# Pharmacy Medical Necessity Guidelines: Growth Hormone Replacement Therapy

*Effective: January 1, 2021*

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|---|---|---|---|
| Prior Authorization Required | √ | Type of Review – Care Management | |
| Not Covered | | Type of Review – Clinical Review | √ |
| Pharmacy (RX) or Medical (MED) Benefit | RX | Department to Review | RXUM |

These pharmacy medical necessity guidelines apply to the following:

**Commercial Products**

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

**Tufts Health Public Plans Products**

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

**Fax Numbers:**

RXUM: 617.673.0988

**Note:** This guideline does not apply to Medicare Members (includes dual eligible Members).

## OVERVIEW

Somatropin is a synthetic form of human growth hormone that is produced by using recombinant DNA (rDNA) technology. Somatropin (i.e., Genotropin®, Humatrope®, Norditropin®, Nutropin®, Omnitrope®, Saizen®, Serostim®, Zomacton®, Zorbtive®). Several formulations of somatropin are available under different brand names. While growth hormone is Food and Drug Administration-approved to treat a variety of conditions, not every growth hormone formulation is FDA-approved to treat all of the same conditions. There is no reported difference between the clinical effects of available somatropin products.

## COVERAGE GUIDELINES

The plan may authorize coverage of Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Saizen, Serostim, Zomacton, or Zorbtive, for Members when the following criteria are met:

**Pediatric Growth Hormone Deficiency or Panhypopituitarism**

1. The Member is less than 18 years of age

**AND**

2. Documented diagnosis of growth hormone deficiency or panhypopituitarism

**AND**

3. Documentation of short stature or growth failure defined by **one (1)** of the following:
    a. Pre-treatment height less than -2 standard deviations below mean or below 3rd percentile on standard pediatric growth chart
    b. Height dropping below initial percentile curve on standard pediatric growth chart when monitored over 1 year

**AND**

4. Documentation of **one (1)** of the following:
    a. Results of two abnormal tests, which can be either:
        i. Two abnormal growth hormone stimulation tests
        ii. One abnormal stimulation test and one abnormal IGF-1/IGFBP-3 level
    b. One abnormal test (growth hormone stimulation, IGF-1, or IGFBP-3 test) with either:
        i. Abnormal pituitary imaging
        ii. Deficiency of at least three other pituitary hormones (TSH, ACTH, LH, FSH, or AVP/ADH)
        iii. Appropriate current medication claims suggesting deficiency of at least three other pituitary hormones (levothyroxine, hydrocortisone or other glucocorticoid, testosterone [for males] or estrogen/progesterone [for females], or desmopressin)

**AND**

5. Documentation of **one (1)** of the following:
    a. Member is under the care of an endocrinologist

b. Other possible causes of short stature or growth failure have been ruled out (e.g., hypothyroidism, malnutrition, chronic illness, skeletal disorders, pituitary tumor)

**AND**

6. Requests for all agents other than Genotropin, prescriber provides clinical rationale for use of the requested agents instead of Genotropin

**Hypoglycemia due to Growth Hormone Deficiency**

1. The Member is less than 18 years of age

**AND**

2. Documented diagnosis of hypoglycemia due to growth hormone deficiency

**AND**

3. Documentation of laboratory results indicated growth hormone deficiency defined as at least one abnormal growth hormone stimulation test

**AND**

4. Documentation of hypoglycemia symptoms and low glucose level (lower end of normal range is 75 mg/dL [4.2 mM/L])

**AND**

5. Requests for all agents other than Genotropin, prescriber provides clinical rationale for use of the requested agents instead of Genotropin

**Noonan, Prader-Willi, and Turner Syndrome**

1. The Member is less than 18 years of age

**AND**

2. Documented diagnosis of short stature or growth failure due to Noonan syndrome, Prader-Willi syndrome, or Turner syndrome

**AND**

3. Documentation of short stature or growth failure defined by **one (1)** of the following:
    a. Pre-treatment height less than -2 standard deviations below mean or below 3rd percentile on standard pediatric growth chart
    b. Height dropping below initial percentile curve on standard pediatric growth chart when monitored over 1 year

**AND**

4. Documentation of **one (1)** of the following:
    a. Genetic testing confirming diagnosis
    b. Appropriate clinical rationale for why genetic testing cannot be provided (e.g., member is new to prescriber and current prescriber has no means of obtaining labs used for diagnosis, diagnosis made many years ago)

**AND**

5. Requests for all agents other than Genotropin, prescriber provides clinical rationale for use of the requested agents instead of Genotropin

**Chronic Renal Failure up to Time of Renal Transplantation**

1. The Member is less than 18 years of age

**AND**

2. Documented diagnosis of short stature or growth failure due to chronic renal failure up to time of renal transplantation

**AND**

3. Documentation of short stature or growth failure defined by **one (1)** of the following:
    a. Pre-treatment height less than -2 standard deviations below mean or below 3rd percentile on standard pediatric growth chart
    b. Height dropping below initial percentile curve on standard pediatric growth chart when monitored over 1 year

**AND**

4. Documentation of **one (1)** of the following:
    a. Other chronic renal failure-associated etiologies have been excluded (e.g., acidosis, secondary hyperparathyroidism, malnutrition, or zinc deficiency)
    b. Member is under the care of a renal specialist

**AND**

5. Requests for all agents other than Genotropin, prescriber provides clinical rationale for use of the requested agents instead of Genotropin

**Small for gestational age/Intrauterine growth restriction (SGA/IUGR) with Failed Catch-up Growth Between Age 2 to 4**

1. The Member is less than 18 years of age

**AND**

2. Documented diagnosis of short stature or growth failure due to small for gestational age/intrauterine growth restriction with failed catch-up growth by age 2 to 4

**AND**

3. The Member is 2 years of age or older

**AND**

4. Documentation of short stature or growth failure defined by **one (1)** of the following:
    a. Pre-treatment height less than -2 standard deviations below mean or below 3rd percentile on standard pediatric growth chart
    b. Height dropping below initial percentile curve on standard pediatric growth chart when monitored over 1 year

**AND**

5. Documented diagnosis of short for gestational age/intrauterine growth restriction of **one (1)** of the following:
    a. Birth weight less than -2 standard deviations below mean or below 3rd percentile for gestational age
    b. Birth length less than -2 standard deviations below mean or below 3rd percentile for gestational age

**AND**

6. Documentation of catch-up growth not achieved between the ages of 2 to 4 years defined as height continually less than -2 standard deviations below mean or below 3rd percentile from age 2 to current age

**AND**

7. Requests for all agents other than Genotropin, prescriber provides clinical rationale for use of the requested agents instead of Genotropin

**Adult Growth Hormone Deficiency or Panhypopituitarism**

1. The Member is 18 years of age or older

**AND**

2. Documented diagnosis of growth hormone deficiency or panhypopituitarism

**AND**

3. Documentation of **one (1)** of the following:
    a. Results of two abnormal tests, which can be either:
        i. Two abnormal growth hormone stimulation tests
        ii. One abnormal stimulation test and one abnormal IGF-1/IGFBP-3 level
    b. One abnormal test (growth hormone stimulation, IGF-1, or IGFBP-3 test) with either:
        i. Abnormal pituitary imaging
        ii. Deficiency of at least three other pituitary hormones (TSH, ACTH, LH, FSH, or AVP/ADH)
        iii. Appropriate current medication claims suggesting deficiency of at least three other pituitary hormones (levothyroxine, hydrocortisone or other glucocorticoid, testosterone [for males] or estrogen/progesterone [for females], or desmopressin)

**AND**

4. Documentation of at least **one (1)** complication of growth hormone deficiency
    a. Increased fat mass and reduced lean body mass
    b. Reduced extracellular volume
    c. Reduced bone mineral content and density
    d. Elevated cholesterol
    e. Diminished renal function without other etiology
    f. Congestive heart failure
    g. Reduced exercise capacity
    h. Impaired quality of life

**AND**

5. Requests for all agents other than Genotropin, prescriber provides clinical rationale for use of the requested agents instead of Genotropin

**HIV/AIDS-associated Wasting or Cachexia**

1. Documented diagnosis of HIV/AIDS-associated wasting or cachexia

**AND**

2. Documentation Member is receiving concurrent antiretroviral therapy

**AND**

3. Documentation of evidence of wasting, as indicated by any of the following:
    a. An involuntary loss of at least 10% of body weight within one year
    b. An involuntary loss of at least 7.5% of body weight within six months
    c. A reduction in lean body mass (measured via bioelectrical impedance assay or BIA)
    d. Body mass index <20 kg/$m^2$

**AND**

4. Documentation the Member has had a trial of an FDA-approved appetite stimulant (e.g., dronabinol, megestrol acetate oral suspension)

**AND**

5. Documentation of **one (1)** of the following:
    a. Other causes of weight loss have been ruled out (e.g., gastrointestinal tract opportunistic infections; decrease in food intake due to oral, pharyngeal, esophageal lesions or candidiasis; gonadal dysfunction; adverse effects due to medications; or psychosocial factors)
    b. Member is under the care of an Infectious Disease specialist

**AND**

6. Requests for all agents other than Genotropin, prescriber provides clinical rationale for use of the requested agents instead of Genotropin

**Short Bowel Syndrome**

1. Documented diagnosis of short bowel syndrome

**AND**

2. Requests for all agents other than Genotropin, prescriber provides clinical rationale for use of the requested agents instead of Genotropin

## LIMITATIONS

- Patients who present with, or develop, an active neoplasm (tumor), or with an active intracranial lesion, will be excluded from coverage.
- Based on the interchangeability of the growth hormone agents in practice, lack of FDA-approval of the preferred growth hormone agent for any indication and stability on a non-preferred agent is not rationale to bypass medical necessity for a non-preferred growth hormone agent.

## CODES

Medical billing codes may not be used for this medication. This medication must be obtained via the Member's pharmacy benefit.

## REFERENCES


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## APPROVAL HISTORY

December 12, 2017: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
1. August 7, 2018: No changes
2. August 13, 2019: Updated the definition of SGA to the "Child does not show catch up growth between ages 2 and 4 years of age…" from previous language of "before 2 years of age."
3. November 24, 2020: Effective January 1, 2021, criteria updated to be in line with MassHealth ACPP/MCO Partial Unified Formulary coverage requirements. Criteria for all indications have been adjusted and reauthorization criteria has been removed. The following Limitation has been added "Based on the interchangeability of the growth hormone agents in practice, lack of FDA-approval of the preferred growth hormone agent for any indication and stability on a non-preferred agent is not rationale to bypass medical necessity for a non-preferred growth hormone agent."

## 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.