

Growth Hormone Utilization Management Criteria

Drug Class:	Growth Hormone
Non-Preferred Agents:	Serostim(somatropin), Zomacton (somatropin), Humatrope (somatropin), Omnitrope (somatropin), Nutropin AQ Pen (somatropin), Sogroya (somapacitan-beco), Skytrofa (lonapegsomatropin-tcgd), Ngenla Pen (somatrogon-ghla)
Preferred Agents:	Genotropin (somatropin), Norditropin (somatropin)
Implementation Date:	1/1/2026
Prepared For:	CT Medicaid
PDL Status:	Nonpreferred Agents
Background	<p>Growth hormone deficiency (GHD) is a rare disorder characterized by the inadequate secretion of growth hormone from the pituitary gland and presents as short stature and slow growth. GHD can be present at birth (congenital), acquired (as a result of trauma, infection, or radiation), or idiopathic. GHD is treated by injections of synthetic growth hormones for several years to increase the chance the child will attain near-normal adult height.</p> <p>Other conditions that utilize synthetic growth hormones to treat short stature include Turner syndrome, Prader-Willi syndrome (PWS), Noonan syndrome, short stature homeobox-containing gene (SHOX) deficiency, idiopathic short stature (ISS), children born small for gestational age (SGA) and chronic renal insufficiency. Turner syndrome is a condition that affects only females and results from one of the X chromosomes being missing or partially missing. This condition causes short stature, ovarian failure, and heart defects. Turner syndrome does not cause GHD, but patients respond well to GH therapy. PWS is a genetic disorder characterized by low muscle tone, short stature, incomplete sexual development, and a chronic feeling of hunger. Noonan syndrome is a congenital genetic disorder causing short stature, chest deformity, and a distinctive facial appearance. SHOX deficiency is a disease in which short stature is caused by a mutation in one copy of the SHOX gene, resulting in short stature. ISS is defined as having a height significantly shorter than the normal population and no detectable cause for short stature. SGA is any infant whose birth weight and/or length is less than the 3rd percentile (adjusted for prematurity). Characteristics for these children include low birth weight, short birth length, inadequate catch-up growth in the first two years,</p>

	<p>and lack of muscle tone. Additionally, growth failure is a common complication in chronic kidney disease (CKD) and occurs in about one-third of all children with moderate to severe CKD.</p> <p>The following clinical PA criteria was developed following a comprehensive analysis of key synthetic growth hormones and related agents, including Skytrofa®, Sogroya®, Ngenla®, Genotropin®, Norditropin®, Nutropin® AQ, Omnitrope®, Saizen®, Serostim®, Zomacton®, Zorbitive®. Each branded product has distinct labeled indications. Norditropin holds the most indications with seven, followed by Genotropin, Humatrope, Omnitrope, and Zomacton, each with six indications. Serostim is exclusively approved for wasting or cachexia associated with human immunodeficiency virus (HIV) infection. Ngenla is approved solely for pediatric growth hormone (GH) deficiency. Sogroya and Skytrofa are approved for use in children and adults with GH deficiency. Notably, none of these agents have generic equivalents.</p> <p>Contraindications are generally consistent across these products, except for allergies to different diluent preservatives. Meta-cresol is used in the diluents for Humatrope, Saizenprep®, Zomacton 10 mg vials, and Genotropin® cartridges, while benzyl alcohol is the preservative for all other GH products. Additionally, several delivery devices are available for the convenient administration of somatotropin.</p> <p>Clinical practice guidelines generally recommend somatotropin products for treatment of GHD, but do not provide a preference for one agent over another.</p>
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Table 1. Growth Hormone Somatotropin Agents

Generic Name	Brand Name	Approved Indications	Route of Administration	Generic Availability
Lona pegsomatotropin-tcgd	Skytrofa®	Growth failure due to GHD in children; adults with GHD	SC	N
Somapacitan-beco	Sogroya®	Growth failure due to GHD in children; adults with GHD	SC	N
Somatogon-ghla	Ngenla®	Growth failure due to GHD in children	SC	N
Somatotropin	Genotropin®	Growth failure due to GHD, PWS, SGA, TS in children; ISS in children; adults with GHD	SC	N
	Humatrope®	Growth failure due to GHD, TS, SHOX deficiency, SGA in children; ISS in children; adults with GHD	SC	N
	Norditropin® FlexPro®	Growth failure due to GHD, PWS, SGA, TS, and Noonan syndrome in children; ISS in children; adults with GHD	SC	N
	Nutropin AQ® Nuspin	Growth failure due to GHD, CKD, ISS, TS; adults with GHD	SC	N
	Omnitrope®	Growth failure due to GHD, PWS, SGA, TS in children; ISS in children; adults with GHD	SC	N
	Serostim®	Cachexia due to HIV	SC	N
	Zomacton®	growth failure due to GHD, TS, SHOX deficiency, SGA in children; ISS in children; adults with GHD	SC	N

Abbreviations: CKD, chronic kidney disease; GH, growth hormone; GHD, growth hormone deficiency; HIV, human immunodeficiency virus; ISS, idiopathic short stature; PWS, Prader-Willi syndrome; SC, subcutaneous; SGA, short for gestational age; SHOX, short stature homeobox-containing gene; TS, Turner Syndrome.

All authorizations must be prescribed in accordance with FDA approved labeling. Use of samples to initiate therapy does not meet step therapy and/or continuation of therapy prior authorization requirements. Prior therapies will be verified through pharmacy claims and/or submitted chart notes.

Initial Therapy – All the following must be met:

Pediatric Approvals (patients < 18 years of age):

- Prescribed by or in consultation with a pediatric endocrinologist, nephrologist, clinical geneticist, endocrinologist, or gastroenterologist (or as appropriate for diagnosis) **AND**
- No concurrent use with another somatropin agent **AND**
- Must have trialed and failed **ONE** preferred agent with supporting documentation indicating trial dates and reason for failure **AND**
- Documented diagnosis of **ONE** of the following:
 - Prader-Willi syndrome confirmed by genetic testing who are not severely obese or have severe respiratory impairment (*contraindication to therapy*)
 - Turner Syndrome confirmed by chromosome analysis
 - Noonan syndrome confirmed with genetic testing
 - Short stature homeobox-containing gene (SHOX) deficiency confirmed with genetic testing
 - Growth failure in children small for gestational age (SGA)- must meet all of the following:
 - Child was born small for gestational age (SGA), defined as birth weight or length 2 or more standard deviations below the mean for gestational age **AND** participant fails to manifest catch up growth by age two years, defined as height 2 or more standard deviations below the mean for age and sex
 - Chronic renal insufficiency/chronic kidney disease (CKD) with lack of renal transplant in the past year
 - Idiopathic short stature with lack of other identifiable causes of subnormal growth (i.e., hypothyroidism, chronic illness, undernutrition, or genetic disorders)–must meet all of the following:
 - Height is more than 2.25 standard deviations below the mean for chronological age and sex; **AND** Growth velocity measured over 1 year is less than 5 cm/year
 - Growth hormone deficiency or growth failure due to inadequate secretion of endogenous growth hormone–must meet **one** of the following:
 - Height is greater than 2 standard deviations below the mean for age and sex and who have poor growth velocity despite adequate control of metabolic abnormalities and good nutrition **OR**
 - Growth velocity is more than 2 standard deviations below the mean for chronological age and sex **OR**
 - Documentation of suboptimal response (< 10 ng/mL) to any **TWO** standard growth hormone stimulation tests (e.g., arginine, clonidine glucagon, propranolol, levodopa, or insulin); **OR**
 - Low serum insulin-like growth factor I (IGF-I) defined as below -1 standard deviation **AND** failure of 1 GH stimulation test with GH response value < 10 ng/mL **AND**

- *Patients requesting the following growth hormones must meet age and weight requirements per label:*
 - For Skytrofa: Must be at least 1 years of age and weigh at least 11.5 kg
 - For Sogroya: Must be at least 2.5 years of age
 - For Ngenla: Must be at least 3 years of age

Adult Patients (18 years and older)

- Prescribed by or in consultation with an endocrinologist, nephrologist, or gastroenterologist (or as appropriate for diagnosis) **AND**
- No concurrent use with another somatropin agent **AND**
- Must have trialed and failed **ONE** preferred agent with supporting documentation indicating trial dates and reason for failure (*see exceptions for Serostim*) **AND**
- Documented diagnosis of **ONE** of the following:
 - Growth hormone deficiency- must meet **one** of the following:
 - Failure of 2 GH stimulation tests(e.g., insulin, glucagon, arginine, or macimorelin); **OR** Low serum insulin-like growth factor I (IGF-I) defined as below -1 standard deviations **AND** failure of 1 GH stimulation test (e.g., insulin, glucagon, arginine, or macimorelin)

For Serostim: Requests will be approved following documentation of AIDS wasting/cachexia with unintentional weight loss of more than 5% body weight in the past 6 months or >10% loss over 12 months (*no trial and failure of preferred agents required*)

Initial PA length: 6 months (180 days)

Exclusion Criteria:

- Concomitant use of somatropin agent

Continuation Therapy:

- Documented compliance on current therapy regimen (*Exception: Initial therapy requirements apply to both new starts and continued therapy requests for non-preferred somatropin formulations*) **AND**
- Must provide documentation of patient's clinical response to treatment and ongoing safety monitoring (i.e., height, weight gain, improved body composition). For children, evidence that epiphyses have not yet closed. For adults: must provide documentation by endocrinologist that discontinuing agent would have a detrimental effect on body composition or other metabolic parameters.

Continuation Length: 1 year

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Revision History

Date	Version	Revisions
11/14/2025	V1	Document approved by DSS