Washington State Health Care Authority

Human Growth Hormone

Medical policy no. 30.10.00-2 Effective Date: 12/1/2025

Related medical policies:

Policy Name	Indications
N/A	N/A

Note: *New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class documentation of inadequate response to ONE preferred agent is needed. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.*

To see the list of the current Apple Health Preferred Drug List (AHPDL), please visit: https://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx

Medical necessity

Drug	Medical Necessity
lonapegsomatropin (Skytrofa) somapacitan (Sogroya) somatrogon (Ngenla) somatropin (Genotropin MiniQuick) somatropin (Genotropin) somatropin (Humatrope) somatropin (Norditropin FlexPro) somatropin (Nutropin AQ) somatropin (Omnitrope) somatropin (Saizen Click Easy) somatropin (Saizen) somatropin (Saizenprep) somatropin (Serostim) somatropin (Zomacton) somatropin (Zorbtive)	**Human Growth Hormones** may be considered medically necessary in patients who meet the criteria described in the clinical policy below. If all criteria are not met, the clinical reviewer may determine there is a medically necessary need and approve on a case-by-case basis. The clinical reviewer may choose to use the reauthorization criteria when a patient has been previously established on therapy and is new to Apple Health. Patients new to Apple Health or new to an MCO who are requesting regimens for continuation of therapy are reviewed following the reauthorization criteria listed below.

Clinical policy:

Clinical Criteria	
Growth Hormone Therapy in Children and Adolescents (<18 years old) lonapegsomatropin (Skytrofa)	Somatropin (Genotropin MiniQuick), somatropin (Genotropin), or somatropin (Norditropin FlexPro) may be approved when all of the following documented criteria are met: 1. Prescribed by, or in consultation with, an endocrinologist; **AND**

somatrogon-ghla (Ngenla) somapacitan (Sogroya) somatropin (Genotropin MiniQuick) somatropin (Genotropin) somatropin (Humatrope) somatropin (Norditropin FlexPro) somatropin (Nutropin AQ) somatropin (Omnitrope) somatropin (Saizen Click Easy) somatropin (Saizen) somatropin (Saizenprep) somatropin (Zomacton)	2. Patient's epiphyses are not closed (as confirmed by radiograph of the wrist and hand); **AND** 3. Patient has not reached final height; **AND** 4. A diagnosis of one of the following: a. Prader-Willi Syndrome; **OR** b. Short stature associated with chronic renal insufficiency; **AND** i. Dialysis or a glomerular filtration rate (GFR) less than 60 ml/min/1.73m^2; **AND** ii. Height is below the 5th percentile for age and sex; **AND** iii. Growth velocity is below the 25th percentile for age and sex for a minimum of 1 year; **OR** c. Short stature associated with Turner Syndrome, Noonan Syndrome, or SHOX gene deficiency; **AND** i. Height is below the 10th percentile for age and sex; **OR** d. Diagnosis of Growth Hormone Deficiency (GHD); **AND** i. Patient meets one of the following: 1. Height is below the 3rd percentile (more than 2SDs for age and sex); **OR** 2. Height is below the 5th percentile for age and sex with a growth velocity below the 25th percentile for a minimum of 1 year; **AND** ii. Patient meets one of the following: 1. At least two growth hormone stimulation tests less than reference range; **OR** 2. At least one growth hormone stimulation test less than reference range and IGF-1 and IGFBP-3 are below normal; **OR** 3. IGF-1 and IGFBP-3 are severely low (<-2 SD) with delayed bone age; **OR** 4. GHD with additional pituitary hormone deficiencies (e.g. TSH, ACTH, gonadotropins, ADH, etc.); **OR** e. The patient has congenital GHD represented by an acute episode of hypoglycemia with low serum growth hormone levels; **OR** f. Diagnosis of idiopathic short stature or growth failure in children born small for gestational age (SGA); **AND** i. Height remains more than 2.25 SDs below the mean age and gender at two years of age; **AND** ii. Adult height, based on bone age, is expected to be below the normal range (less than 63 inches for males and 59 inches for females)**; AND**

	iii. Provider attests risks and benefits of growth hormone treatment have been discussed with patient and patient's guardian(s) Lonapegsomatropin (Skytrofa), somapacitan (Sogroya), somatrogon-ghla (Ngenla), somatropin (Humatrope), somatropin (Nutropin AQ), somatropin (Omnitrope), somatropin (Saizen Click Easy), somatropin (Saizen), somatropin (Saizenprep), or somatropin (Zomacton) may be approved when all of the following documented criteria are met: 1. Criteria 1 through 4 is met above; **AND** 2. One of the following: a. Treatment with at least two preferred human growth hormone products on the Apple Health Preferred Drug List (PDL) has been ineffective, contraindicated, or not tolerated; **OR** b. A preferred product is not FDA approved for the requested indication per Table 1 in the appendix If ALL criteria are met, the request will be authorized for **6 months.** **Criteria (Reauthorization)** Somatropin (Genotropin MiniQuick), somatropin (Genotropin), somatropin (Norditropin FlexPro) Lonapegsomatropin (Skytrofa), somapacitan (Sogroya), somatrogon-ghla (Ngenla), somatropin (Humatrope), somatropin (Nutropin AQ), somatropin (Omnitrope), somatropin (Saizen Click Easy), somatropin (Saizen), somatropin (Saizenprep), or somatropin (Zomacton) may be approved when all of the following documented criteria are met: 1. Patient's epiphyses are not closed (as confirmed by radiograph of the wrist and hand); **AND** 2. Patient has not reached final height; **AND** 3. Patient has shown a response to growth hormone therapy (i.e., increase in height, increase in height velocity) If ALL criteria are met, the request will be authorized for **12 months.**
Growth Hormone Therapy in Adults (18 or older) somapacitan (Sogroya) somatropin (Genotropin MiniQuick) somatropin (Genotropin) somatropin (Humatrope) somatropin (Norditropin FlexPro) somatropin (Nutropin AQ) somatropin (Omnitrope) somatropin (Saizen Click Easy)	Somatropin (Genotropin MiniQuick), somatropin (Genotropin), or somatropin (Norditropin FlexPro) may be approved when all of the following documented criteria are met: 1. Prescribed by, or in consultation with, endocrinologist; **AND** 2. Diagnosis of Growth Hormone Deficiency (GHD); **AND** a. Documentation of three or more pituitary hormone deficiencies (e.g. TSH, ACTH, gonadotropins, ADH, etc.) with a low IGF-1 level (<-2 standard deviation score); **OR**

somatropin (Saizen) somatropin (Saizenprep) somatropin (Zomacton)	b. Child onset GHD, or GHD due to pituitary disease, hypothalamic disease, pituitary surgery, cranial radiation therapy, traumatic brain injury, or other condition affecting pituitary function; **AND** i. Low IGF-1 level (<0 standard deviation score); **AND** ii. A subnormal response to a provocative growth hormone (GH) stimulation test defined as one of the following: 1. Macimorelin test - ≤2.8 ng/mL 2. Insulin tolerance test (ITT) -≤5 ng/mL 3. Glucagon-stimulation test (GST) - ≤ 3 ng/mL; **AND** 3. Clinical features of GHD, including but not limited to osteopenia, increased cardiovascular risk, or decreased quality of life, are documented in the chart notes. Somapacitan (Sogroya), somatropin (Humatrope), somatropin (Norditropin FlexPro), somatropin (Nutropin AQ), somatropin (Omnitrope), somatropin (Saizen Click Easy), somatropin (Saizen), somatropin (Saizenprep), and somatropin (Zomacton) may be approved when all of the following documented criteria are met: 1. Criteria 1 through 3 are met above; **AND** 2. Treatment with at least two preferred human growth hormone products on the Apple Health Preferred Drug List (PDL) has been ineffective, contraindicated, or not tolerated If ALL criteria are met, the request will be authorized for **6 months.**
	Criteria (Reauthorization) Somapacitan (Sogroya), somatropin (Genotropin MiniQuick), somatropin (Genotropin), somatropin (Humatrope), somatropin (Norditropin FlexPro), somatropin (Nutropin AQ), somatropin (Omnitrope), somatropin (Saizen Click Easy), somatropin (Saizen), somatropin (Saizenprep), somatropin (Zomacton), may be approved when all of the following documented criteria are met: 1. Diagnosis of Growth Hormone Deficiency (GHD); **AND** 2. Patient has shown clinical benefits from growth hormone replacement as assessed by one of the following: a. Normalization of insulin-like growth factor I (IGF-I); **OR** b. Improvement in body composition (i.e. bone density increase, lipolysis changes) If ALL criteria are met, the request will be authorized for **12 months.**
Short Bowel Syndrome somatropin (Zorbtive)	Somatropin (Zorbtive) may be approved when all the following documented criteria are met:

	1. Prescribed by, or in consultation with, an endocrinologist or gastroenterologist; **AND** 2. Patient is 18 years of age or older; **AND** 3. Patient has a diagnosis of short bowel syndrome; **AND** 4. Patient is currently on specialized nutritional support that has been protein, calorie, and fluid intake-optimized for at least two weeks; **AND** 5. The request is for somatropin (Zorbtive) If ALL criteria are met, the request will be authorized for a 4-week treatment course to be used within **6 months.** **Criteria (Reauthorization)** Somatotropin (Zorbitive) may not be reauthorized
HIV/AIDS associated wasting or cachexia Somatropin (Serostim)	Somatotropin (Serostim) may be approved when all the following documented criteria are met: 1. Prescribed by, or in consultation with, an endocrinologist or HIV specialist; **AND** 2. Patient is 18 years of age or older; **AND** 3. Patient has a diagnosis of HIV/AIDs with wasting or cachexia; **AND** 4. Treatment with an appetite stimulant (dronabinol or megestrol) has been ineffective, contraindicated, or not tolerated; **AND** 5. The request is for somatropin (Serostim); **AND** 6. Patient has not received more than 48 continuous weeks of somatropin therapy If ALL criteria are met, the request will be authorized for **6 months** **Criteria (Reauthorization)** Somatropin (Serostim) may be approved when all the following documented criteria are met: 1. Diagnosis of HIV/AIDS with wasting or cachexia; **AND** 2. Patient has shown clinical benefits by an increase in muscle mass and weight from growth hormone replacement; **AND** 3. Patient has not received more than 48 continuous weeks of therapy If ALL criteria are met, the request will be authorized for **6 months**

Dosage and quantity limits

Drug	Indication	FDA Approved Dosing and Quantity Limit	Dosage Form
Genotropin	• Growth hormone deficiency (GHD), children • Growth hormone deficiency (GHD), adults • Idiopathic short stature • Prader-Willi syndrome • Small for gestational age • Turner syndrome	• Pediatric GHD: 0.24 mg/kg/week • Adult GHD: 0.08 mg/kg/week • Idiopathic short stature: 0.47 mg/kg/week • Prader-Willi syndrome: 0.24 mg/kg/week • Small for gestational age: 0.48 mg/kg/week	• 5 mg/mL cartridge • 12 mg/mL cartridge
Genotropin MiniQuick	• Growth hormone deficiency (GHD), children • Growth hormone deficiency (GHD), adults • Idiopathic short stature • Prader-Willi syndrome • Small for gestational age • Turner syndrome	• Pediatric GHD: 0.24 mg/kg/week • Adult GHD: 0.08 mg/kg/week • Idiopathic short stature: 0.47 mg/kg/week • Prader-Willi syndrome: 0.24 mg/kg/week • Small for gestational age: 0.48 mg/kg/week	• 0.2 mg/0.25 mL syringe • 0.4 mg/0.25 mL syringe • 0.6 mg/0.25 mL syringe • 0.8 mg/0.25 mL syringe • 1 mg/0.25 mL syringe • 1.2 mg/0.25 mL syringe • 1.4 mg/0.25 mL syringe • 1.6 mg/0.25 mL syringe • 1.8 mg/0.25 mL syringe • 2 mg/0.25 mL syringe
Humatrope	• Growth hormone deficiency (GHD), children • Growth hormone deficiency (GHD), adults • Idiopathic short stature • Short stature homeobox-containing gene (SHOX) deficiency • Small for gestational age • Turner syndrome	• Pediatric GHD: 0.3 mg/kg/wee • Adult GHD: 0.0875 mg/kg/week (0.0125 mg/kg/day) • Idiopathic short stature: 0.37 mg/kg/week • SHOX deficiency: 0.35 mg/kg/week • Small for gestational age: 0.47 mg/kg/week • Turner syndrome: 0.375 mg/kg week	• 5 mg vial • 6 mg cartridge • 12 mg cartridge • 24 mg cartridge
Norditropin FlexPro	• Growth hormone deficiency (GHD), children • Growth hormone deficiency (GHD), adults • Idiopathic short stature • Noonan syndrome • Prader-Willi syndrome • Small for gestational age • Turner syndrome	• Pediatric GHD: 0.24 mg/kg/week • Adult GHD: 0.112 mg/kg/week (0.016 mg/kg/day) • Idiopathic short stature: 0.47 mg/kg/week • Noonan syndrome: 0.46 mg/kg/week • Prader-Willi syndrome: 0.24 mg/kg/week • Small for gestational age: 0.47 mg/kg/week • Turner syndrome: 0.47 mg/kg week	• 5 mg/1.5 mL pen injector • 10 mg/1.5 mL pen injector • 15 mg/1.5 mL pen injector • 30 mg/3 mL pen injector

Nutropin AQ	• Growth hormone deficiency (GHD), children
	• Growth hormone deficiency (GHD), adults
	• Growth failure associated with chronic renal insufficiency (CRI)
	• Idiopathic short stature
	• Turner syndrome
		• Pediatric GHD: 0.3 mg/kg/week
		• Adult GHD:
		  ○ Age 18-35 years: 0.175 mg/kg/week (0.025 mg/kg/day)
		  ○ Age >36 years: 0.0875 mg/kg/week (0.0125 mg/kg/day)
		• CRI: 0.35 mg/kg/week
		• Idiopathic short stature: 0.3 mg/kg/week
		• Turner syndrome: 0.375 mg/kg week
			• 5 mg/2 mL pen injector
			• 10 mg/2 mL pen injector
			• 20 mg/2 mL pen injector

Omnitrope	• Growth hormone deficiency (GHD), children • Growth hormone deficiency (GHD), adults • Idiopathic short stature • Prader-Willi syndrome • Small for gestational age • Turner syndrome	• Pediatric GHD: 0.24 mg/kg/week • Adult GHD: 0.08 mg/kg/week • Idiopathic short stature: 0.47 mg/kg/week • Prader-Willi syndrome: 0.24 mg/kg/week • Small for gestational age: 0.48 mg/kg/week • Turner syndrome: 0.33 mg/kg week	• 5.8 mg vial • 5 mg/1.5 mL cartridge • 10 mg/1.5 mL cartridge
Saizen	• Growth hormone deficiency (GHD), children • Growth hormone deficiency (GHD), adults	• Pediatric GHD: 0.18 mg/kg/week • Adult GHD: 0.07 mg/kg/week (0.01 mg/kg/day)	• 5 mg vial • 8.8 mg vial • 8.8 mg/1.51 mL cartridge • 8.8 mg cartridge
Saizen Click Easy	• Growth hormone deficiency (GHD), children • Growth hormone deficiency (GHD), adults	• Pediatric GHD: 0.18 mg/kg/week • Adult GHD: 0.07 mg/kg/week (0.01 mg/kg/day)	• 5 mg vial • 8.8 mg vial • 8.8 mg/1.51 mL cartridge • 8.8 mg cartridge
Saizenprep	• Growth hormone deficiency (GHD), children • Growth hormone deficiency (GHD), adults	• Pediatric GHD: 0.18 mg/kg/week • Adult GHD: 0.07 mg/kg/week (0.01 mg/kg/day)	• 5 mg vial • 8.8 mg vial • 8.8 mg/1.51 mL cartridge • 8.8 mg cartridge
Serostim	Wasting or cachexia associated with HIV	• 28 vials/28 days	• 4 mg vial • 5 mg vial • 6 mg vial
Sogroya	• Growth hormone deficiency (GHD), children • Growth hormone deficiency (GHD), adults	• 6 mL/28 days	• 10 mg/1.5 mL pen
Zomacton	• Growth hormone deficiency (GHD), children • Growth hormone deficiency (GHD), adults • Idiopathic short stature • Short stature homeobox-containing gene (SHOX) deficiency • Small for gestational age • Turner syndrome	• Pediatric GHD: 0.3 mg/kg/week • Adult GHD: 0.0875 mg/kg/week (0.0125 mg/kg/day) • Idiopathic short stature: 0.37 mg/kg/week • SHOX deficiency: 0.35 mg/kg/week • Small for gestational age: 0.47 mg/kg/week • Turner syndrome: 0.375 mg/kg week	• 5 mg vial • 10 mg vial
Zorbtive	Short bowel syndrome	• 28 vials/28 days	• 8.8 mg vial
Ngenla	Growth hormone deficiency (GHD), children	• 1.2mL/28 days	• 24mg/1.2mL • 60mg/1.2mL
Skytrofa	Growth hormone deficiency (GHD), children	• 4 cartridges/28 days	• 3.0 mg cartridge • 3.6 mg cartridge • 4.3 mg cartridge • 5.2 mg cartridge • 6.3 mg cartridge • 7.6 mg cartridge • 9.1 mg cartridge • 11.0 mg cartridge • 13.3 mg cartridge

Coding:

HCPCS Code	Description
J2941	Injection, somatropin, 1 mg

Background:

Prescription human growth hormones are purified polypeptide hormones of recombinant DNA origin. Other than device and FDA approved indications, there is little to no differentiation between these products. Human growth hormone stimulates growth of linear bone, skeletal muscle, and organs, and stimulates erythropoietin which increases red blood cell mass, exerts both insulin-like and diabetogenic effects, and enhances the transmucosal transport of water, electrolytes, and nutrients across the gut. In short- bowel syndrome, growth hormone may directly stimulate receptors in the intestinal mucosa or indirectly stimulate the production of insulin-like growth factor-I which is known to mediate many of the cellular actions of growth hormone.

Growth Hormone Therapy in Children and Adolescents
The most common causes of short stature beyond the first year or two of life are familial (genetic) short stature and delayed (constitutional) growth, which are normal, non-pathologic variants of growth. Pathologic causes of short stature in children can be varied. These can include but are not be limited to genetic diseases (Turner syndrome, SHOX gene variants, Prader-Willi syndrome, Noonan syndrome), growth hormone deficiency, infants born small for gestational age (SGA), and chronic renal insufficiency. Pediatric Endocrine Society guidelines provide recommendations for the clinical management of children and adolescents with growth failure however guidelines do not recommend one product over another.

Growth Hormone Therapy in Adults
Growth hormone deficiency in an adult is based on the combination of documented pituitary or hypothalamic disease, panhypopituitarism, and a subnormal serum insulin-like growth factor-1 (IGF-1) concentration. AACE guidelines provide recommendations for the clinical management for the management of growth hormone deficiency in adults; however, guidelines do not recommend one product over another.

Approval of human growth hormone (Zorbtive) for short bowel syndrome (SBS) was based on the results of a randomized, double-blind, controlled, parallel-group phase III clinical study of growth hormone in subjects with SBS who were dependent on intravenous parenteral nutrition (IPN) for nutritional support. There is a lack of data to support other growth hormone agents for use in SBS.

Growth hormone (Serostim) has been approved for HIV/AIDS wasting syndrome. Wasting syndrome refers to unwanted weight loss of more than 10 percent of a person's body weight, with either diarrhea or weakness and fever that have lasted at least 30 days. Per package insert, there is no safety or efficacy data available from controlled studies in which patients were treated with Serostim continuously for more than 48 weeks. There is a lack of data to support other growth hormone agents for use in HIV/AIDS wasting syndrome.

References

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History

Approved Date	Effective Date	Version	Action and Summary of Changes
4/16/2025	12/1/2025	30.10.00-2	Updated criteria for provocative growth hormone (GH) stimulation test criteria in Growth Hormone Therapy in Adults (18 or older)
4/16/2025	10/1/2025	30.10.00-2	- Updated formatting - Updated children growth hormone therapy to align with standard of care - Aligned adult growth hormone deficiency criteria with 2019 American Academy of Endocrinology guidelines - Specified preferred products

Previous policy changes (relevant from Human Growth Hormone policy version 1)	
Date	**Action and Summary of Changes**
10/14/2024	Added note and Apple Health PDL link to the top of the page.
08/16/2017	New Policy.

Appendix

Table 1

FDA Approved Indications for Growth Hormone Products											
Brand	**GHD**		**TS**	**ISS**	**SGA**	**PWS**	**CKD**	**NS**	**SHOX**	**HIV**	**SBS**
	Ch	**Ad**									
Genotropin	x	x	x	x	x	x					
Humatrope	x	x	x	x	x				x		
Ngenla	x										
Norditropin	x	x	x	x	x	x		x			
Nutropin AQ	x	x	x	x			x				
Omnitrope	x	x	x	x	x	x					
Saizen	x	x									
Zomacton	x	x	x	x	x				x		
Skytrofa	x										
Sogroya	x	x									
Serostim										x	
Zorbtive											x

GHD = Growth Hormone Deficiency (Ch = Children, Ad = Adult)
TS = Turner Syndrome
ISS = Idiopathic Short Stature
SGA = Growth failure in children born Small for Gestational Age
PWS = Prader-Willi Syndrome in children
CKD = Growth failure due to chronic kidney disease
NS = Noonan Syndrome
SHOX = Short stature homeobox-containing gene deficiency
HIV = HIV-associated Wasting or Cachexia
SBS = Short Bowel Syndrome