

New Hampshire Medicaid Fee-for-Service Program

Human Growth Hormones Criteria

Approval Date: July 12, 2022

Pharmacology

Somatropin (rDNA Origin) is a polypeptide hormone of recombinant DNA origin. The amino acid sequence of these products is identical to that of human growth hormone of pituitary origin. Human growth hormone (hGH) is a 191-amino acid polypeptide hormone secreted by the anterior pituitary gland. It has important metabolic effects, including stimulation of protein synthesis and cellular uptake of amino acids. Lonapegsomatropin-tcgd (Skytrofa®) is a pegylated formulation of human growth hormone to extend the dosing interval.

Indications

| Drug | GHD (ped) | PWS | Turner Syndrome | CKD | SGA | GHD (adult) | ISS | SHOX | SBS | HIV wasting or cachexia | Other |
|--------------|-----------|-----|-----------------|-----|-----|-------------|-----|------|-----|-------------------------|--|
| Genotropin® | X | X | X | | X | X | X | | | | |
| Humatrope® | X | | X | | X | X | X | X | | | Hypopituitarism (Adults) |
| Norditropin® | X | X | X | | X | X | X | | | | Noonan Syndrome |
| Nutropin AQ® | X | | X | X | | X | X | | | | CKD up to the time of renal transplantation. (Pediatric) |
| Omnitrope® | X | X | X | | X | X | X | | | | |
| Saizen® | X | | | | | X | | | | | |
| Serostim® | | | | | | | | | | X | |
| Skytrofa® | X | | | | | | | | | | Pediatric patients ≥ 1 year old and ≥ 11.5 kg |
| Zomacton® | X | | X | | X | X | X | X | | | |
| Zorbtive® | | | | | | | | | X | | |

GHD = growth hormone deficiency; PWS = Prader-Willi Syndrome; CKD = chronic kidney disease; SGA = small gestational age; ISS = idiopathic short stature; SHOX = short stature homeobox gene; SBS = short bowel syndrome.

Proprietary & Confidential

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Medications

| Brand Name | Generic Name | Dosage Strengths |
|--------------|------------------------|---|
| Genotropin® | somatropin | 5, 12 mg cartridge, 0.2, 0.4, 0.6, 0.8, 1, 1.2, 1.4, 1.6, 1.8, 2 mg syringe device |
| Humatrope® | somatropin | 6, 12, 24 mg cartridge kits |
| Norditropin® | somatropin | 5, 10, 15, 30 mg prefilled pen |
| Nutropin AQ® | somatropin | 5, 10, 20 mg NuSpin prefilled cartridge |
| Omnitrope® | somatropin | 5.8 mg vial, 5 mg, 10 mg cartridge |
| Saizen® | somatropin | 5 mg, 8.8 mg vial, 8.8 mg cartridge |
| Serostim® | somatropin | 5, 6 mg single dose vial, 4 mg multi dose vial |
| Skytrofa® | lonapegsomatropin-tcgd | 3, 3.1, 4.3, 5.2, 6.3, 7.6, 9.1, 11, 13.3 mg cartridge |
| Zomacton® | somatropin | 5, 10 mg vial |
| Zorbtive® | somatropin | 8.8 mg vial |

Criteria for Approval

Pediatrics (18 and Under)

1. Prescriber is an endocrinologist or nephrologist or one has been consulted on this case; **AND**
2. MRI of the brain has been performed (to document absence of a brain tumor); **AND**
3. **ONE** of the following diagnoses:
 - a. Patient has a diagnosis of growth hormone deficiency; **AND**
 - i. Patient's height is more than 2 SD below average for the population mean height for age and sex, and a height velocity measured over one year to be 1 SD below the mean for chronological age; or for children over two years of age, a decrease in height SD of more than 0.5 over one year; **AND**
 - ii. Other causes of poor growth have been ruled out, including hypothyroidism, chronic illness, malnutrition, malabsorption, and genetic syndrome; **AND**
 - iii. Growth hormone response of less than 10 ng/ml to at least two provocative stimuli of growth hormone release: insulin, levodopa, L-Arginine, clonidine, or glucagons; **OR**
 - b. Patient has a diagnosis of Noonan Syndrome, short stature homeobox gene, Turner Syndrome, Prader-Willi Syndrome, or chronic kidney disease (Nutropin AQ only) **AND** meets auxological criteria for short stature – height more than two standard deviations below normal for age; **OR**

- c. Patient has a diagnosis of small for gestational age (including Russell-Silver variant) **AND** height is more than 2.25 standard deviations below normal for age and sex **AND** failure to catch up in growth by two years of age; **OR**
 - d. Patient is newborn with hypoglycemia and a diagnosis of hypopituitarism or panhypopituitarism; **AND**
4. (Skytrofa® only): Patient will have had an intolerance to a trial of a short-acting somatropin.

Adults (Over 18)

1. **ALL** of the following diagnoses and conditions have been met:
 - a. Patient has a diagnosis of growth hormone deficiency; **AND**
 - b. The etiology for patient's diagnosis of growth hormone deficiency is adult-onset growth hormone deficiency (AO-GHD), alone or with multiple hormone deficiencies, such as hypopituitarism as a result of hypothalamic or pituitary disease, radiation therapy, surgery, or trauma; **AND**
 - c. GHD has been confirmed by growth hormone stimulation tests and rule-out of other hormonal deficiency as follows: growth hormone response of fewer than five nanograms per mL to at least two provocative stimuli of growth hormone release: insulin, levodopa, L-Arginine, clonidine, or glucagon when measured by polyclonal antibody (RIA) or fewer than 2.5 nanograms per mL when measured by monoclonal antibody (IRMA); **AND**
 - d. Rule-out other hormonal deficiencies (thyroid, cortisol, or sex steroids)
 - i. Stimulation testing would not produce a clinical response such as in a diagnosis of panhypopituitarism as defined by the absence of all anterior pituitary hormones: luteinizing hormone (LH), follicle stimulating hormone (FSH), thyroid stimulating hormone (TSH), adrenocorticotrophic hormone (ACTH), and growth hormone (GH); **OR**
 - e. Patient has a diagnosis of AIDS Wasting or cachexia (for Serostim® only); **AND**
 - i. Patient has a documented failure, intolerance, or contraindication to appetite stimulants and/or other anabolic agents (both Megace® and Marinol®); **OR**
 - f. Patient has a diagnosis of short bowel syndrome (Zorbitive® only).

Criteria for Denial

1. Failure to meet criteria for authorization; **OR**
2. Constitutional delay of growth and development; **OR**
3. Skeletal dysplasias; **OR**
4. Osteogenesis imperfecta; **OR**
5. Down syndrome and other syndromes associated with short stature and malignant diathesis (Fanconi syndrome and Bloom syndrome); **OR**
6. Continuation of growth hormone treatment once epiphyses are closed; **OR**

7. The following diagnoses for which GH cannot be the primary treatment:
 - a. Obesity; **OR**
 - b. Osteoporosis; **OR**
 - c. Muscular dystrophy; **OR**
 - d. Infertility; **OR**
 - e. Increased athletic performance; **OR**
 - f. Somatopause.

Length of Authorization

Pediatrics: One year.

1. Reauthorization is contingent upon response as shown by growth curve chart. Patient must demonstrate improved/normalized growth velocity. Growth velocity has increased by at least 2 cm in the first year and is greater than 2.5 cm per year and that epiphyses are not fused.

Adults: One year.

1. Reauthorization is contingent upon prescriber affirmation of positive response to therapy (e.g., improved body composition, reduced body fat, and increased lean body mass).

Adults/Serostim: Three months initial; then one year.

1. Reauthorization is contingent upon improvement in lean body mass or weight measurements.

References

Available upon request.

| Review | Reason for Review | Date Approved |
|----------------------------------|-------------------|---------------|
| Pharmacy & Therapeutic Committee | New | 11/02/2006 |
| Commissioner | New | 11/16/2006 |
| Pharmacy & Therapeutic Committee | Update | 04/16/2009 |
| Commissioner | Approval | 05/12/2009 |
| DUR Board | Update | 06/22/2010 |
| Commissioner | Approval | 08/03/2010 |
| DUR Board | Update | 10/11/2016 |
| Commissioner | Approval | 11/22/2016 |
| DUR Board | Update | 09/27/2018 |
| Commissioner Designee | Approval | 11/27/2018 |
| DUR Board | Update | 10/28/2019 |
| Commissioner Designee | Approval | 12/03/2019 |

| Review | Reason for Review | Date Approved |
|-----------------------|-------------------|---------------|
| DUR Board | Update | 12/15/2020 |
| Commissioner Designee | Approval | 02/24/2021 |
| DUR Board | Revision | 06/02/2022 |
| Commissioner Designee | Approval | 07/12/2022 |