON (CONTINUED)

For the diagnosis of short stature or growth failure in children with SHOX deficiency, approval requires:

- The medication is prescribed by or given in consultation with an endocrinologist
- The patient had a previous trial of or contraindication to Norditropin
- The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
- 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

For the diagnosis of adult growth hormone deficiency, approval requires:

- The medication is prescribed by or given in consultation with an endocrinologist
- The patient had a previous trial of or contraindication to 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

RENEWAL CRITERIA

SEROSTIM

1. Has the patient received more than 24 weeks of therapy within plan year?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the **SEROSTIM** guideline.
   If no, continue to #2.

2. Is the request for Serostim for a patient with HIV wasting/cachexia and meet the following criteria?
   - The requested agent is NOT prescribed for athletic enhancement or anti-aging purposes
   - The patient has shown clinical benefit in muscle mass and weight as indicated by the following criteria:
     - ≥ 10% increase in weight or BCM from baseline (**NOTE**: Current and baseline weight must be documented including dates of measurement)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the **SEROSTIM** guideline.

3. Is the patient on HIV anti-retroviral therapy?

   If yes, **approve Serostim for 12 weeks by GPID.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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SOMATROPIN

RENEWAL CRITERIA - SEROSTIM (CONTINUED)

RENEWAL DENIAL TEXT: The guideline named **SOMATROPIN (Serostim)** renewal requires a diagnosis of HIV wasting/cachexia. The following criteria must also be met.

- The requested agent is NOT prescribed for athletic enhancement or anti-aging purposes
- The patient has shown clinical benefit in muscle mass and weight as indicated by the following criteria:
  - ≥ 10% increase in weight or BCM from baseline (**NOTE**: current and baseline weight must be documented including dates of measurement)
- Patient must be on HIV anti-retroviral therapy

ZORBTIVE

1. Does the patient have a diagnosis of short bowel syndrome?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the **ZORBTIVE** guideline.

2. Has the patient been on the medication for 4 weeks?

   If yes, do not approve. [**Note**: The patient should only be approved for one 4 week fill in a lifetime.]
   RENEWAL DENIAL TEXT: The guideline named **SOMATROPIN (Zorbtive)** renewal requires a diagnosis of short bowel syndrome. Therapy is limited to 4 weeks of treatment.

   If no, **approve Zorbtive by GPID for the remainder of therapy with a maximum of 4 weeks of therapy. (Please subtract any previous fills; maximum cumulative approval is for 4 weeks.)**

GENOTROPIN

1. Is the request for the 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 **GENOTROPIN** guideline.
   If no, continue to #2.

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RENEWAL CRITERIA - GENOTROPIN (CONTINUED)

2. Does the patient have one of the following diagnoses and meet the following criteria?
   For the diagnosis of pediatric growth hormone deficiency (GHD), renewal requires:
   - The medication is prescribed by or given 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 the diagnosis of short stature associated with Turner Syndrome, renewal requires:
   - The medication is prescribed by or given 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 the diagnosis of growth failure due to Prader-Willi Syndrome (PWS), renewal requires:
   - The medication is prescribed by or given in consultation with an endocrinologist
   - Improvement in body composition

   For the diagnosis of growth failure in children born small for gestational age (SGA), renewal requires:
   - The medication is prescribed by or given 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 the diagnosis of adult growth hormone deficiency, renewal requires:
   - The medication is prescribed by or given in consultation with an endocrinologist

   If yes, **approve Genotropin for 12 months by GPID.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: The guideline named **SOMATROPIN (Genotropin)** renewal requires a diagnosis of Pediatric Growth Hormone Deficiency, Short Stature Associated with Turner Syndrome, Growth Failure Due to Prader-Willi Syndrome (PWS), Growth Failure in Child Born Small for Gestation Age, or Adult Growth Hormone Deficiency.
   This medication will not be approved for treatment of **ANY** of the following conditions:
   - Athletic enhancement
   - Anti-aging purposes
   - Idiopathic Short Stature

   The following criteria must also be met.
   For the diagnosis of pediatric growth hormone deficiency (GHD), renewal requires:
   - The medication is prescribed by or given 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 denial text continued on next page)

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SOMATROPIN

RENEWAL CRITERIA - GENOTROPIN (CONTINUED)

For the diagnosis of short stature associated with Turner Syndrome, renewal requires:
- The medication is prescribed by or given 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 the diagnosis of growth failure due to Prader-Willi Syndrome (PWS), renewal requires:
- The medication is prescribed by or given in consultation with an endocrinologist
- Improvement in body composition

For the diagnosis of growth failure in children born small for gestational age (SGA), renewal requires:
- The medication is prescribed by or given 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 the diagnosis of adult growth hormone deficiency, renewal requires:
- The medication is prescribed by or given in consultation with an endocrinologist

HUMATROPE

1. Is the request for the 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 **HUMATROPE** guideline.
   If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses and meet the following criteria?
   For the diagnosis of pediatric growth hormone deficiency (GHD), renewal requires:
   - The medication is prescribed by or given 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 the diagnosis of short stature associated with Turner Syndrome, renewal requires:
   - The medication is prescribed by or given 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

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RENEWAL CRITERIA - HUMATROPE (CONTINUED)

For the diagnosis of short stature or growth failure in children with SHOX deficiency, renewal requires:
- The medication is prescribed by or given 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 the diagnosis of growth failure in children born small for gestational age (SGA), renewal requires:
- The medication is prescribed by or given 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 the diagnosis of adult growth hormone deficiency, renewal requires:
- The medication is prescribed by or given in consultation with an endocrinologist

If yes, **approve Humatrope for 12 months by GPID.**
If no, do not approve.
RENEWAL DENIAL TEXT: The guideline named **SOMATROPIN (Humatrope)** renewal requires a diagnosis of pediatric growth hormone deficiency, short stature associated with Turner Syndrome, short stature or growth failure in children with SHOX deficiency, growth failure in children born small for gestational age, or adult growth hormone deficiency.
This medication will not be approved for treatment of **ANY** of the following conditions:
- Athletic enhancement
- Anti-aging purposes
- Idiopathic Short Stature

The following criteria must also be met.

For the diagnosis of pediatric growth hormone deficiency (GHD), renewal requires:
- The medication is prescribed by or given 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 the diagnosis of short stature associated with Turner Syndrome, renewal requires:
- The medication is prescribed by or given 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

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RENEWAL CRITERIA - HUMATROPE (CONTINUED)

For the diagnosis of short stature or growth failure in children with SHOX deficiency, renewal requires:
- The medication is prescribed by or given 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 the diagnosis of growth failure in children born small for gestational age (SGA), renewal requires:
- The medication is prescribed by or given 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 the diagnosis of adult growth hormone deficiency, renewal requires:
- The medication is prescribed by or given in consultation with an endocrinologist

NORDITROPIN FLEXPRO

1. Is the request for the 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 **NORDITROPIN FLEXPRO** guideline.
   If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses and meet the following criteria?
   For the diagnosis of pediatric growth hormone deficiency (GHD), renewal requires:
   - The medication is prescribed by or given 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 the diagnosis of short stature associated with Noonan Syndrome, renewal requires:
   - The medication is prescribed by or given 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)

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SOMATROPIN

RENEWAL CRITERIA (CONTINUED)

For the diagnosis of short stature associated with Turner Syndrome, renewal requires:
- The medication is prescribed by or given in consultation with an endocrinologist
- The patient's epiphyses is 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 the diagnosis of short stature born small for gestational age (SGA) in a pediatric patient, renewal requires:
- The medication is prescribed by or given 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 the diagnosis of adult growth hormone deficiency, renewal requires:
- The medication is prescribed by or given in consultation with an endocrinologist

For the diagnosis of growth failure due to Prader-Willi Syndrome (PWS), renewal requires:
- The medication is prescribed by or given in consultation with an endocrinologist
- Improvement in body composition

If yes, **approve Norditropin Flexpro for 12 months by GPID.**
If no, do not approve.
RENEWAL DENIAL TEXT: The guideline named **SOMATROPIN (Norditropin Flexpro)** renewal requires a diagnosis of Pediatric Growth Hormone Deficiency, Short Stature Associated with Noonan Syndrome, Short Stature Associated with Turner Syndrome, Short Stature Born Small for Gestational Age in a pediatric patient Adult Growth hormone Deficiency, or growth failure due to Prader-Willi syndrome.
This medication will not be approved for treatment of **ANY** of the following conditions:
- Athletic enhancement
- Anti-aging purposes
- Idiopathic Short Stature

The following criteria must also be met.
For the diagnosis of pediatric growth hormone deficiency, renewal requires:
- The medication is prescribed by or given 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 the diagnosis of short stature associated with Noonan Syndrome, renewal requires:
- The medication is prescribed by or given 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 denial text continued on next page)

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SOMATROPIN

RENEWAL CRITERIA - NORDITROPIN FLEXPRO (CONTINUED)

For the diagnosis of short stature associated with Turner Syndrome, renewal requires:
- The medication is prescribed by or given 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 the diagnosis of short stature born small for gestational age (SGA) in a pediatric patient, renewal requires:
- The medication is prescribed by or given 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 the diagnosis of adult growth hormone deficiency, renewal requires:
- The medication is prescribed by or given in consultation with an endocrinologist

For the diagnosis of growth failure due to Prader-Willi Syndrome (PWS), renewal requires:
- The medication is prescribed by or given in consultation with an endocrinologist
- Improvement in body composition

NUTROPIN AQ NUSPIN

1. Is the request for Nutropin AQ NuSpin for the 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 **NUTROPIN AQ NUSPIN** guideline.
   If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses and meet the following criteria?
   For the diagnosis of pediatric growth hormone deficiency (GHD), renewal requires:
   - The medication is prescribed by or given 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)

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SOMATROPIN

RENEWAL CRITERIA - NUTROPIN AQ NUSPIN (CONTINUED)

For the diagnosis of growth failure secondary to chronic kidney disease (CKD), renewal requires:
- 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 the diagnosis of short stature associated with Turner Syndrome, renewal requires:
- The medication is prescribed by or given 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 the diagnosis of adult growth hormone deficiency, renewal requires:
- The medication is prescribed by or given in consultation with an endocrinologist

If yes, **approve for 12 months by GPID.**
If no, do not approve.
RENEWAL DENIAL TEXT: The guideline named **SOMATROPIN (Nutropin AQ Nuspin)** renewal requires **ONE** of the following diagnoses:
- Pediatric Growth Hormone Deficiency (GHD)
- Growth Failure Secondary to Chronic Kidney Disease (CKD)
- Short Stature Associated with Turner Syndrome
- Adult Growth Hormone Deficiency

This medication will not be approved for treatment of **ANY** of the following conditions.
- Athletic enhancement
- Anti-aging purposes
- Idiopathic Short Stature

The following criteria must also be met.
For the diagnosis of pediatric growth hormone deficiency (GHD), renewal requires:
- The medication is prescribed by or given 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 the diagnosis of growth failure secondary to chronic kidney disease (CKD), renewal requires:
- 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

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SOMATROPIN

RENEWAL CRITERIA - NUTROPIN AQ NUSPIN (CONTINUED)

For the diagnosis of short stature associated with Turner Syndrome, renewal requires:
- The medication is prescribed by or given 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 the diagnosis of adult growth hormone deficiency, renewal requires:
- The medication is prescribed by or given in consultation with an endocrinologist

OMNITROPE

1. Is the request for the 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 **OMNITROPE** guideline.
   If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses and meet the following criteria?
   For the diagnosis of pediatric growth hormone deficiency (GHD), renewal requires:
   - The medication is prescribed by or given 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 the diagnosis of growth failure due to Prader-Willi Syndrome (PWS), renewal requires:
   - The medication is prescribed by or given in consultation with an endocrinologist
   - Improvement in body composition

   For the diagnosis of growth failure in children born small for gestational age (SGA), renewal requires:
   - The medication is prescribed by or given 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)

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SOMATROPIN

RENEWAL CRITERIA - OMNITROPE (CONTINUED)

For the diagnosis of growth failure associated with Turner Syndrome, renewal requires:
- The medication is prescribed by or given 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 the diagnosis of adult growth hormone deficiency, renewal requires:
- The medication is prescribed by or given in consultation with an endocrinologist

If yes, **approve Omnitrope for 12 months by GPID.**
If no, do not approve.
RENEWAL DENIAL TEXT: The guideline named **SOMATROPIN (Omnitrope)** renewal requires **ONE** of the following diagnoses:
- Pediatric growth hormone deficiency (GHD)
- Growth failure due to Prader-Willi Syndrome (PWS)
- Growth failure in children born small for gestational age (SGA)
- Growth failure associated with Turner Syndrome
- Adult growth hormone deficiency

This medication will not be approved for treatment of **ANY** of the following conditions:
- Athletic enhancement
- Anti-aging purposes
- Idiopathic Short Stature

The following criteria must also be met:
For the diagnosis of pediatric growth hormone deficiency (GHD), renewal requires:
- The medication is prescribed by or given 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 the diagnosis of growth failure due to Prader-Willi Syndrome (PWS), renewal requires:
- The medication is prescribed by or given in consultation with an endocrinologist
- Improvement in body composition

For the diagnosis of growth failure in children born small for gestational age (SGA), renewal requires:
- The medication is prescribed by or given 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

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RENEWAL CRITERIA - OMNITROPE (CONTINUED)

For the diagnosis of growth failure associated with Turner Syndrome, renewal requires:
- The medication is prescribed by or given 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 the diagnosis of adult growth hormone deficiency, renewal requires:
- The medication is prescribed by or given in consultation with an endocrinologist

SAIZEN

1. Is the request for the 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 **SAIZEN** guideline.
   If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses and meet the following criteria?
   For the diagnosis of pediatric growth hormone deficiency (GHD), renewal requires:
   - The medication is prescribed by or given 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 the diagnosis of adult growth hormone deficiency, renewal requires:
   - The medication is prescribed by or given in consultation with an endocrinologist

   If yes, **approve Saizen for 12 months by GPID.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the **SAIZEN** guideline.

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SOMATROPIN

RENEWAL CRITERIA - SAIZEN (CONTINUED)

RENEWAL DENIAL TEXT: The guideline named **SOMATROPIN (Saizen)** renewal requires a diagnosis of pediatric growth hormone deficiency or adult growth hormone deficiency.
This medication will not be approved for treatment of **ANY** of the following conditions:

- Athletic enhancement
- Anti-aging purposes
- Idiopathic Short Stature

The following criteria must also be met.
For the diagnosis of pediatric growth hormone deficiency (GHD), renewal requires:

- The medication is prescribed by or given 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 the diagnosis of adult growth hormone deficiency, renewal requires:

- The medication is prescribed by or given in consultation with an endocrinologist

ZOMACTON

1. Is the request for the 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 **ZOMACTON** guideline.
   If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses and meet the following criteria?
   For the diagnosis of pediatric growth hormone deficiency (GHD), renewal requires:
   - The medication is prescribed by or given 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 the diagnosis of short stature associated with Turner Syndrome, renewal requires:
   - The medication is prescribed by or given 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)

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SOMATROPIN

RENEWAL CRITERIA - ZOMACTON (CONTINUED)

For the diagnosis of short stature in children born small for gestational age (SGA), renewal requires:

- The medication is prescribed by or given 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 the diagnosis of short stature or growth failure in children with SHOX deficiency, renewal requires:

- The medication is prescribed by or given 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 the diagnosis of adult growth hormone deficiency, renewal requires:

- The medication is prescribed by or given in consultation with an endocrinologist

If yes, **approve Zomacton for 12 months by GPID.**
If no, do not approve.
RENEWAL DENIAL TEXT: The guideline named **SOMATROPIN (Zomacton)** renewal requires a diagnosis of pediatric growth hormone deficiency, short stature associated with Turner Syndrome, short stature in children born small for gestational age (SGA), short stature or growth failure in children with SHOX deficiency, or adult growth hormone deficiency.
This medication will not be approved for treatment of **ANY** of the following conditions:

- Athletic enhancement
- Anti-aging purposes
- Idiopathic Short Stature

The following criteria must also be met.

For the diagnosis of pediatric growth hormone deficiency (GHD), renewal requires:

- The medication is prescribed by or given 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 the diagnosis of short stature associated with Turner Syndrome, renewal requires:

- The medication is prescribed by or given 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

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SOMATROPIN

RENEWAL CRITERIA - ZOMACTON (CONTINUED)

For the diagnosis of short stature in children born small for gestational age (SGA), renewal requires:

- The medication is prescribed by or given 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 the diagnosis of short stature or growth failure in children with SHOX deficiency, renewal requires:

- The medication is prescribed by or given 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 the diagnosis of adult growth hormone deficiency, renewal requires:

- The medication is prescribed by or given in consultation with an endocrinologist

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RATIONALE

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

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SOMATROPIN

FDA APPROVED INDICATIONS

	Ped growth hormone deficiency	Adult growth hormone deficiency	Small for gestational Age	Idiopathic short stature	Turner syndrome	Prader willi syndrome	Hiv-associated wasting	Short bowel syndrome	Noonan syndrome	Short stature homeobox-containing gene (shox) deficiency	Chronic kidney disease (chronic renal insufficiency)
Zorbtive								✓			
Serostim							✓				
Genotropin	✓	✓	✓	✓	✓	✓					
Norditropin	✓	✓	✓	✓	✓	✓			✓		
Humatrope	✓	✓	✓	✓	✓					✓	
Nutropin	✓	✓		✓	✓						✓
Omnitrope	✓	✓	✓	✓	✓	✓					
Saizen	✓	✓									
Zomacton	✓	✓	✓	✓	✓					✓	

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