New Hampshire Medicaid Fee-for-Service Program Human Growth Hormones Criteria

Approval Date: November 17, 2025

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. Somapacitan-beco (Sogroya) and somatrogon-ghla (Ngenla) are human growth hormone analogs.

Indications

Drug	GHD (ped)	PWS	Turner Syndrome	CKD	SGA	GHD (Adult)	ISS	SHOX	HIV wasting or cachexia	Other
Genotropin	X	X	X		X	X	X			
Humatrope	X		X		X	X	X	X		
Ngenla	X									
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			
Serostim									X	
Skytrofa	X					X				Pediatric patients ≥ 1 year of age and ≥ 11.5 kg
Sogroya	X					X				
Zomacton	X		X		X	X	X	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.

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
Ngenla	somatrogon-ghla	24 mg, 60 mg prefilled pen
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
Serostim	somatropin	5, 6 mg single dose vial, 4 mg multi dose vial
Skytrofa	lonapegsomatropin-tcgd	3, 3.6, 4.3, 5.2, 6.3, 7.6, 9.1, 11, 13.3 mg cartridge
Sogroya	somapacitan-beco	5, 10, 15 mg prefilled pen
Zomacton	somatropin	5, 10 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. (Ngenla, Skytrofa, and Sogroya only): Patient will have had an intolerance to or treatment failure with or inability to comply with 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), adrenocorticotropic hormone (ACTH), and growth hormone (GH); **OR**
2. (Skytrofa and Sogroya only): Patient will have had an intolerance to or treatment failure with or inability to comply with a trial of a short-acting somatropin.

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 (pediatric patients only); **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.

Serostim Only

1. Patient is 18 years of age and older; **AND**
1. Patient has a diagnosis of AIDS Wasting or cachexia; **AND**
2. Patient has a documented failure, intolerance, or contraindication to appetite stimulants and/or other anabolic agents (both Megace and Marinol).

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.

Reviewed By	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
DUR Board	Update	12/15/2020
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