Pharmacy Medical Necessity Guidelines:
Growth Hormone Replacement Therapy

Effective: August 1, 2026

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: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

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., **Humatrope, Genotropin, Norditropin, Nutropin, Omnitrope, Saizen, Zomacton**) is used in growth hormone deficient adults to maintain body composition and metabolism.

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

Serostim (somatropin) is indicated for the treatment of HIV patients with wasting or cachexia to increase lean body mass and body weight, and improve physical endurance.

COVERAGE GUIDELINES

Norditropin, Norditropin FlexPro and Norditropin Nordiflex (somatropin)

The plan may authorize coverage of Norditropin, Norditropin FlexPro and Norditropin Nordiflex (somatropin) for Members when 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

Serostim (somatropin)

The plan may authorize coverage of Serostim (somatropin) for Members when the following criteria are met:

1. Documented diagnosis of human immunodeficiency virus (HIV)-associated wasting or cachexia

AND

2. Documentation of **one (1)** of the following:
    a. Unintentional weight loss of at least 10% from baseline
    b. Body mass index less than 20 kg/m^2

AND

3. Documentation that other treatable causes of weight loss have been ruled out (e.g., depression, mycobacterium avium complex, chronic infectious diarrhea

AND

4. Documentation the patient is concurrently receiving antiretroviral medications indicated for the treatment of human immunodeficiency virus (HIV)

LIMITATIONS

- The plan does not provide coverage of Growth Hormone Replacement Therapy for other conditions that include, but are not limited to, the following:
    - Constitutional delay
    - Idiopathic short stature
    - Genetic short stature
    - Glucocorticoid-induced growth failure
    - Down's Syndrome
- Authorizations for Norditropin products will be provided in 12-month intervals.
- Patients new to the plan stable on a Norditropin product should be reviewed against Reauthorization Criteria.
- Authorizations for Serostim will be limited to 24 months.
- 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

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

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APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

- August 8, 2023: No changes
- June 11, 2024: No changes (eff 6/11/24)
- July 8, 2025: No changes (eff 7/8/25)
- July 14, 2026: Removed Zorbtive from Medical Necessity Guideline due to drug discontinuation (eff 8/1/26).

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.

Provider Services