

5.30.097

Section: Prescription Drugs **Effective Date:** January 1, 2026

Subsection: Endocrine and Metabolic Drugs **Original Policy Date:** January 1, 2026

Subject: Growth Hormone Long-Acting **Page:** 1 of 13

Last Review Date: December 12, 2025

Growth Hormone Long-Acting

Description

Ngenla* (somatrogon-ghla)

Skytrofa* (lonapegsomatropin-tcgd)

Sogroya (smapacitan-beco)

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).

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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:

Ngenla is indicated for the treatment of pediatric patients aged 3 years and older who have growth failure due to inadequate secretion of endogenous growth hormone (3).

Skytrofa is indicated for the treatment of pediatric patients 1 year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormone (4).

Sogroya is indicated: (5)

- For the treatment of pediatric patients aged 2.5 years and older who have growth failure due to inadequate secretion of endogenous growth hormone (GH).
- As replacement of endogenous growth hormone in adults with growth hormone 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

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

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

Prior-Approval Requirements

Sogroya 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

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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)

Ngenla and Skytrofa 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

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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.

Sogroya 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

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- 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 \leq 5 ng/ml
 - ii. Glucagon, peak GH \leq 3 ng/ml
 - iii. Arginine/L-Dopa, peak GH \leq 1.5 ng/ml
 - iv. Arginine, peak GH \leq 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], adrenocorticotrophic 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)

Skytrofa 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

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- 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 \leq 5 ng/ml
 - ii. Glucagon, peak GH \leq 3 ng/ml
 - iii. Arginine/L-Dopa, peak GH \leq 1.5 ng/ml
 - iv. Arginine, peak GH \leq 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], adrenocorticotrophic 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

Sogroya only

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

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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 Vosszogo (vosoritide)

Ngenla and Skytrofa 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

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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.

Sogroya only

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

Diagnoses

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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)

Skytrofa 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:

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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 Long-Acting while maintaining optimal therapeutic outcomes.

References

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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. Ngenla [package insert]. New York, NY: Pfizer Inc.; June 2023.
4. Skytrofa [package insert]. Palo Alto, CA: Ascendis Pharma, Inc.; April 2022.
5. Sogroya [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; April 2023.

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 Ngenla and Skytrofa

Keywords

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

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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>