New Hampshire Medicaid Fee-for-Service Program

Human Growth Hormones Criteria

Approval Date: January 22, 2024

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		Hypopituitarism (Adults)
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			
Saizen®	X					X				
Serostim®									X	
Skytrofa®	X									Pediatric patients ≥ 1 year old 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
Saizen®	somatropin	5 mg, 8.8 mg vial
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 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**
   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®); **AND**
2. (Sogroya® only): Patient will have had an intolerance to 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.

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
DUR Board	Update	12/15/2020
Commissioner Designee	Approval	02/24/2021
DUR Board	Revision	06/02/2022
Commissioner Designee	Approval	07/12/2022
DUR Board	Revision	12/08/2023
Commissioner Designee	Approval	01/22/2024