

SOMATROPIN

Generic	Brand	HICL	GCN	Exception/Other
SOMATROPIN	GENOTROPIN HUMATROPE NORDITROPIN FLEXP NORDITROPIN NORDIFLEX NUTROPIN NUTROPIN AQ NUTROPIN AQ NUSPIN, OMNITROPE SAIZEN SEROSTIM ZOMACTON ZORBTIVE	02824		

GUIDELINES FOR USE

NOTE: Please use the criteria for the specific drug requested.

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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SOMATROPIN

INITIAL CRITERIA

SEROSTIM:

1. Is the request for Serostim for a patient with a diagnosis of HIV wasting/cachexia and meets **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
 - Patient is on HIV anti-retroviral therapy
 - Patient has inadequate response to previous therapy (i.e., exercise training, nutritional supplements, appetite stimulants, or anabolic steroids)
 - 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

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.**

SOMATROPIN

INITIAL CRITERIA - SEROSTIM (CONTINUED)

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.

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

SEROSTIM 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).
- 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

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SOMATROPIN

INITIAL CRITERIA - SEROSTIM (CONTINUED)

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).

ZORBTIVE:

1. Is the request for Zorbtive for a patient with a diagnosis of short bowel syndrome and meets **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.

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 meets **ALL** of the following criteria?

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

- The medication is prescribed by or in consultation with an endocrinologist
- Patient has tried Norditropin **AND** Omnitrope (unless contraindicated)
- 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

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

- The medication is prescribed by or in consultation with an endocrinologist
- Patient has tried Norditropin **AND** Omnitrope (unless contraindicated)
- 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 diagnosis of PWS
- The medication is prescribed by or given in consultation with an endocrinologist
- Patient has tried Norditropin **AND** Omnitrope (unless contraindicated)

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

- The medication is prescribed by or in consultation with an endocrinologist
- Patient has tried Norditropin **AND** Omnitrope (unless contraindicated)
- 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 in consultation with an endocrinologist
- Patient has tried Norditropin **AND** Omnitrope (unless contraindicated)
- Adults with 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 Genotropin for 12 months by GPID.**

If no, do not approve.

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

SOMATROPIN

INITIAL CRITERIA - GENOTROPIN (CONTINUED)

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 in consultation with an endocrinologist
- Patient has tried Norditropin **AND** Omnitrope (unless contraindicated)
- 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

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

- The medication is prescribed by or in consultation with an endocrinologist
- Patient has tried Norditropin **AND** Omnitrope (unless contraindicated)
- 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 diagnosis of PWS
- The medication is prescribed by or given in consultation with an endocrinologist
- Patient has tried Norditropin **AND** Omnitrope (unless contraindicated)

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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 in consultation with an endocrinologist
- Patient has tried Norditropin and Omnitrope (unless contraindicated)
- 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 in consultation with an endocrinologist
- Patient has tried Norditropin **AND** Omnitrope (unless contraindicated)
- Adults with 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 meets the following criteria?

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

- The medication is prescribed by or in consultation with an endocrinologist
- Patient has tried Norditropin **AND** Omnitrope (unless contraindicated)
- 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

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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 in consultation with an endocrinologist
- Patient has tried Norditropin **AND** Omnitrope (unless contraindicated)
- 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 of growth failure in children with SHOX deficiency, approval requires:

- The medication is prescribed by or in consultation with an endocrinologist
- Patient has tried Norditropin **AND** Omnitrope (unless contraindicated)
- 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 in consultation with an endocrinologist
- Patient has tried Norditropin **AND** Omnitrope (unless contraindicated)
- 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 in consultation with an endocrinologist
- Patient has tried Norditropin **AND** Omnitrope (unless contraindicated)
- Adults with 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)

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 of 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 in consultation with an endocrinologist
- Patient has tried Norditropin **AND** Omnitrope (unless contraindicated)
- 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

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

- The medication is prescribed by or in consultation with an endocrinologist
- Patient has tried Norditropin **AND** Omnitrope (unless contraindicated)
- 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 of growth failure in children with SHOX deficiency, approval requires:

- The medication is prescribed by or in consultation with an endocrinologist
- Patient has tried Norditropin **AND** Omnitrope (unless contraindicated)
- 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 in consultation with an endocrinologist
- Patient has tried Norditropin **AND** Omnitrope (unless contraindicated)
- 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 in consultation with an endocrinologist
- Patient has tried Norditropin **AND** Omnitrope (unless contraindicated)
- Adults with 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 FLEXPPO, NORDITROPIN NORDIFLEX

1. Is the request for Norditropin FlexPro, or Norditropin NordiFlex 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 FLEXPPO, and NORDITROPIN NORDIFLEX** guideline.

If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses and meets 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)
 - 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

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SOMATROPIN

INITIAL CRITERIA - NORDITROPIN FLEXPRO, NORDITROPIN NORDIFLEX (CONTINUED)

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

- The medication is prescribed by or in consultation with an endocrinologist
- The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
- Patient'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 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 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 onset growth hormone deficiency, approval requires:

- The medication is prescribed by or in consultation with an endocrinologist
- Adults with 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 Norditropin for 12 months by GPID.**

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the **NORDITROPIN FLEXPRO, and NORDITROPIN NORDIFLEX** guideline.

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SOMATROPIN

INITIAL CRITERIA - NORDITROPIN FLEXPLO, NORDITROPIN NORDIFLEX (CONTINUED)

DENIAL TEXT: The guideline named **SOMATROPIN (Norditropin Flexpro, Norditropin Nordiflex)**, 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 onset 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'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

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

- The medication is prescribed by or in consultation with an endocrinologist
- The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
- Patient'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 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, NORDITROPIN NORDIFLEX (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 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 onset growth hormone deficiency, approval requires:

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

NUTROPIN, NUTROPIN AQ, NUTROPIN AQ NUSPIN:

1. Is the request for Nutropin, Nutropin AQ, or 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 **NUTROPIN, NUTROPIN AQ, and NUTROPINAQ NUSPIN** guideline.

If no, continue to #2.

2. Does the patient have **ONE** of the following FDA diagnosis and meets 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

- Patient has tried Norditropin **AND** Omnitrope (unless contraindicated)
- 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

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SOMATROPIN

INITIAL CRITERIA NUTROPIN, NUTROPIN AQ, NUTROPIN AQ NUSPIN (CONTINUED)

For the diagnosis of growth failure secondary to chronic renal insufficiency, approval requires:

- The medication is prescribed by or 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 height for normal children of the same age and gender
- Patient has tried Norditropin **AND** Omnitrope (unless contraindicated)

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

- The medication is prescribed by or in consultation with an endocrinologist
- Patient has tried Norditropin **AND** Omnitrope (unless contraindicated)
- 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 hormone deficiency, approval requires:

- The medication is prescribed by or in consultation with an endocrinologist
- Patient has tried Norditropin **AND** Omnitrope (unless contraindicated)
- Adults with 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, NUTROPIN AQ, and NUTROPINAQ NUSPIN** guideline.

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

- Pediatric growth hormone deficiency (GHD)
- Growth failure secondary to chronic renal insufficiency
- Short stature associated with Turner Syndrome
- Adult 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:

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SOMATROPIN

INITIAL CRITERIA - NUTROPIN, NUTROPIN AQ, NUTROPIN AQ NUSPIN (CONTINUED)

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

- The medication is prescribed by or in consultation with an endocrinologist
- Patient has tried Norditropin **AND** Omnitrope (unless contraindicated)
- 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

For the diagnosis of growth failure secondary to chronic renal insufficiency, approval requires:

- The medication is prescribed by or 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 height for normal children of the same age and gender
- Patient has tried Norditropin **AND** Omnitrope (unless contraindicated)

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

- The medication is prescribed by or in consultation with an endocrinologist
- Patient has tried Norditropin **AND** Omnitrope (unless contraindicated)
- 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 hormone deficiency, approval requires:

- The medication is prescribed by or in consultation with an endocrinologist
- Patient has tried Norditropin **AND** Omnitrope (unless contraindicated)
- Adults with 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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SOMATROPIN

INITIAL CRITERIA (CONTINUED)

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 diagnosis and meets the following criteria?

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

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

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

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

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 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 growth failure associated with Turner Syndrome, approval requires:

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

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

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

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

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 onset 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 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

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SOMATROPIN

INITIAL CRITERIA - OMNITROPE (CONTINUED)

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

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

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

- The medication is prescribed by or in consultation with an endocrinologist
- The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
- Patient with no catch-up growth by age 2 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 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 adult onset growth hormone deficiency, approval requires:

- Adults with 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

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.

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SOMATROPIN

INITIAL CRITERIA - SAIZEN (CONTINUED)

2. Does the patient have **ONE** of the following diagnoses and meets 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
- Patient has tried Norditropin **AND** Omnitrope (unless contraindicated)
- 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

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

- The medication is prescribed by or in consultation with an endocrinologist
- Patient has tried Norditropin **AND** Omnitrope (unless contraindicated)
- Adults with 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.

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

(Initial denial text continued on next page)

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SOMATROPIN

INITIAL CRITERIA - SAIZEN (CONTINUED)

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

- The medication is prescribed by or given in consultation with an endocrinologist
- Patient has tried Norditropin **AND** Omnitrope (unless contraindicated)
- 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

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

- The medication is prescribed by or in consultation with an endocrinologist
- Patient has tried Norditropin **AND** Omnitrope (unless contraindicated)
- Adults with 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 (formerly TEV-TROPIN):

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 pediatric growth failure and meets the following criteria?
- The medication is prescribed by or given in consultation with an endocrinologist
 - Patient is 18 years of age or younger
 - Patient has tried Norditropin **AND** Omnitrope (unless contraindicated)
 - 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

If yes, **approve Zomacton for 12 months by GPID.**

If no, do not approve.

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

DENIAL TEXT: The guideline named **SOMATROPIN (Zomacton)** requires a diagnosis of pediatric growth failure. The following criteria must also be met.

- The medication is prescribed by or given in consultation with an endocrinologist
- Patient is 18 years of age or younger
- Patient has tried Norditropin **AND** Omnitrope (unless contraindicated)
- 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

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

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

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SOMATROPIN

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 meets the following criteria?
 - **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 **SEROSTIM** guideline.

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

- **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.

SOMATROPIN

RENEWAL CRITERIA - ZORBTIVE (CONTINUED)

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.]

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

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.)**

DENIAL TEXT: The guideline named **SOMATROPIN (Zorbtive)** renewal requires a diagnosis of short bowel syndrome. Therapy is limited to 4 weeks of treatment.

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.

2. Does the patient have one of the following diagnoses and meets the following criteria?

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

- The medication 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 the diagnosis of short stature associated with Turner Syndrome, renewal requires:

- The medication 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 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

(Renewal approval text continued on next page)

SOMATROPIN

RENEWAL CRITERIA - GENOTROPIN (CONTINUED)

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

- The medication 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 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.

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

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 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 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

(Renewal denial text continued on next page)

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SOMATROPIN

RENEWAL CRITERIA - GENOTROPIN (CONTINUED)

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

- The medication 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 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 meets 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 short stature of 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

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SOMATROPIN

RENEWAL CRITERIA - HUMATROPE (CONTINUED)

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.

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

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

(Denial text continued on next page)

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SOMATROPIN

RENEWAL CRITERIA - HUMATROPE (CONTINUED)

For the diagnosis of short stature of 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, NORDITROPIN NORDIFLEX

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, and NORDITROPIN NORDIFLEX** guideline.

If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses and meets 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

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SOMATROPIN

RENEWAL CRITERIA - NORDITROPIN FLEXPRO, NORDITROPIN NORDIFLEX (CONTINUED)

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

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 onset 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.

DENIAL TEXT: See the renewal denial text at the end of the **NORDITROPIN FLEXPRO, and NORDITROPIN NORDIFLEX** guideline.

DENIAL TEXT: The guideline named **SOMATROPIN (Norditropin Flexpro, and Norditropin Nordiflex)** renewal requires a diagnosis of 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, Childhood Onset Growth Hormone Deficiency, or Adult Onset 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

(Renewal denial text continued on next page)

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SOMATROPIN

RENEWAL CRITERIA - NORDITROPIN FLEXPRO, NORDITROPIN NORDIFLEX (CONTINUED)

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

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 onset growth hormone deficiency, renewal requires:

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

NUTROPIN, NUTROPIN AQ, NUTROPIN AQ NUSPIN:

1. Is the request for Nutropin, Nutropin AQ, or 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, NUTROPIN AQ, and NUTROPIN AQ NUSPIN** guideline.

If no, continue to #2.

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SOMATROPIN

RENEWAL CRITERIA - NUTROPIN, NUTROPIN AQ, NUTROPIN AQ NUSPIN (CONTINUED)

2. Does the patient have **ONE** of the following FDA diagnoses and meets 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 secondary to chronic renal insufficiency, 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 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.

DENIALTEXT: See the renewal denial text at the end of the **NUTROPIN, NUTROPIN AQ, and NUTROPIN AQ NUSPIN** guideline.

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

- Pediatric Growth Hormone Deficiency (GHD)
- Growth Failure Secondary to Chronic Renal Insufficiency
- Short Stature Associated with Turner Syndrome
- Adult 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.

(Renewal denial text continued on next page)

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SOMATROPIN

RENEWAL CRITERIA - NUTROPIN, NUTROPIN AQ, NUTROPIN AQ NUSPIN (CONTINUED)

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 renal insufficiency, 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 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.

CONTINUED ON NEXT PAGE

SOMATROPIN

RENEWAL CRITERIA - OMNITROPE (CONTINUED)

2. Does the patient have **ONE** of the following diagnoses and meets 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

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 onset 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.

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

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SOMATROPIN

RENEWAL CRITERIA - OMNITROPE (CONTINUED)

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 onset 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

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 onset growth hormone deficiency, renewal requires:

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

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SOMATROPIN

RENEWAL CRITERIA (CONTINUED)

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 FDA diagnoses and meets 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.

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

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SOMATROPIN

RENEWAL CRITERIA - SAIZEN (CONTINUED)

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 (formerly TEV-TROPIN):

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. Is the request for Zomacton for a patient with a diagnosis of pediatric growth failure and meets the following criteria?

- 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

If yes, **approve Zomacton for 12 months by GPID.**

If no, do not approve.

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

DENIAL TEXT: The guideline named **SOMATROPIN (Zomacton)** renewal requires a diagnosis of growth failure. The following criteria must also be met.

- 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

(Renewal denial text continued on next page)

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SOMATROPIN

RENEWAL CRITERIA - ZOMACTON (CONTINUED)

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

- Athletic enhancement or anti-aging purposes
- Idiopathic Short Stature

RATIONALE

Ensure appropriate use of growth hormone with respect to evidence based guidelines.

Growth hormone (GH) is secreted from the anterior pituitary, and is considered a trophic hormone – that is, its release stimulates other body glands and tissues to release additional hormonally active substances. Release of GH from the pituitary is controlled by the hypothalamic release of growth hormone-releasing hormone (GHRH). The secretion and circulating levels of GH vary with age.

Many safety concerns have been raised with recombinant growth hormone (rhGH) treatment. In 2016, the Growth Hormone Research Society, in conjunction with other endocrinology societies, released a position paper stating that there was insufficient evidence to attribute rhGH treatment with increased risk of all-cause mortality, new or recurrent cancers, or stroke. Treatment with rhGH appears to be safe when used within recommended doses.

Currently, there are nine rhGH products being marketed. With the exception of Serostim and Zorbtive, all of the products are indicated for the treatment of pediatric GH deficiency, and additional indications are product specific. Recombinant GH products are used off-label for anti-aging effects and enhancing athletic performance. Use of rhGH in patients with Idiopathic Short Stature (ISS) is controversial as these patients are not growth hormone deficient.

	PED GROWTH HORMONEH	ADULT GROWTH HORMONE	SMALL FOR GESTATIONAL AGE	IDIOPATHIC SHORT STATURE	TURNER SYNDROME	PRADER WILLI SYNDROME	HIV-ASSOCIATED WASTING	SHORT BOWEL SYNDROME	NOONAN SYNDROME	SHORT STATURE HOMEBOX-CONTAINING GENE (SHOX)	CHRONIC KIDNEY DISEASE (CHRONIC RENAL
ZORBTIVE								√			
SEROSTIM							√				
GENOTROPIN	√	√	√	√	√	√					
NORDITROPIN	√	√	√		√				√		

HUMATROPE	√	√	√	√	√					√	
NUTROPIN	√	√		√	√						√
OMNITROPE	√	√	√	√	√	√					
SAIZEN	√	√									
ZOMACTON	√										

DOSING

Dosing of rhGH products varies amongst the products and their indications. Treatment guidelines recommend that treatment be individualized. For pediatric patients, weight based-dosing is utilized, whereas in adult patients, either weight-base dosing or fixed-doses may be used.

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SOMATROPIN

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