

**Growth Hormone
Effective 01/01/2022**

Plan	<input type="checkbox"/> MassHealth <input checked="" type="checkbox"/> MH UPPL <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
Specialty Limitations	These medications have been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Approvable Diagnoses:

Pediatric requests (linear growth potential remaining):

- Short stature or growth failure due to:
 - GH deficiency
 - Noonan syndrome
 - Prader-Willi syndrome
 - Turner syndrome
 - Chronic renal failure up to time of renal transplantation
 - Small for gestational age/Intrauterine growth restriction (SGA/IUGR) with failed catch-up growth by age 2 to 4
- Hypoglycemia due to GH deficiency

Adult requests (no linear growth potential remaining):

- GH deficiency
- HIV/AIDS-associated wasting or cachexia (not covered for AIDS- or HAART-associated lipodystrophy)
- Short bowel syndrome

No PA	PA Required
	Genotropin [®] (somatropin) ^{PD}
	Humatrope [®] (somatropin)
	Norditropin [®] (somatropin)
	Nutropin AQ [®] (somatropin)

	Omnitrope [®] (somatropin)
	Saizen [®] (somatropin)
	Serostim [®] (somatropin)
	Zomacton [®] (somatropin)
	Zorbtive [®] (somatropin)

^{PD} Preferred Drug. In general, a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

Coverage Guidelines

Pediatric Indications

Pediatric growth hormone (GH) deficiency/ panhypopituitarism:

Prescriber provides documentation of **ALL** of the following:

1. Member has a diagnosis of GH deficiency or panhypopituitarism
2. Member has a short stature or growth failure, documented by one of the following:
 - Pre-treatment height less than -2 standard deviations below mean or below 3rd percentile on standard pediatric growth chart
 - Height dropping below initial percentile curve on standard pediatric growth chart when monitored over 1 year
 - Growth velocity below the 10th percentile for age and gender as defined by one of the following:
 - Age two to four years: <5.5 cm/year (<2.2 inches/year)
 - Age four to six years: <5 cm/year (<2 inches/year)
 - Females age six years to puberty: <4.5 cm/year (<1.8 inches/year)
 - Males age six years to puberty: <4 cm/year (<1.6 inches/year)
1. Prescriber has provided documentation of **ONE** of the following*:
 - a. Results of two abnormal tests, which can be either:
 - i. Two abnormal GH stimulation tests
 - ii. One abnormal stimulation test and one abnormal IGF-1/IGFBP-3 level
 - b. **ONE** abnormal test (GH stimulation, IGF-1, or IGFBP-3 test), with either:
 - i. Abnormal pituitary imaging
 - ii. Deficiency of at least three other pituitary hormones (TSH, ACTH, LH, FSH, or AVP/ADH)
 - iii. Appropriate current medication claims suggesting deficiency of at least three other pituitary hormones (levothyroxine, hydrocortisone or other glucocorticoid, testosterone [for males] or estrogen/progesterone [for females], or desmopressin)
2. Prescriber has provided documentation of **ONE** of the following:
 - a. Member is under the care of an endocrinologist
 - b. Other possible causes of short stature or growth failure have been ruled out (i.e. hypothyroidism, malnutrition, chronic illness, skeletal disorders, pituitary tumor)
3. Requests for all agents other than Genotropin[®], prescriber provides clinical rationale for use of the requested agent instead of Genotropin[®]

**Cases where imaging shows NO PITUITARY may be approved without requiring laboratory tests, if the member meets all other criteria.*

Hypoglycemia due to growth hormone (GH) deficiency:

Prescriber provides documentation of **ALL** of the following:

1. Member has a diagnosis of hypoglycemia due to growth hormone (GH) deficiency

2. Laboratory results indicating GH deficiency: At least one abnormal GH stimulation test.
3. Hypoglycemia-symptoms and low glucose level. Lower end of normal range is 75 mg/dL (4.2 mM/L) although symptoms are rare unless glucose is lower than 50 mg/dL.
4. Prescriber has provided laboratory results indicating GH deficiency (at least one abnormal GH stimulation test)
5. Requests for all agents other than Genotropin[®], prescriber provides clinical rationale for use of the requested agent instead of Genotropin[®]

Noonan, Prader-Willi, or Turner syndrome:

Prescriber provides documentation of **ALL** of the following:

1. Member has a diagnosis of Noonan, Prader-Willi, or Turner syndrome **AND**
2. Member has a short stature or growth failure, documented by one of the following:
 - a. Pre-treatment height less than -2 standard deviations below mean or below 3rd percentile on standard pediatric growth chart
 - b. Height dropping below initial percentile curve on standard pediatric growth chart when monitored over 1 year
 - c. Growth velocity below the 10th percentile for age and gender as defined by one of the following:
 - Age two to four years: <5.5 cm/year (<2.2 inches/year)
 - Age four to six years: <5 cm/year (<2 inches/year)
 - Females age six years to puberty: <4.5 cm/year (<1.8 inches/year)
 - Males age six years to puberty: <4 cm/year (<1.6 inches/year)
3. Prescriber has provided documentation of **ONE** of the following*:
 - a. Genetic testing confirming diagnosis
 - b. Appropriate clinical rationale for why genetic testing cannot be provided (i.e. member is new to prescriber and current prescriber has no means of obtaining labs used for diagnosis, diagnosis made many years ago)
4. Requests for all agents other than Genotropin[®], prescriber provides clinical rationale for use of the requested agent instead of Genotropin[®]

Chronic renal failure up to time of renal transplantation:

1. Member has a diagnosis of chronic renal failure up to time of renal transplantation
2. Member has a short stature or growth failure, documented by one of the following:
 - a. Pre-treatment height less than -2 standard deviations below mean or below 3rd percentile on standard pediatric growth chart
 - b. Height dropping below initial percentile curve on standard pediatric growth chart when monitored over 1 year
 - c. Growth velocity below the 10th percentile for age and gender as defined by one of the following:
 - Age two to four years: <5.5 cm/year (<2.2 inches/year)
 - Age four to six years: <5 cm/year (<2 inches/year)
 - Females age six years to puberty: <4.5 cm/year (<1.8 inches/year)
 - Males age six years to puberty: <4 cm/year (<1.6 inches/year)
3. Prescriber has provided documentation of **ONE** of the following:
 - a. Other CRF-associated etiologies have been excluded: acidosis, secondary hyperparathyroidism, malnutrition or zinc deficiency
 - b. Member is under the care of a renal specialist
4. Requests for all agents other than Genotropin[®], prescriber provides clinical rationale for use of the



requested agent instead of Genotropin®

Small for gestational age/Intrauterine growth restriction (SGA/IUGR) with failed catch-up growth by age 2 to 4:

1. Member has a diagnosis of small for gestational age/intrauterine growth restriction (SGA/IUGR) with failed catch-up growth by age 2 to 4
2. Member is at least 2 years of age or older
3. Member has a short stature or growth failure, documented by **ONE** of the following:
 - a. Pre-treatment height less than -2 standard deviations below mean or below 3rd percentile on standard pediatric growth chart
 - b. Height dropping below initial percentile curve on standard pediatric growth chart when monitored over 1 year
 - c. Growth velocity below the 10th percentile for age and gender as defined by one of the following:
 - Age two to four years: <5.5 cm/year (<2.2 inches/year)
 - Age four to six years: <5 cm/year (<2 inches/year)
 - Females age six years to puberty: <4.5 cm/year (<1.8 inches/year)
 - Males age six years to puberty: <4 cm/year (<1.6 inches/year)
4. Diagnosis of SGA/IUGR, **ONE** of the following: *
 - a. Birth weight less than -2 standard deviations below mean or below 3rd percentile for gestational age
 - b. Birth length less than -2 standard deviations below mean or below 3rd percentile for gestational age
5. Catch-up growth not achieved by age 2 to 4 as indicated by **BOTH** of the following:
 - a. At least one height measurement less than -2 standard deviations below mean or below 3rd percentile between age 2 to 4 years
 - b. Member does not have evidence of consistent catch-up growth, defined as either of the following:
 - From age 2 to current age (or age 4, whichever is less), no consecutive years with height measurements greater than -2 standard deviations below mean or greater than 3rd percentile*
6. Requests for all agents other than Genotropin®, prescriber provides clinical rationale for use of the requested agent instead of Genotropin®

**For approval, members must meet both criteria 4 AND 5, independently.*

Adult Indications

Growth hormone (GH) deficiency or panhypopituitarism:

1. Member has a diagnosis of GH deficiency or panhypopituitarism
2. Prescriber has provided documentation of **ONE** of the following*:
 - a. Results of two abnormal tests, which can be either:
 - i. Two abnormal GH stimulation tests
 - ii. One abnormal stimulation test and one abnormal IGF-1/IGFBP-3 level
 - b. **ONE** abnormal test (GH stimulation, IGF-1, or IGFBP-3 test), with either:
 - i. Abnormal pituitary imaging
 - ii. Deficiency of at least three other pituitary hormones (TSH, ACTH, LH, FSH, or

- AVP/ADH)
- iii. Appropriate current medication claims suggesting deficiency of at least three other pituitary hormones (levothyroxine, hydrocortisone or other glucocorticoid, testosterone [for males] or estrogen/progesterone [for females], or desmopressin)
 3. At least one symptom consistent with GH deficiency**
 4. Requests for all agents other than Genotropin[®], prescriber provides clinical rationale for use of the requested agent instead of Genotropin[®]

**Cases where imaging shows NO PITUITARY may be approved without requiring laboratory tests, if the member meets all other criteria including appropriate diagnosis and at least one complication of GHD.*

Adults with a history of traumatic brain injury (TBI) or subarachnoid hemorrhage may present with GHD. This GHD may be transient, and may correct within one year's time. If the documented diagnosis is adult isolated GHD (without organic/acquired causes such as septo-optic dysplasia, pituitary ablation, pan- or multiple hypopituitarism, or surgical resection), provocative stimulation testing in members with a TBI or subarachnoid hemorrhage should be performed at least 12 months after the event.

** A complication of GH deficiency is required:

1. Increased fat mass and reduced lean body mass (as documented, in part, by increased waist-hip ratio). Waist-hip ratio of = 1.0 for men and > 0.8 for woman is indicative of central obesity. Other methods of central obesity documentation include CT and/or MRI abdominal imaging results and waist measurement of > 40 inches in males or 35 inches in females.
2. Reduced extracellular volume (as documented by measurement of extracellular material)
3. Reduced bone mineral content and density (as documented by bone density study). As per the World Health Organization (WHO), bone density of -1 standard deviation (-1 S.D.) may indicate a 2.5 fold increased risk of fracture.
4. Elevated cholesterol (National Institutes of Health, National Heart, Lung, and Blood Institute: fasting total cholesterol = 240 mg/dL = high, LDL cholesterol 160 - 189 mg/dL = high, = 190 = very high).
5. Diminished renal function without other etiology (laboratory values and clinical rationale required)
6. Congestive heart failure (CHF)
7. Reduced exercise capacity (quantified, such as isometric/isokinetic strength, physical performance, maximal oxygen consumption and maximum work capacity increase)
8. Impaired quality of life-Quality of Life-Assessment of Growth Hormone Deficiency in Adults (QoLAGHDA) measure may be useful, although there are no studies to validate the predictive value of any specific cut off for a low score.

HIV/AIDS-associated wasting or cachexia (not covered for AIDS- or HAART-associated lipodystrophy)

1. Member has a diagnosis of HIV/AIDS-associated wasting or cachexia
2. Member is receiving concurrent antiretroviral therapy
3. Prescriber has provided evidence of wasting, as indicated by any of the following (with or without chronic fever, weakness, or diarrhea):
 - a. An involuntary loss of at least 10% of body weight within one year
 - b. An involuntary loss of at least 7.5% of body weight within six months
 - c. A reduction in lean body mass (measured via bioelectrical impedance assay or BIA)

- d. A BMI of $< 20 \text{ kg/m}^2$
4. Member has had a trial of an FDA-approved appetite stimulant, such as dronabinol or megestrol acetate oral suspension, prior to initiation of GH therapy if the etiology of wasting or cachexia is decreased caloric intake
5. Prescriber has provided documentation of ONE of the following:
 - a. Other causes of weight loss have been ruled out:
 - i. gastrointestinal tract opportunistic infections, decrease in food intake due to oral, pharyngeal, esophageal lesions or candidiasis, gonadal dysfunction, adverse effects due to medications, or psychosocial factors. Correction of factors such as these may alleviate the need for GH therapy.
 - b. Member is under the care of an Infectious Disease specialist.
6. Requests for all agents other than Genotropin[®], prescriber provides clinical rationale for use of the requested agent instead of Genotropin[®]

Adults-Short Bowel Syndrome (SBS)

1. Member has a diagnosis of SBS **AND**
2. Member is receiving specialized nutritional support, including enteral or parenteral nutrition and/or fluid and micronutrient supplements
3. Requests for all agents other than Genotropin[®], prescriber provides clinical rationale for use of the requested agent instead of Genotropin[®]

Continuation of Therapy

Reauthorization requires physician documentation of continued medical necessity and the following Diagnosis-Specific criteria:

1. **For Pediatric GHD, SGA/IUGR with failed catch-up growth, Noonan Syndrome, Turner Syndrome, and Pediatric Prader-Willi Syndrome (PWS)**, documentation indicating a measured growth velocity is at least 2.5 cm per year is required.
2. **For Adult GHD and panhypopituitarism (PHP)**, documentation of appropriate IGF-1 or IGFBP-3 levels (within lab-specific reference range) **AND** continued positive response regarding documented GH complication are required.
3. **For Adult GHD from organic/acquired causes (i.e. septo-optic dysplasia, pituitary ablation, pan- or multiple hypopituitarism, or surgical resection)**, documentation of appropriate IGF-1 or IGFBP-3 levels (within lab-specific reference range) is required.
4. **Short bowel syndrome**, treatment 4 weeks has not been studied and will be reviewed on a case by case basis.
5. **Chronic renal failure up to the time of renal transplantation for pediatric patient**, reauthorization will be reviewed on a case by case basis.
6. **For all other indications**, physician attestation to positive response to therapy.

Limitations

1. Initial approvals will be varied based on the treatment:
 - a. **For Short Bowel Syndrome**, approvals will be for up to 4 weeks
 - b. **For adult GHD**, approvals will be for up to 12 months.
 - c. **For ALL other indications**, approvals will be for up to 6 months.
2. Reauthorizations will be varied based on the treatment:
 - a. **For adult GHD**, approvals will be for up to 12 months.
 - b. **For ALL other indications**, approvals will be for up to 6 months.



- c. Treatment for Short Bowel Syndrome past 4 weeks has not been studied and will be reviewed on a case by case basis.

Appendix

Appendix A: Off-Label Indications

Pediatric Status Post-Renal Transplant may be evaluated using the following criteria on a case by case basis:

1. Appropriate diagnosis
2. Short stature or growth failure, documented by one of the following:
 - a. Pre-treatment height less than -2 standard deviations below mean or below 3rd percentile on standard pediatric growth chart
 - b. Height dropping below initial percentile curve on standard pediatric growth chart when monitored over 1 year
 - c. Growth velocity below the 10th percentile for age and gender as defined by one of the following:
 - i. Age two to four years: <5.5 cm/year (<2.2 inches/year)
 - ii. Age four to six years: <5 cm/year (<2 inches/year)
 - iii. Females age six years to puberty: <4.5 cm/year (<1.8 inches/year)
 - iv. Males age six years to puberty: <4 cm/year (<1.6 inches/year)
3. ONE of the following:
 - a. Other CRF-associated etiologies have been excluded: acidosis, secondary hyperparathyroidism, malnutrition, or zinc deficiency.
 - b. Member is under the care of a renal specialist
4. Growth has been monitored for at least one-year post transplant, without catch-up growth documented as height continually less than -2 standard deviations below mean or below 3rd percentile from time of transplant to current request
5. Requests for all agents other than Genotropin[®], prescriber provides clinical rationale for use of the requested agent instead of Genotropin[®]

Pediatric GHD Associated with Genetic Defects (other than Noonan, Prader-Willi or Turner syndrome)

With documentation of a genetic defect associated with GHD, other than Noonan, Prader-Willi or Turner syndrome, **only one abnormal GH stimulation test will be required.** However, the member must meet all other criteria for approval, including short stature or growth failure and being under the care of an endocrinologist or other possible causes of short stature or growth failure being ruled out.

Appendix B: Dosing

Medication	PEDIATRIC INDICATIONS	ADULT INDICATIONS
Genotropin [®] cartridge Genotropin [®] MiniQuick [®] cartridge	<u>Idiopathic Short Stature:</u> up to 0.47 mg/kg subcutaneously (SC) weekly <u>Pediatric GHD:</u> 0.16 to 0.24 mg/kg SC weekly <u>Prader-Willi Syndrome:</u> 0.24 mg/kg SC weekly	<u>Adult GHD:</u> 0.04 mg/kg SC weekly to be increased as tolerated to not more than 0.08 mg/kg SC weekly at 4 to 8 week intervals, or a starting dose of approximately 0.2 mg SC daily (range, 0.15 to 0.30 mg SC daily) increased gradually by increments of 0.1 to 0.2 mg SC daily every 1 to 2 months

	<p><u>Small for Gestational Age:</u> 0.48 mg/kg SC weekly</p> <p><u>Turner Syndrome:</u> 0.33 mg/kg SC weekly</p>	
<p>Humatrope® Cartridge Humatrope® vial</p>	<p><u>Idiopathic short stature:</u> up to 0.37 mg/kg SC weekly</p> <p><u>Pediatric GHD:</u> 0.18 to 0.3 mg/kg SC weekly</p> <p><u>Turner Syndrome:</u> up to 0.375 mg/kg SC weekly</p> <p><u>SHOX deficiency:</u> 0.35 mg/kg SC weekly</p> <p><u>Small for gestational age:</u> up to 0.47 mg/kg SC weekly</p>	<p><u>Adult GHD:</u></p> <p><u>Initial:</u> not more than 0.006 mg/kg SC daily and may be increased up to a max of 0.0125 mg/kg SC daily.</p> <p><u>Alternative schedule:</u> 0.15 to 0.30 mg SC daily may be used without consideration of body weight and may be increased gradually by increments of approximately 0.1 to 0.2 mg SC daily every 1 to 2 months</p>
<p>Norditropin® FlexPro® Cartridge Norditropin® NordiFlex® cartridge</p>	<p><u>Noonan Syndrome:</u> Up to 0.066 mg/kg SC daily</p> <p><u>Pediatric GHD:</u> 0.024 to 0.034 mg/kg SC daily, 6 to 7 times a week</p> <p><u>Small for gestational age:</u> up to 0.067 mg/kg SC daily</p> <p><u>Turner Syndrome:</u> Up to 0.067 mg/kg SC daily</p>	<p><u>Adult GHD:</u> 0.004 mg/kg SC daily to be increased as tolerated to not more than 0.016 mg/kg SC daily after approximately 6 weeks, or a starting dose of approximately 0.2 mg SC daily (range, 0.15 to 0.30 mg SC daily) increased gradually by increments of approximately 0.1 to 0.2 mg SC daily every 1 to 2 months</p>
<p>Nutropin AQ® vial, pen cartridge Nutropin AQ® NuSpin® pen cartridge</p>	<p><u>Chronic renal insufficiency:</u> up to 0.35 mg/kg SC weekly</p> <p><u>Idiopathic short stature:</u> up to 0.3 mg/kg SC weekly</p> <p><u>Pediatric GHD:</u> up to 0.3 mg/kg SC weekly (up to 0.7 mg/kg SC weekly in pubertal patients)</p> <p><u>Turner Syndrome:</u> up to 0.375 mg/kg SC weekly.</p>	<p><u>Adult GHD: Initial:</u> not more than 0.006 mg/kg SC daily. Dose may be increased to a maximum of 0.025 mg/kg SC daily in patients under 35 years old and to a maximum of 0.0125 mg/kg SC daily in patients over 35 years old.</p> <p><u>Alternative schedule:</u> starting dose of approximately 0.02 mg SC daily (range, 0.15 to 0.30 mg SC daily) may be used without consideration of body weight and may be increased gradually by increments of approximately 0.1 to 0.2 mg SC daily every 1 to 2 months.</p>

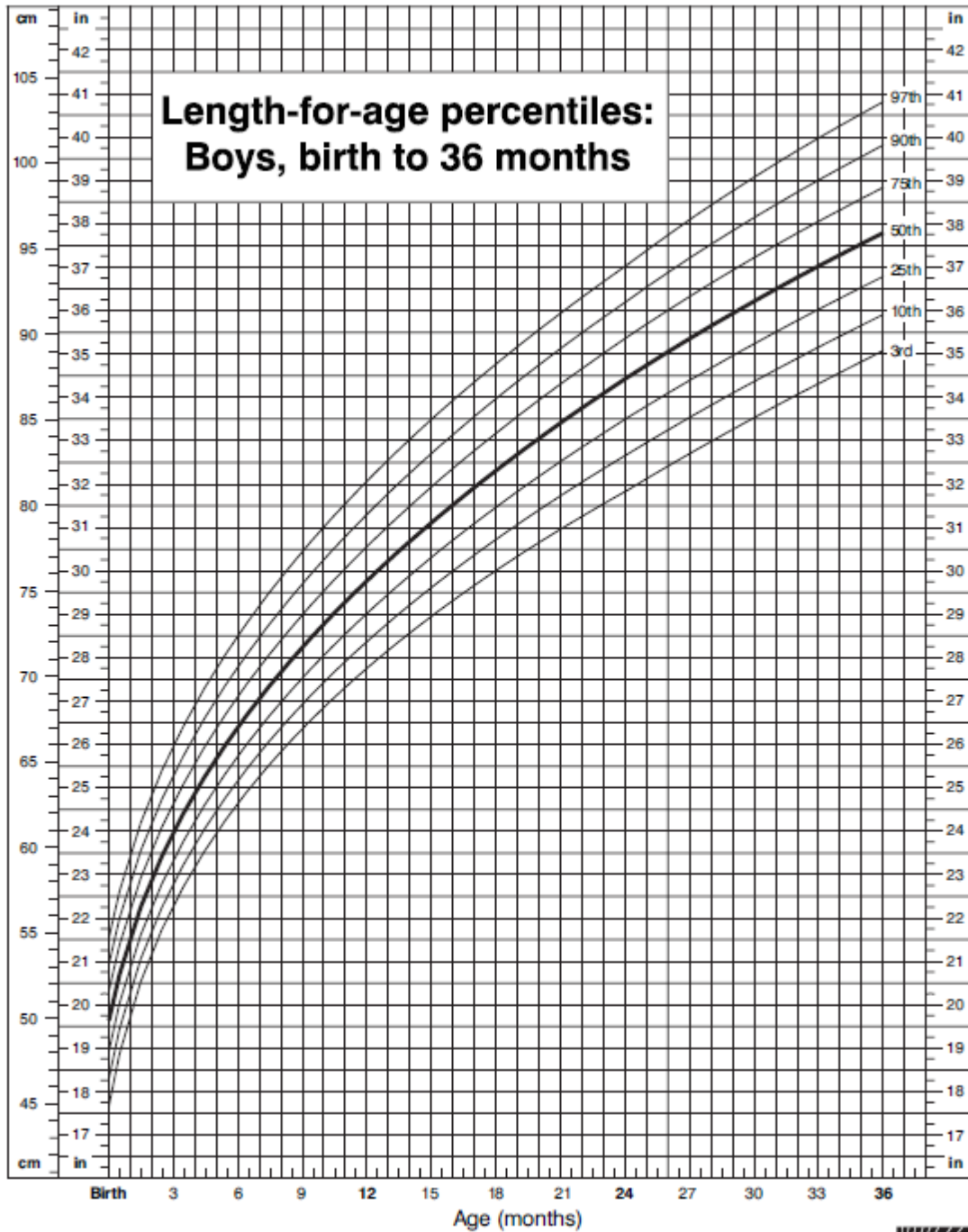
<p>Omnitrope® vial, cartridge</p>	<p><u>Idiopathic short stature:</u> up to 0.47 mg/kg SC weekly</p> <p><u>Pediatric GHD:</u> 0.16 to 0.24 mg/kg SC weekly</p> <p><u>Prader-Willi syndrome:</u> 0.24 mg/mg SC weekly</p> <p><u>Small for gestational age:</u> up to 0.48 mg/kg SC weekly</p> <p><u>Turner syndrome:</u> 0.33 mg/kg SC weekly</p>	<p><u>Adult GHD:</u> not more than 0.04 mg/kg SC weekly to be increased as tolerated to not more than 0.08 mg/kg SC weekly); to be increased gradually every 1 to 2 months</p>
<p>Saizen® vial Saizen® click easy® cartridge</p>	<p><u>Pediatric GHD:</u> 0.18 mg/kg SC weekly</p>	<p><u>Adult GHD:</u> <u>Initial:</u> not more than 0.005 mg/kg SC daily. Dose may be increased to a maximum of 0.01 mg/kg SC daily after 4 weeks.</p> <p><u>Alternative schedule:</u> starting dose of approximately 0.02 mg SC daily (range, 0.15 to 0.30 mg SC daily) may be used without consideration of body weight and may be increased gradually by increments of approximately 0.1 to 0.2 mg SC daily every 1 to 2 months.</p>
<p>Serostim® vial</p>		<p><u>AIDS wasting syndrome:</u> <u>Initial:</u> 0.1 mg/kg daily (up to 6 mg).</p> <p><u>Recommended dosing:</u> >55kg (>121 lb) 6 mg SC daily 45-55 kg (99-121 lb) 5 mg SC daily 35-45 kg (75-99 lb) 4 mg SC daily <35 kg (<75 lb) 0.1 mg/kg SC daily</p> <p>A starting dose of 0.1 mg/kg every other day should be considered in patients at increased risk for adverse effects related to growth hormone therapy</p>
<p>Zomacton® vial</p>	<p><u>Pediatric GHD:</u> up to 0.1 mg/kg SC administered 3 times per week</p>	



Zorbtive® vial		<u>Short Bowel Syndrome:</u> dose of approximately 0.1 mg/kg SC to a maximum of 8 mg SC daily. Administration for more than 4 weeks has not been adequately studied.
Please note: The appearance of a medication in this chart does not indicate formulary coverage		

Appendix C: Pediatric Growth Charts – also available at http://www.cdc.gov/growthcharts/cdc_charts.htm

CDC Growth Charts: United States

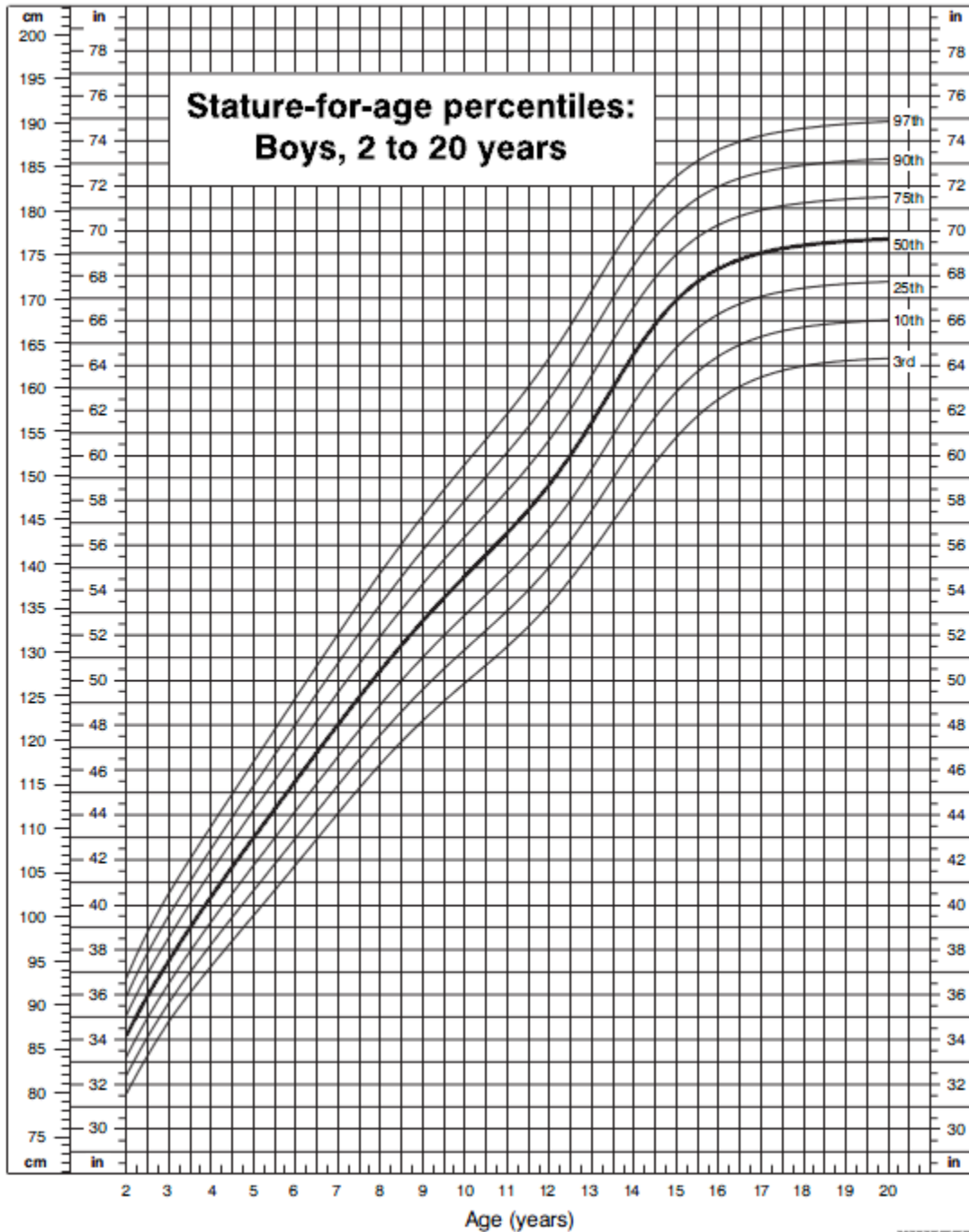


Published May 30, 2000.
SOURCE: Developed by the National Center for Health Statistics in collaboration with
the National Center for Chronic Disease Prevention and Health Promotion (2000).



SAFER • HEALTHIER • PEOPLE™

CDC Growth Charts: United States



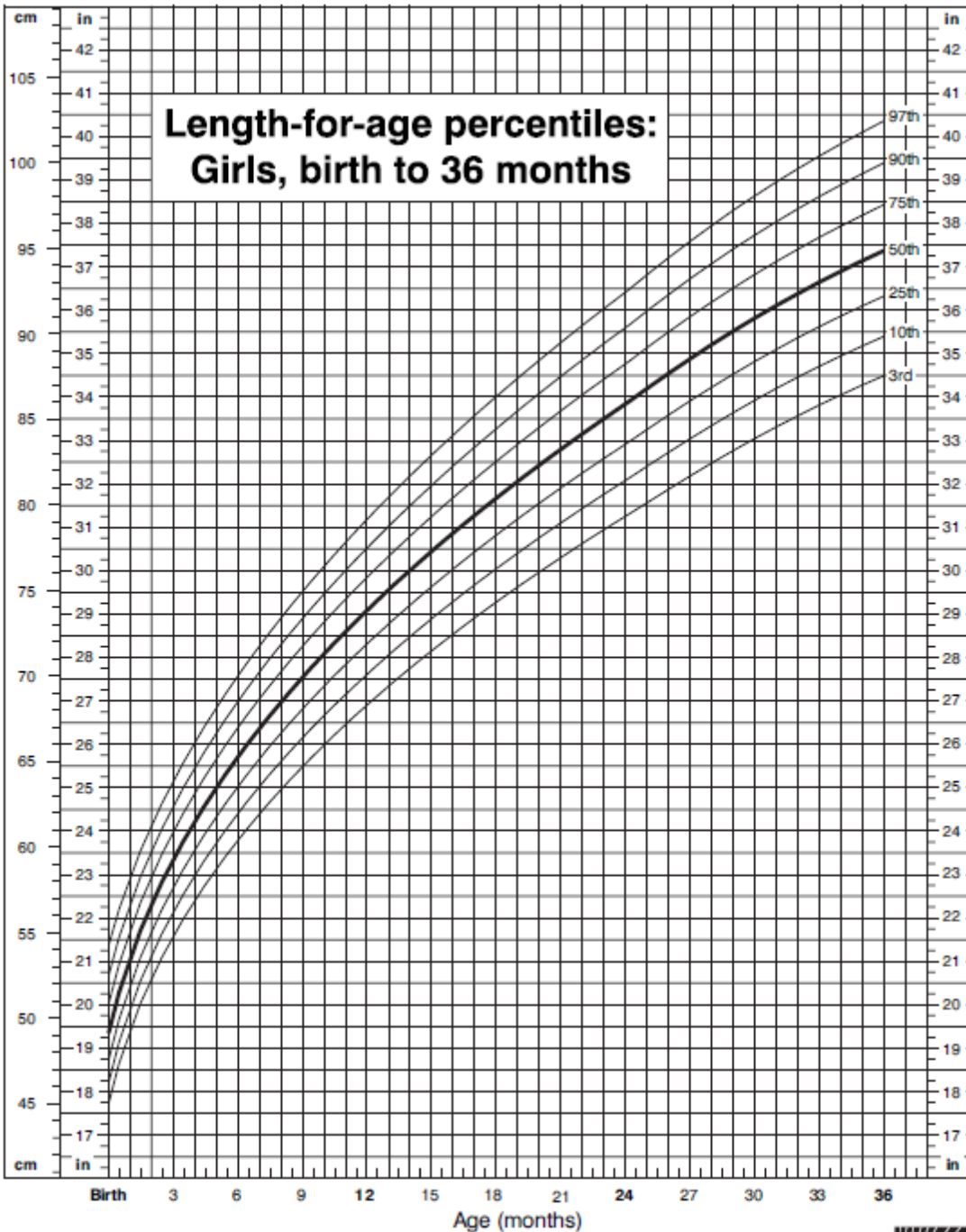
Published May 30, 2000.

SOURCE: Developed by the National Center for Health Statistics in collaboration with the National Center for Chronic Disease Prevention and Health Promotion (2000).



SAFER • HEALTHIER • PEOPLE™

CDC Growth Charts: United States



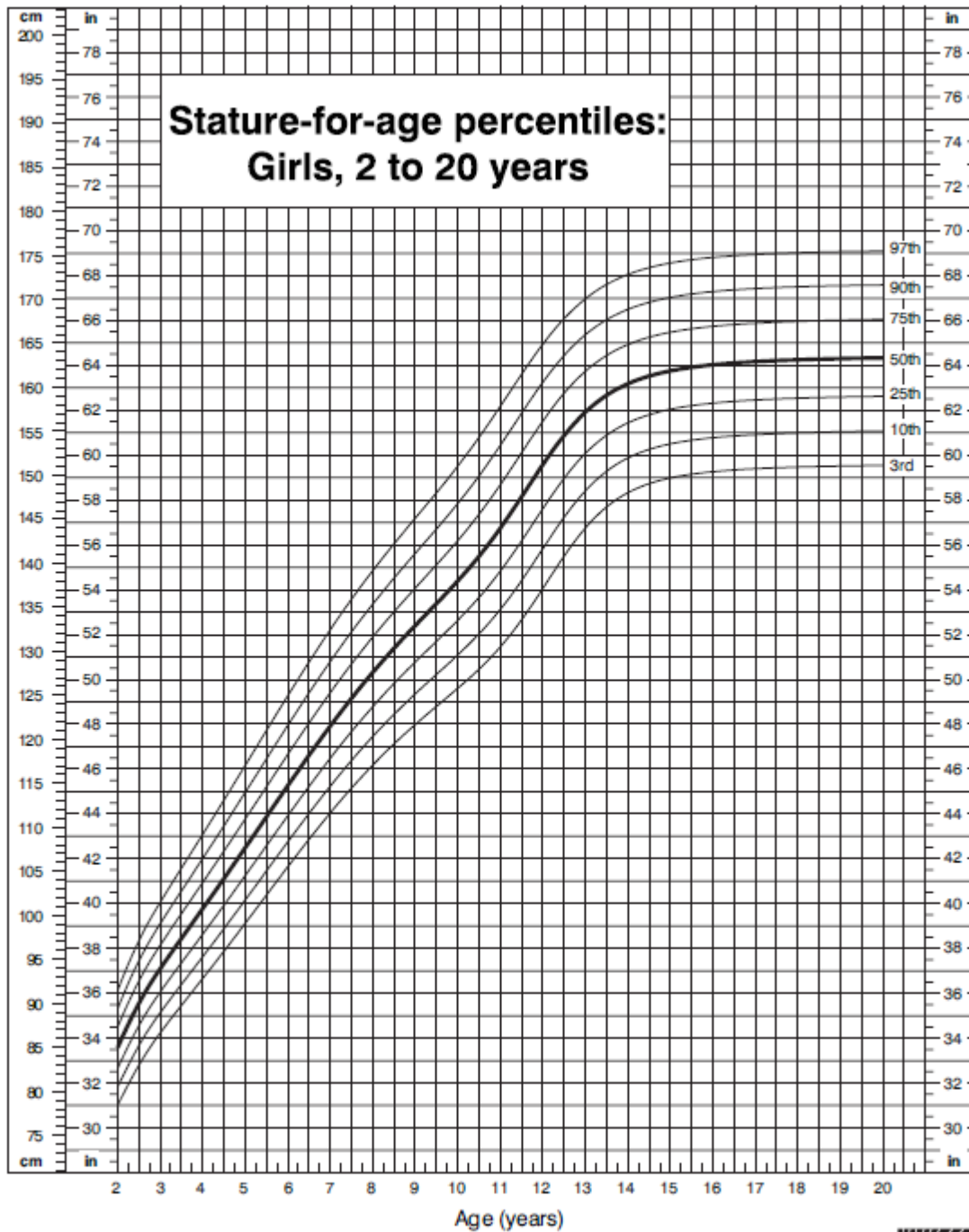
Published May 30, 2000.

SOURCE: Developed by the National Center for Health Statistics in collaboration with the National Center for Chronic Disease Prevention and Health Promotion (2000).



SAFER • HEALTHIER • PEOPLE™

CDC Growth Charts: United States



Published May 30, 2000.
SOURCE: Developed by the National Center for Health Statistics in collaboration with
the National Center for Chronic Disease Prevention and Health Promotion (2000).



References

399 Revolution Drive, Suite 810, Somerville, MA 02145 | allwayshealthpartners.org

AllWays Health Partners includes AllWays Health Partners, Inc. and AllWays Health Partners Insurance Company



1. Genotropin [package insert]. New York, NY: Pfizer Inc.; January 2019.
2. Humatrope [package insert]. Indianapolis, IN: Eli Lilly and Company; December 2016.
3. Norditropin [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; February 2018.
4. Nutropin AQ [package insert]. South San Francisco, CA: Genentech, Inc.; December 2016.
5. Saizen [package insert]. Rockland, MA: EMD Serono Inc.; December 2016.
6. Zomacton [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; January 2018.
7. Omnitrope [package insert]. Princeton, NJ: Sandoz Inc.; December 2016.
8. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed February 16, 2017.
9. Quintos JB, Vogiatzi MG, Harbison MD, et al. Growth hormone therapy alone or in combination with gonadotropin-releasing hormone analog therapy to improve the height deficit in children with congenital adrenal hyperplasia. *J Clin Endocrinol Metab.* 2001;86(4):1511-1517.
10. National Institute for Clinical Excellence: Guidance on the use of human growth hormone (somatropin) for the treatment of growth failure in children. May 2010. <http://www.nice.org.uk/nicemedia/live/12992/48715/48715.pdf>. Accessed February 10, 2017.

Review History

06/16/08 – Reviewed

06/15/09 – Reviewed (I.S.S.)

06/21/10 – Reviewed

06/27/11 – Reviewed

06/25/12 – Reviewed

06/24/13 – Reviewed

06/23/14 – Reviewed

06/22/15 – Reviewed

06/2016 – Reviewed

02/2017 – Reviewed (adopted SGM) in P&T Meeting

11/20/17 – Reviewed (adopted MH RS)

02/20/19 – Reviewed in P&T Meeting

11/17/2021 – Reviewed and updated; added non UPPL (non preferred agents to table). Multiple criteria changes were updated based on literature for growth hormone deficiency or panhypopituitarism, Noonan, Prader-Willi, Turner syndrome, chronic renal failure up to time of renal transplantation, and (SGA/IUGR) with failed catch-up growth between age 2 to 4. Matched with MH UPPL Effective 1/1/2022

Disclaimer

AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.