Washington State Health Care Authority

Human Growth Hormone

Medical policy no. 30.10.00-2 Effective Date: TBD

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 2.25 SDs 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 two 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 a provocative growth hormone (GH) stimulation test defined as: 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. Prescribed by, or in consultation with, endocrinologist; **AND** 2. Criteria 1 through 3 are met above; **AND** 3. 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 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 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 (Humatrope, Genotropin Nutropin, Biotropin, Genotropin, Genotropin Miniquick, Norditropin, Nutropin,

	Nutropin AQ, Saizen, Saizen Somatropin RDNA Origin, Serostim, Zorbtive)

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

1. Somatropin. Drug Facts & Comparisons [online; updated periodically]. Available from Wolters Kluwer Health, Inc.
2. Somatropin. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com/
3. Omnitrope [Prescribing information]. Princeton, NJ: Sandoz Inc. March 2024.
4. Norditropin [Prescribing Information]. Bagsvaerd, Denmar: Novo Nordisk; March 2020.
5. Saizen [Prescribing Information]. Rockland, MA: EMD Serono Inc.; Feburary 2020.
6. Serostim [Prescribing Information]. Rockland, MA: EMD Serono Inc.; June 2019.
7. Zorbtive[Prescribing Information]. Rockland, MA: EMD Serono Inc.; May 2017.

8. Humatrope [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC; December 2023.
9. Genotropin [Prescribing Information]. Belgium N.V., Puurs, Belgium: Pfizer Manufacturing; August 2024.
10. Zomacton [Prescribing Information]. Parsippany, NJ: Ferring Pharmaceuticals; April 2024.
11. Sogroya [Prescribing information]. Plainsboro, NJ: Novo Nordisk. October 2021. Updated April 2023.
12. Skytrofa [Prescribing information]. Palo Alto, CA: Ascendis Pharma, Inc. May 2024.
13. Ngenla [Prescribing information]. Pfizer. New York, NY. June 2023.
14. Grimberg A, DiVall SA, Polychronakos C, et al. Guidelines for growth hormone and insulin-like growth factor-i treatment in children and adolescents: growth hormone deficiency, idiopathic short stature, and primary insulin-like growth factor-i deficiency. *Horm Res Paediatr*. 2016;86(6):361-397.
15. Yuen KCJ, Biller BMK, Radovick S, et al. American association of clinical endocrinologists and american college of endocrinology guidelines for management of growth hormone deficiency in adults and patients transitioning from pediatric to adult care. *Endocr Pract*. 2019;25(11):1191-1232.
16. Grimberg A, Divall SA, Polychronakos C, et al. Guidelines for Growth Hormone and Insulin-Like Growth Factor-I Treatment in Children and Adolescents: Growth Hormone Deficiency, Idiopathic Short Stature, and Primary Insulin-Like Growth Factor-I Deficiency. Horm Res Paediatr. 2016;86(6):361-397.
17. Molitch ME, Clemmons DR, Malozowski S, Merriam GR, Vance ML. Evaluation and treatment of adult growth hormone deficiency: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2011;96(6):1587-609.
18. Consensus guidelines for the diagnosis and treatment of growth hormone (GH) deficiency in childhood and adolescence: summary statement of the GH Research Society. GH Research Society. J Clin Endocrinol Metab. 2000;85(11):3990-3.
19. Deal CL, Tony M, Höybye C, et al. GrowthHormone Research Society workshop summary: consensus guidelines for recombinant human growth hormone therapy in Prader-Willi syndrome. *J Clin Endocrinol Metab*. 2013;98(6):E1072-1087.
20. Drube J, Wan M, Bonthuis M, et al. Clinical practice recommendations for growth hormone treatment in children with chronic kidney disease. *Nat Rev Nephrol*. 2019;15(9):577-589.
21. Gravholt CH, Andersen NH, Christin-Maitre S, et al. Clinical practice guidelines for the care of girls and women with Turner syndrome. *Eur J Endocrinol*. 2024;190(6):G53-G151.

History

Approved Date	Effective Date	Version	Action and Summary of Changes
TBD	**TBD**	XX.XX.XX-X	Pending Approval (draft/unpublished version) -Creation of 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

Washington State Health Care Authority

Human Growth Hormone

Please provide the information below, please print your answer, attach supporting documentation, sign, date, and return to our office as soon as possible to expedite this request. **Without this information, we may deny the request in seven (7) working days.**

Date of request:	Reference #:	MAS:	
Patient	Date of birth	ProviderOne ID	
Pharmacy name	Pharmacy NPI	Telephone number	Fax number
Prescriber	Prescriber NPI	Telephone number	Fax number
Medication and strength	Directions for use	Qty/Days supply	

1. Is this request for a continuation of existing therapy? ☐ Yes ☐ No

2. Is this prescribed by, or in consultation with, any of the following? Check all that apply:
   ☐ Endocrinologist ☐ Gastroenterologist ☐ HIV specialist
   ☐ Other. Specify: _____

3. If request is non-preferred, has patient had treatment with one or more preferred growth hormone medications on the Apple Health Preferred Drug List (AHPDL) that was ineffective, contraindicated or not tolerated?
   ☐ Yes. List each medication and duration of trial:

   Medication Name: _____ Duration: _____
   Medication Name: _____ Duration: _____
   Medication Name: _____ Duration: _____

   ☐ No. Explain why a preferred product(s) has not been tried (i.e., preferred product(s) is not FDA approved for the requested indication): _____

4. What is patient weight?
   Baseline weight (pre-treatment): _____kg Date taken: _____
   Current weight: _____kg Date taken: _____

5. What is patient's height?
   Baseline height (pre-treatment): _____kg Date taken: _____
   Current height: _____ Date taken: _____

6. Indicate patient's diagnosis and answer the associated questions as indicated:
   ☐ Growth Hormone Deficiency in Children and Adolescents, <18 years old (questions 7-9)
   ☐ Growth Hormone Deficiency in Adults, 18 or older (questions 10 – 11)
   ☐ HIV/AIDS associated wasting or cachexia (questions 13 - 15)
   ☐ Short bowel syndrome (question 12)
   ☐ Other. Specify: _____

For Growth Hormone Therapy in Children and Adolescents (<18 years old)

7. Indicate all that apply:
   - ☐ Patient's epiphyses are not closed (as confirmed by radiograph of the wrist and hand)
   - ☐ Patient has not reached final height

8. Indicate patient diagnosis and answer associated questions:
   - ☐ Prader-Willi Syndrome

   - ☐ Short stature associated with chronic renal insufficiency:
     - Is dialysis or a glomerular filtration rate (GFR) less than 60 ml/min/1.73m^2? ☐ Yes ☐ No
     - Is height is below the 5th percentile for age and sex? ☐ Yes ☐ No
     - Is growth velocity is below the 25th percentile for age and sex for a minimum of 1 year? ☐ Yes ☐ No

   - ☐ Short stature associated with Turner Syndrome, Noonan Syndrome, or SHOX gene deficiency:
     - Is height is below the 10th percentile for age and sex? ☐ Yes ☐ No

   - ☐ Growth Hormone Deficiency (GHD):
     - Does the patient have congenital GHD represented by acute hypoglycemia with low serum growth hormone levels? ☐ Yes ☐ No
     - Is height is below the 3rd percentile (more than 2.25 SDs for age and sex)? ☐ Yes ☐ No
     - Is height is below the 5th percentile for age and sex with a growth velocity below the 25th percentile for a minimum of 1 year? ☐ Yes ☐ No
     - Does patient meet one of the following?:
       - ☐ At least two growth hormone stimulation tests less than reference range
       - ☐ At least one growth hormone stimulation test less than reference range and IGF-1 and IGFBP-3 are below normal
       - ☐ IGF-1 and IGFBP-3 are severely low (<-2 SD) with delayed bone age
       - ☐ GHD with additional pituitary hormone deficiencies

   - ☐ Idiopathic short stature or growth failure in children born small for gestational age (SGA):
     - Does height remain more than two SDs below the mean age and gender at two years of age? ☐ Yes ☐ No
     - Is adult height, based on bone age, expected to be below the normal range (less than 63 inches for males and 59 inches for females)? ☐ Yes ☐ No
     - Does provider attest risks and benefits of growth hormone treatment have been discussed with patient and patient's guardian(s)? ☐ Yes ☐ No

9. **For continuation of therapy:** Has patient shown a response to growth hormone therapy (i.e., increase in height, increase in height velocity)? ☐ Yes ☐ No

For Growth Hormone Deficiency (18 or older)

10. Indicate if patient has any of the following (check all that apply):
    - ☐ 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)
    - ☐ Documentation of childhood onset GHD or GHD due to pituitary disease, hypothalamic disease, pituitary surgery, cranial radiation therapy, traumatic brain injury, or other condition affecting pituitary function
    - ☐ Documented clinical features of GHD, including but not limited to osteopenia, increased cardiovascular risk, or decreased quality of life
    - ☐ Low IGF-1 level (<0 standard deviation score)

☐ A subnormal response to a provocative growth hormone (GH) stimulation test defined by(check all that apply):
- ☐ Macimorelin test - ≤2.8 ng/mL
- ☐ Insulin tolerance test (ITT) -≤5 ng/mL
- ☐ Glucagon-stimulation test (GST) - ≤ 3 ng/mL

11. **For continuation of therapy:** Has patient shown clinical benefits from growth hormone replacement as assessed by one of the following:
    - ☐ Normalization of insulin-like growth factor I (IGF-I)
    - ☐ Improvement in body composition (i.e. bone density increase, lipolysis changes)

For Short Bowel Syndrome:

12. Is patient currently on specialized nutritional support that has been protein, calorie, and fluid intake-optimized for at least two weeks? ☐ Yes ☐ No

For HIV/AIDS associated wasting or cachexia:

13. Has patient been treated with an appetite stimulant (dronabinol or megestrol) that has been ineffective, contraindicated, or not tolerated? ☐ Yes ☐ No

14. Has patient previously received somatropin therapy? ☐ Yes ☐ No
    If yes, how many weeks of somatropin therapy has patient received? _____Weeks

15. **For continuation of therapy:** Has patient shown clinical benefits by an increase in muscle mass and weight from growth hormone replacement? ☐ Yes ☐ No

CHART NOTES ARE REQUIRED WITH THIS REQUEST		
Prescriber signature	Prescriber specialty	Date