Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: **Growth Hormones**

Effective: May 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Somatropin is a synthetic form of human growth hormone that is produced by using recombinant DNA (rDNA) technology. Somatropin (i.e., **Humatrope, Genotropin, Norditropin, Nutropin, Omnitrope, Saizen, Zomacton**) is used in growth hormone deficient adults to maintain body composition and metabolism.

Omnitrope is the preferred growth hormone product. **Humatrope, Genotropin, Norditropin, Nutropin, Saizen** and **Zomacton** are non-formulary medications.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of a Growth Hormone product for Members when **ALL** of the following criteria are met:

Turner Syndrome, Chronic Renal Failure, Prader-Willi Syndrome, Noon Syndrome, Short Stature Homeobox-Containing Gene (SHOX) Deficiency

Initial Authorization Criteria

1. Patient is less than 18 years old

AND

2. Documented diagnosis with short stature or growth failure due to **one (1)** of the following conditions:
    a. Turner Syndrome
    b. Chronic renal failure
    c. Prader-Willi Syndrome
    d. Noonan Syndrome
    e. Short stature homeobox-containing gene (SHOX) deficiency

AND

3. Prescribed by or in consultation with an endocrinologist or nephrologist

Reauthorization Criteria

1. Patient is less than 18 years old

AND

2. Documented diagnosis with short stature or growth failure due to **one (1)** of the following conditions:
    a. Turner Syndrome
    b. Chronic renal failure
    c. Prader-Willi Syndrome
    d. Noonan Syndrome
    e. Short stature homeobox-containing gene (SHOX) deficiency

AND

3. Prescribed by or in consultation with an endocrinologist or nephrologist

AND

4. Documentation the patient's epiphyses are open confirmed by radiograph of the wrist and hand

AND

5. Documentation the patient has experienced a therapeutic response defined as growth velocity of greater than or equal to 2 centimeters compared with that observed during the previous year

AND

6. If the documented diagnosis is short stature or growth failure due to chronic renal failure, documentation the patient has not received a kidney transplant

Intrauterine Growth Retardation (IUGR), Small for Gestational Age (SGA)

Initial Authorization Criteria

1. Patient is less than 18 years old

AND

2. Documented diagnosis with **one (1)** of the following conditions:
    a. Intrauterine growth retardation (IUGR)
    b. Small for gestational age (SGA)

AND

3. Documentation the patient's birth weight or length is more than 2 standard deviations below the mean (or below the 3rd percentile) for gestational age

AND

4. Documentation the patient has failed to catch up by age 2 years

AND

5. Prescribed by or in consultation with an endocrinologist

Reauthorization Criteria

1. Patient is less than 18 years old

AND

2. Documented diagnosis with **one (1)** of the following conditions:
    a. Intrauterine growth retardation (IUGR)
    b. Small for gestational age (SGA)

AND

3. Prescribed by or in consultation with an endocrinologist

AND

4. Documentation the patient's epiphyses are open confirmed by radiograph of the wrist and hand

AND

5. Documentation the patient has experienced a therapeutic response defined as growth velocity of greater than or equal to 2 centimeters compared with that observed during the previous year

Growth Hormone Deficiency due to Lack of Endogenous Secretion, Idiopathic Growth Hormone Deficiency

Initial Authorization Criteria

1. Patient is less than 18 years of age

AND

2. Documented diagnosis of **one (1)** of the following conditions:
    a. Growth hormone deficiency due to lack of endogenous secretion
    b. Idiopathic growth hormone deficiency

AND

3. Documentation of **one (1)** of the following:
    a. The patient's pituitary gland has been removed
    b. Patient has failed to respond to **one (1)** standard growth hormone stimulation test (e.g., insulin, levodopa, arginine, propranolol, clonidine, glucagon, macrlien) defined as a peak measured growth hormone level of less than 10 ng/mL

AND

4. Prescribed by or in consultation with an endocrinologist

Reauthorization Criteria

1. Patient is less than 18 years old

AND

2. Documented diagnosis of **one (1)** of the following conditions:
    a. Growth hormone deficiency due to lack of endogenous secretion
    b. Idiopathic growth hormone deficiency

AND

3. Prescribed by or in consultation with an endocrinologist

AND

4. Documentation the patient's epiphyses are open confirmed by radiograph of the wrist and hand

AND

5. Documentation the patient has experienced a therapeutic response defined as growth velocity of greater than or equal to 2 centimeters compared with that observed during the previous year

Acquired Growth Hormone Deficiency, Childhood Onset Growth Hormone Deficiency

Initial Authorization Criteria

1. Patient is 18 years of age or older

AND

2. Documented diagnosis of **one (1)** of the following conditions:
    a. Childhood onset growth hormone deficiency
    b. Acquired growth hormone deficiency resulting from hypothalamic-pituitary disease, craniopharyngioma, head trauma, radiation, or surgery

AND

3. Documentation of **one (1**) of the following:
    a. The patient's pituitary gland has been removed
    b. Patient has multiple other pituitary hormone deficiencies due to organic disease or congenital/genetic growth hormone deficiency
    c. Patient has failed to respond to **one (1)** standard growth hormone stimulation test (e.g., insulin, levodopa, arginine, propranolol, clonidine, glucagon, macrlien) defined as a peak measured growth hormone level of less than 5 ng/mL

AND

4. Prescribed by or in consultation with an endocrinologist

Reauthorization Criteria

1. Patient is 18 years of age or older

AND

2. Documented diagnosis of **one (1)** of the following conditions:
    a. Childhood onset growth hormone deficiency
    b. Acquired growth hormone deficiency resulting from hypothalamic-pituitary disease, craniopharyngioma, head trauma, radiation, or surgery

AND

3. Prescribed by or in consultation with an endocrinologist

Limitations

1. The plan does not provide coverage of Growth Hormone products for other conditions that include, but are not limited to:
    - Constitutional delay
    - Idiopathic short stature
    - Genetic short stature
    - Glucocorticoid-induced growth failure
    - Down's Syndrome
2. For all indications, authorizations for Growth Hormone products will be provided in 12 months.
3. Reauthorization requests for preferred products will be approved for 12 months. Reauthorizations for non-preferred products due to shortage will be approved for 3 months.
4. Patients new to the plan stable on a Growth Hormone product should be reviewed against Reauthorization Criteria, but if the request is for a non-preferred product, rationale must be provided why preferred product cannot be used. Any reauthorizations due to shortage will be for a period of 3 months.
5. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary

Exceptions and submit a formulary exception request to the plan as indicated.

Codes

None

References

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Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- August 8, 2023: No changes
- June 11, 2024: No changes (eff 6/11/24)
- July 8, 2025: No changes. (eff 7/8/25)
- February 10, 2026: Effective May 1, 2026 clarified approval durations for reauthorizations and authorization due to shortage.
- February 2026: Administrative update to remove CareLink from Medical Necessity Guideline template.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.