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Section:	Prescription Drugs	**Effective Date:**	January 1, 2026
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	January 1, 2026
Subject:	Growth Hormone Short-Acting	**Page:**	1 of 14

Last Review Date: December 12, 2025

Growth Hormone Short-Acting

Description

Genotropin*, Humatrope*, **Norditropin**, Omnitrope*, Saizen*, Zomacton* (somatropin)

Bolded medications are the preferred products.

*Prior authorization for non-preferred formulations applies only to formulary exceptions

Background

Somatropin is a synthetically manufactured genetic copy of natural human growth hormone produced in the pituitary gland. It has the same effect as natural human growth hormone made in the body. Growth hormone (GH) contributes to overall bone, muscle, and organ growth and development in humans. Children with inadequate production of growth hormone, which can be due to various diseases and reasons, require growth hormone replacement in order to complete their development from childhood to adulthood (1-2).

Use of any growth hormone in children can cause a number of potentially serious adverse effects; therefore, regular and routine monitoring is required. Sometimes treatment may need to be permanently stopped. These adverse effects include the development of impaired glucose tolerance and diabetes mellitus, upper airway obstruction and sleep apnea in patients with Prader-Willi syndrome, progression or recurrence of tumors in patients with preexisting tumors, intracranial hypertension, the worsening of hypothyroidism, the worsening of pre-existing scoliosis, and pancreatitis (1-2).

Growth hormone deficiency (GHD) in adulthood, associated with hypothalamic-pituitary dysfunction is now widely accepted as a distinct clinical syndrome, and is linked to a substantial number of significant co-morbidities, many of which can be ameliorated with growth hormone replacement therapy (1).

The FDA has approved growth hormone replacement for use in adult patients with growth hormone deficiency. Approved indications are for the treatment of adults with either adult onset or childhood onset GHD. With the exception of idiopathic adult onset GHD, GHD should be confirmed as due to pituitary disease from known causes, including pituitary tumor, pituitary surgical damage, hypothalamic disease, irradiation, trauma, or reconfirmed childhood GHD. Growth hormone should only be prescribed to patients with clinical features suggestive of adult GHD and biochemically proven evidence of adult GHD (1).

Regulatory Status
FDA-approved indications:

Genotropin is indicated for: (3)

- Treatment of children with growth failure due to growth hormone deficiency (GHD), Prader-Willi syndrome, Small for Gestational Age, Turner syndrome, and Idiopathic Short Stature
- Treatment of adults with either adult onset or childhood onset GHD

Humatrope is indicated for: (4)

- Growth failure due to inadequate secretion of endogenous growth hormone (GH); short stature associated with Turner syndrome; Idiopathic Short Stature (ISS), height standard deviation score (SDS) <-2.25, and associated with growth rates unlikely to permit attainment of adult height in the normal range; short stature or growth failure in short stature homeobox-containing gene (SHOX) deficiency; short stature born small for gestational age (SGA) with no catch-up growth by 2 years to 4 years of age
- Replacement of endogenous GH in adults with GH deficiency

Norditropin is indicated for: (5)

- Treatment of pediatric patients with growth failure due to inadequate secretion of endogenous growth hormone (GH), short stature associated with Noonan syndrome, short stature associated with Turner syndrome, short stature born small for gestational age (SGA) with no catch-up growth by age 2 to 4 years, Idiopathic Short Stature (ISS), and growth failure due to Prader-Willi Syndrome

- Replacement of endogenous GH in adults with growth hormone deficiency

Omnitrope is indicated for: (6)

- Treatment of children with growth failure due to growth hormone deficiency (GHD), Prader-Willi Syndrome, Small for Gestational Age, Turner Syndrome, and Idiopathic Short Stature
- Treatment of adults with either adult onset or childhood onset GHD

Saizen is indicated for: (7)

- Treatment of children with growth failure due to growth hormone deficiency (GHD)
- Treatment of adults with either adult onset or childhood onset GHD

Zomacton is indicated: (8)

- Treatment of pediatric patients with growth failure due to inadequate secretion of endogenous growth hormone (GH), short stature associated with Turner syndrome, idiopathic short stature (ISS), short stature or growth failure in short stature homeobox-containing gene (SHOX) deficiency, and short stature born small for gestational age (SGA) with no catch-up growth by 2 years to 4 years
- Replacement of endogenous GH in adults with GH deficiency

Conditions that may cause inadequate secretion of growth hormone may include: growth hormone deficiency (GHD)/insufficiency; growth failure secondary to chronic renal insufficiency pre-transplantation, Noonan Syndrome, Prader-Willi Syndrome, Turner Syndrome or SHOX (short stature homeobox-containing gene) deficiency; small for gestational age (SGA) for children who have not reached a normal height range by age 2 to 4 years or idiopathic short stature (ISS).

Related policies

Growth Hormone Long-Acting, Serostim, Zorbtive

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Growth Hormone Short-Acting may be considered **medically necessary** if the conditions indicated below are met.

Growth Hormone Short-Acting may be considered **investigational** for all other indications.

Prior-Approval Requirements

Norditropin only

Age 17 years of age or under
18 years of age or older **WITH** open epiphyses

Diagnoses

Patient must have **ONE** of the following:

1. Growth failure due to inadequate secretion of endogenous growth hormone as defined by having **ALL** of the following:
    a. Height below 3rd percentile for age or acquired growth hormone deficiency due to CNS lesions
    b. Growth hormone level less than 10 on stimulation test or subnormal IGF-1 level for age or subnormal IGFBP-3 level for age
2. Growth failure in children born small for gestational age who fail to manifest catch-up growth by age 2 to 4 years
3. Growth failure due to chronic renal insufficiency up to the time of renal transplantation
4. Growth failure due to Noonan Syndrome
5. Growth failure due to Prader-Willi Syndrome
6. Growth failure due to SHOX (short stature homeobox-containing gene) deficiency
7. Growth failure due to Turner Syndrome
8. Idiopathic short stature (ISS), also called non-growth hormone-deficient short stature, defined by height standard deviation score (SDS) ≤ -2.25, and associated with growth rates unlikely to permit attainment of adult height in the normal range, and in whom diagnostic evaluation excludes other causes associated with short stature that should be observed or treated by other means

AND ALL of the following:

1. Open epiphyses (as determined within the last year by radiographic evidence)
2. **NO** evidence of tumor activity or active neoplasm
3. **NOT** used in combination with another somatropin agent (such as Serostim, Zorbtive, or any other GH)
4. **NOT** used in combination with Voxzogo (vosoritide)

Genotropin, Humatrope, Omnitrope, Saizen, and Zomacton only

Age
17 years of age or under
18 years of age or older **WITH** open epiphyses

Diagnoses

Patient must have **ONE** of the following with provided documentation (e.g., medical records, laboratory values):

1. Growth failure due to inadequate secretion of endogenous growth hormone as defined by having **ALL** of the following:
   a. Height below 3rd percentile for age or acquired growth hormone deficiency due to CNS lesions
   b. Growth hormone level less than 10 on stimulation test or subnormal IGF-1 level for age or subnormal IGFBP-3 level for age
2. Growth failure in children born small for gestational age who fail to manifest catch-up growth by age 2 to 4 years
3. Growth failure due to chronic renal insufficiency up to the time of renal transplantation
4. Growth failure due to Noonan Syndrome
5. Growth failure due to Prader-Willi Syndrome
6. Growth failure due to SHOX (short stature homeobox-containing gene) deficiency
7. Growth failure due to Turner Syndrome
8. Idiopathic short stature (ISS), also called non-growth hormone-deficient short stature, defined by height standard deviation score (SDS) ≤ -2.25, and associated with growth rates unlikely to permit attainment of adult height in the normal range, and in whom diagnostic evaluation excludes other causes associated with short stature that should be observed or treated by other means

AND ALL of the following:

1. Open epiphyses (as determined within the last year by radiographic evidence)
2. **NO** evidence of tumor activity or active neoplasm
3. **NOT** used in combination with another somatropin agent (such as Serostim, Zorbtive, or any other GH)
4. **NOT** used in combination with Voxzogo (vosoritide)
5. Patient **MUST** have tried the preferred product(s) (see Appendix 1) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Norditropin only

Age 18 years of age or older*
*Patients with open epiphyses must meet pediatric criteria above

Diagnoses

Patient must have **ONE** of the following:

1. Burn wounds (used for promotion of wound healing in burn patients)
2. Growth hormone deficiency
    a. Growth hormone deficiency is due to at least **ONE** of the following:
        i. Hypothalamic disease
        ii. Pituitary disease
        iii. Radiation therapy
        iv. Surgery
        v. Trauma
        vi. Idiopathic childhood-onset or adult-onset growth hormone deficiency
    b. Documentation of GH stimulation test result from **ONE** of the following:
        i. Insulin tolerance test peak GH ≤ 5 ng/ml

ii. Glucagon, peak GH ≤ 3 ng/ml
iii. Arginine/L-Dopa, peak GH ≤ 1.5 ng/ml
iv. Arginine, peak GH ≤ 0.4 ng/ml

3. Documented IGF-1 level below the age and sex appropriate reference range **AND** panhypopituitarism (defined as a deficiency of three or more pituitary hormones such as gonadotropin [LH and/or FSH], adrenocorticotropic hormone [ACTH], thyroid-stimulation hormone [TSH], arginine vasopressin [AVP])

AND ALL of the following:

1. Confirmation that GH is not being used for cosmetic, anti-aging or athletic performance enhancement
2. Not being used in combination with another somatropin agent (such as Serostim, Zorbtive, or any other GH)

Genotropin, Humatrope, Omnitrope, Saizen, and Zomacton only

Age 18 years of age or older*
*Patients with open epiphyses must meet pediatric criteria above

Diagnoses

Patient must have **ONE** of the following with provided documentation (e.g., medical records, laboratory values):

1. Burn wounds (used for promotion of wound healing in burn patients)
2. Growth hormone deficiency
    a. Growth hormone deficiency is due to at least **ONE** of the following:
        i. Hypothalamic disease
        ii. Pituitary disease
        iii. Radiation therapy
        iv. Surgery
        v. Trauma
        vi. Idiopathic childhood-onset or adult-onset growth hormone deficiency
    b. Documentation of GH stimulation test result from **ONE** of the following:
        i. Insulin tolerance test peak GH ≤ 5 ng/ml

ii. Glucagon, peak GH ≤ 3 ng/ml
iii. Arginine/L-Dopa, peak GH ≤ 1.5 ng/ml
iv. Arginine, peak GH ≤ 0.4 ng/ml

3. Documented IGF-1 level below the age and sex appropriate reference range **AND** panhypopituitarism (defined as a deficiency of three or more pituitary hormones such as gonadotropin [LH and/or FSH], adrenocorticotropic hormone [ACTH], thyroid-stimulation hormone [TSH], arginine vasopressin [AVP])

AND ALL of the following:

1. Confirmation that GH is not being used for cosmetic, anti-aging or athletic performance enhancement
2. Not being used in combination with another somatropin agent (such as Serostim, Zorbtive, or any other GH)
3. Patient **MUST** have tried the preferred product(s) (see Appendix 1) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Prior – Approval *Renewal* Requirements

Norditropin only

Age
17 years of age or under
18 years of age or older **WITH** open epiphyses

Diagnoses

Patient must have **ONE** of the following:

1. Growth failure due to inadequate secretion of endogenous growth hormone
2. Growth failure in children born small for gestational age who fail to manifest catch-up growth by age 2 to 4 years
3. Growth failure due to chronic renal insufficiency up to the time of renal transplantation
4. Growth failure due to Noonan Syndrome

5. Growth failure due to Prader-Willi Syndrome
6. Growth failure due to SHOX (short stature homeobox-containing gene) deficiency
7. Growth failure due to Turner Syndrome
8. Idiopathic short stature (ISS), also called non-growth hormone-deficient short stature

AND ALL of the following:

1. Open epiphyses (as determined within the last year by radiographic evidence)
2. **NO** evidence of tumor activity or active neoplasm
3. Growth velocity > 2cm/year
4. Absence of significant side effects
5. Compliance with therapy
6. **NOT** used in combination with another somatropin agent (such as Serostim, Zorbtive, or any other GH)
7. **NOT** used in combination with Voxzogo (vosoritide)

Genotropin, Humatrope, Omnitrope, Saizen, and Zomacton only

Age

17 years of age or under

18 years of age or older **WITH** open epiphyses

Diagnoses

Patient must have **ONE** of the following with provided documentation (e.g., medical records, laboratory values):

1. Growth failure due to inadequate secretion of endogenous growth hormone
2. Growth failure in children born small for gestational age who fail to manifest catch-up growth by age 2 to 4 years
3. Growth failure due to chronic renal insufficiency up to the time of renal transplantation
4. Growth failure due to Noonan Syndrome
5. Growth failure due to Prader-Willi Syndrome
6. Growth failure due to SHOX (short stature homeobox-containing gene) deficiency
7. Growth failure due to Turner Syndrome

8. Idiopathic short stature (ISS), also called non-growth hormone-deficient short stature

AND ALL of the following:

1. Open epiphyses (as determined within the last year by radiographic evidence)
2. **NO** evidence of tumor activity or active neoplasm
3. Growth velocity > 2cm/year
4. Absence of significant side effects
5. Compliance with therapy
6. **NOT** used in combination with another somatropin agent (such as Serostim, Zorbtive, or any other GH)
7. **NOT** used in combination with Voxzogo (vosoritide)
8. Patient **MUST** have tried the preferred product(s) (see Appendix 1) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Norditropin only

Age 18 years of age or older
*Patients with open epiphyses must meet pediatric criteria above

Diagnoses

Patient must have **ONE** of the following:

1. Burn wounds (used for promotion of wound healing in burn patients)
2. Growth hormone deficiency due to at least **ONE** of the following:
    a. Hypothalamic disease
    b. Pituitary disease
    c. Radiation therapy
    d. Surgery
    e. Trauma
    f. Idiopathic childhood-onset or adult-onset growth hormone deficiency

g. Panhypopituitarism

AND ALL of the following:

1. Confirmation that GH is not being used for cosmetic, anti-aging or athletic performance enhancement
2. Not being used in combination with another somatropin agent (such as Serostim, Zorbtive, or any other GH)

Genotropin, Humatrope, Omnitrope, Saizen, and Zomacton only

Age 18 years of age or older
*Patients with open epiphyses must meet pediatric criteria above

Diagnoses

Patient must have **ONE** of the following with provided documentation (e.g., medical records, laboratory values):

1. Burn wounds (used for promotion of wound healing in burn patients)
2. Growth hormone deficiency due to at least **ONE** of the following:
    a. Hypothalamic disease
    b. Pituitary disease
    c. Radiation therapy
    d. Surgery
    e. Trauma
    f. Idiopathic childhood-onset or adult-onset growth hormone deficiency
    g. Panhypopituitarism

AND ALL of the following:

1. Confirmation that GH is not being used for cosmetic, anti-aging or athletic performance enhancement
2. Not being used in combination with another somatropin agent (such as Serostim, Zorbtive, or any other GH)
3. Patient **MUST** have tried the preferred product(s) (see Appendix 1) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Pediatric patients with inadequate production of growth hormone may require growth hormone replacement in order to complete their development from childhood to adulthood. Growth hormone deficiency (GHD) in adulthood, associated with hypothalamic-pituitary dysfunction is now widely accepted as a distinct clinical syndrome, and is linked to a substantial number of significant co-morbidities, many of which can be ameliorated with growth hormone replacement therapy (1-2).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Growth Hormone Short-Acting while maintaining optimal therapeutic outcomes.

References

1. Cook DM, Yuen KC, Biller BM, Kemp SF, Vance ML. American Association of Clinical Endocrinologists medical guidelines for clinical practice for growth hormone use in growth hormone-deficient adults and transition patients - 2009 update: executive summary of recommendations. Endocr Pract 15:580-586.
2. Wilson TA, Rose SR, Cohen P, et al. Update of guidelines for the use of growth hormone in children: The Lawson Wilkins Pediatric Endocrinology Society Drug and Therapeutics Committee. J Pediatrics. 2003; 143:415-21.
3. Genotropin [package insert]. New York, NY: Pfizer Inc.; April 2019.

4. Humatrope [package insert]. Indianapolis IN: Eli Lilly and Company Ltd.; December 2023.
5. Norditropin [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; March 2020.
6. Omnitrope [package insert]. Princeton, NJ: Sandoz Inc.; June 2019.
7. Saizen [package insert]. Rockland, MA: EMD Serono Inc.; February 2020.
8. Zomacton [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; April 2024.

Policy History

Date	Action
December 2025	Addition to PA. Annual review. Separated the long-acting and short-acting growth hormones to separate policies. Added documentation requirement for non-preferred

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 12, 2025 and is effective on January 1, 2026.

Appendix 1 - List of Preferred Products

List of preferred products:
https://info.caremark.com/content/dam/enterprise/caremark/microsites/dig/pdfs/pa-fep/fep-misc/FEP_ProductMedChx.pdf

Refer to formulary documents for confirmation of coverage:
https://www.fepblue.org/pharmacy/prescriptions#drug-lists