Growth Hormone
Effective 07/01/2022

Plan	☐ MassHealth ☒ MH UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ 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)
	Skytrofa® (lonapegsomatropin-tcgd)
	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:
    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 less than four years: <5.5 cm/year (<2.2 inches/year)
        ii. Age four to less than 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. 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, or
        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)
4. 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)
5. Requests for all agents other than Genotropin®, prescriber provides clinical rationale for use of the requested agent instead of Genotropin® *(Please see appendix for examples of clinical rationale that may be accepted)*

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

Please see Appendix for pediatric GHD requests associated with genetic defects, other than Noonan, Prader-Willi or Turner syndrome.

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. Requests for all agents other than Genotropin®, prescriber provides clinical rationale for use of the requested agent instead of Genotropin® *(Please see appendix for examples of clinical rationale that may be accepted)*

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
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:
        i. Age two to less than four years: <5.5 cm/year (<2.2 inches/year)
        ii. Age four to less than 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. 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® *(Please see appendix for examples of clinical rationale that may be accepted)*

Chronic renal failure up to time of renal transplantation
Prescriber provides documentation of **ALL** of the following:

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:
        i. Age two to less than four years: <5.5 cm/year (<2.2 inches/year)
        ii. Age four to less than 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. Prescriber has provided documentation of **ONE** of the following:
    a. Other CRF-associated etiologies have been excluded: acidosis, secondary hyperparathyroidism, malnutritrion 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® *(Please see appendix for examples of clinical rationale that may be accepted)*

**See Appendix for requests with documented chronic kidney disease after a renal transplantation has occurred*

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

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

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 ≥ 2 years of age
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:
        i. Age two to less than four years: <5.5 cm/year (<2.2 inches/year)
        ii. Age four to less than 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)
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® *(Please see appendix for examples of clinical rationale that may be accepted)*

Notes:

For approval, members must meet both criteria 4 AND 5, independently.
**Based on provided height measurements. It is not necessary for prescriber to specifically document that from age 2 to current age (or age 4, whichever is less) member has no consecutive years when height was greater than -2 SDs below mean or greater than 3rd percentile on standard pediatric growth chart. But, if multiple height measurements are available, requests should be reviewed on a case-by-case basis. Additionally, prescribers do not need to provide height measurements for every year.*

Adult Indications

Growth hormone (GH) deficiency or panhypopituitarism

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

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, or
        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® *(Please see appendix for examples of clinical rationale that may be accepted)*

**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)

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

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 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® *(Please see appendix for examples of clinical rationale that may be accepted)*

Adults-Short Bowel Syndrome (SBS)

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

1. Member has a diagnosis of SBS
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® *(Please see appendix for examples of clinical rationale that may be accepted)*

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 isolated or idiopathic adult GHD**, 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. **AIDs-associated wasting or cachexia**, documentation of clinical response to treatment
5. **Short bowel syndrome (SBS)**, treatment 4 weeks has not been studied and will be reviewed on a case by case basis.
6. **Chronic renal failure up to the time of renal transplantation for pediatric patient,** reauthorization will be reviewed on a case by case basis.
7. **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

Clinical Rationale for Non-preferred Growth Hormone Products

Considerations for clinical rationale for a non-preferred growth hormone agent may include:

- Product-specific adverse reactions (such as injection site reactions)
    - If the prescriber documents adverse reaction to Genotropin®, authorization may be granted for the request for the non-preferred formulation.
- Hypersensitivity to components of the preferred agent
    - Genotropin® MiniQuick® is a preservative-free formulation, while Genotropin® cartridge contains m-cresol as a preservative. As such, Genotropin® MiniQuick® may be an option for a member requiring a preservative free formulation.
- Inability to administer at recommended dosing frequency
    - The weekly dose of Genotropin® should be divided into six or seven injections, indicating a dosing of six to seven days per week.
    - The dosing for alternative somatropin agents ranges from three to seven days per week, depending on the indication and formulation. Skytrofa® (lonapegsomatropin-tcgd) is a long-acting formulation administered once weekly.

- In general, preference for less frequent dosing is not rationale to bypass medical necessity for a non-preferred agent over Genotropin®.
- Requests for Skytrofa® (lonapegsomatropin-tcgd) documenting preference for once weekly dosing should be evaluated for burden of daily administration, impact of administration burden on adherence, and potential risk associated with non-adherence. Requests documenting significant burden from daily administration may be approved. Compelling requests should be forwarded to clinical review.

- Inability to administer due to injection volume
  - After reconstitution, each Genotropin® MiniQuick® (available as 0.2 mg, 0.4 mg, 0.6 mg, 0.8 mg, 1.0 mg, 1.2 mg, 1.4 mg, 1.6 mg, 1.8 mg and 2.0 mg cartridges) delivers 0.25 mL, regardless of strength. The reconstituted Genotropin® cartridge concentrations are 5 mg/mL and 12 mg/mL.
  - The concentrations of alternative growth hormone agents after reconstitution vary and dosing is dependent upon the indication. Difficulty with administration due to injection volume will be evaluated on a case by case basis, taking into consideration the difference in injection volume between the agents.
- Non-preferred growth hormone agents with additional FDA-approved indications
  - Compelling rationale for non-preferred agents will be evaluated on a case by case basis.
  - Pediatric indications:
    - Genotropin® is FDA-approved for treatment of pediatric patients with growth failure due to GHD, Prader Willi syndrome, small for gestational age and Turner syndrome.
    - Genotropin® is not FDA-approved for the following pediatric indications of growth failure due to SHOC deficiency, Noonan syndrome, and chronic renal failure.
  - Adult indications:
    - Genotropin® is FDA-approved for treatment of adult patients with GHD.
    - Genotropin® is not FDA-approved for treatment of adult patients with HIV/AIDs-associated wasting or cachexia and short bowel syndrome.
  - The following table outlines the additional FDA-approved indications for the non-preferred growth hormone agents:

Product	FDA-approved Indication	Requirements/notes
Humatrope®	SHOX deficiency	Clinical rationale for the requested non-preferred agent instead of Genotropin® is required. Lack of FDA-approved indication of Genotropin® is not accepted clinical rationale for approval. Only requests that meet all approval criteria, including clinical rationale for the non-preferred agent, may be approved.
Norditropin®	Noonan syndrome	
Nutropin®	Chronic renal failure up to time of renal transplantation	
Serostim®	HIV/AIDS-associated wasting or cachexia	
Zorbtive®		

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 less thanfour years: <5.5 cm/year (<2.2 inches/year)
    ii. Age four to less than 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**	Idiopathic Short Stature: up to 0.47 mg/kg subcutaneously (SC) weekly Pediatric GHD: 0.16 to 0.24 mg/kg SC weekly Prader-Willi Syndrome: 0.24 mg/kg SC weekly Small for Gestational Age: 0.48 mg/kg SC weekly Turner Syndrome: 0.33 mg/kg SC weekly	Adult GHD: 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

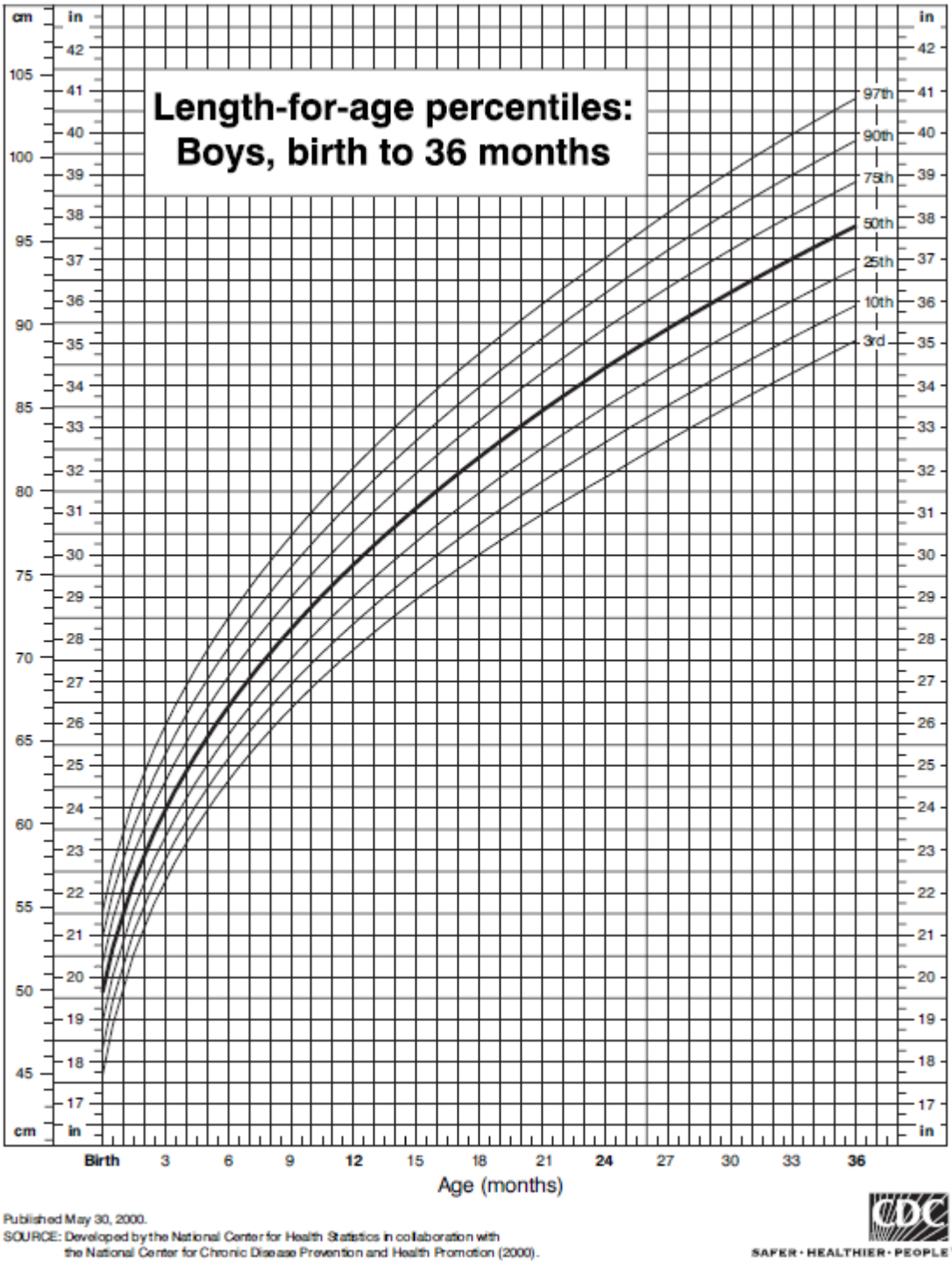
Humatrope® Cartridge **Humatrope® vial**	Idiopathic short stature: up to 0.37 mg/kg SC weekly Pediatric GHD: 0.18 to 0.3 mg/kg SC weekly Turner Syndrome: up to 0.375 mg/kg SC weekly SHOX deficiency: 0.35 mg/kg SC weekly Small for gestational age: up to 0.47 mg/kg SC weekly	Adult GHD: Initial: not more than 0.006 mg/kg SC daily and may be increased up to a max of 0.0125 mg/kg SC daily. Alternative schedule: 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
Norditropin® FlexPro® Cartridge **Norditropin® NordiFlex® cartridge**	Noonan Syndrome: Up to 0.066 mg/kg SC daily Pediatric GHD: 0.024 to 0.034 mg/kg SC daily, 6 to 7 times a week Small for gestational age: up to 0.067 mg/kg SC daily Turner Syndrome: Up to 0.067 mg/kg SC daily	Adult GHD: 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 0.1to 0.2 mg SC daily every 1 to 2 months
Nutropin AQ® vial, pen cartridge **Nutropin AQ®** **NuSpin® pen cartridge**	Chronic renal insufficiency: up to 0.35 mg/kg SC weekly Idiopathic short stature: up to 0.3 mg/kg SC weekly Pediatric GHD: up to 0.3 mg/kg SC weekly (up to 0.7 mg/kg SC weekly in pubertal patients) Turner Syndrome: up to 0.375 mg/kg SC weekly.	Adult GHD: Initial: 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. Alternative schedule: 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.

Omnitrope® vial, cartridge	Idiopathic short stature: up to 0.47 mg/kg SC weekly Pediatric GHD: 0.16 to 0.24 mg/kg SC weekly Prader-Willi syndrome: 0.24 mg/mg SC weekly Small for gestational age: up to 0.48 mg/kg SC weekly Turner syndrome: 0.33 mg/kg SC weekly	Adult GHD: 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
Saizen® vial **Saizen® click easy® cartridge**	Pediatric GHD: 0.18 mg/kg SC weekly	Adult GHD: Initial: 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. Alternative schedule: 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 0.1to 0.2 mg SC daily every 1 to 2 months.
Serostim® vial		AIDS wasting syndrome: Initial: 0.1 mg/kg daily (up to 6 mg). Recommended dosing: >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 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
Skytrofa® cartridge	Pediatric GHD: 0.24 mg/kg once-weekly	
Zomacton® vial	Pediatric GHD: up to 0.1 mg/kg SC administered 3 times per week	

Zorbtive® vial		Short Bowel Syndrome: 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).

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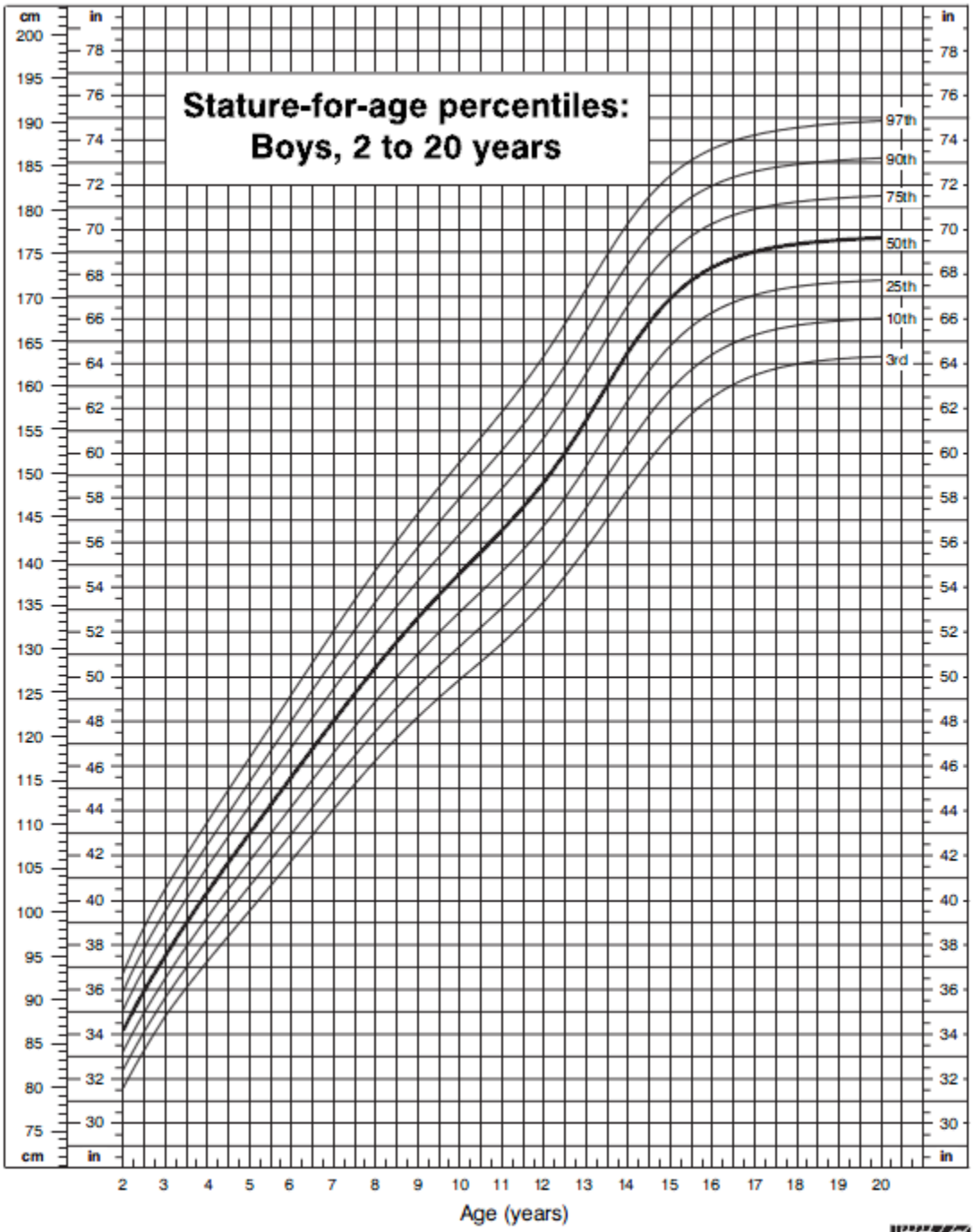
CDC Growth Charts: United States



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).

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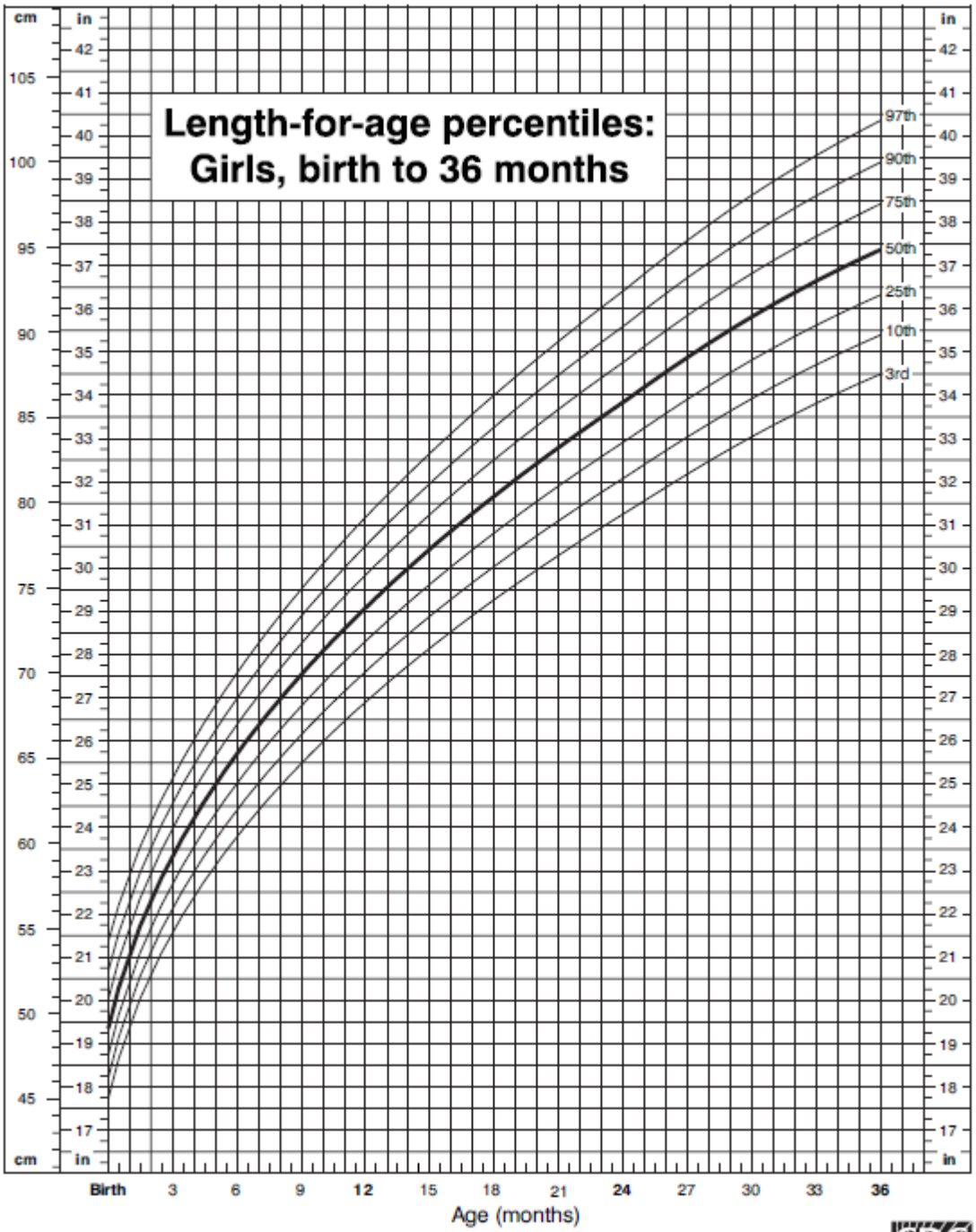
CDC Growth Charts: United States



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

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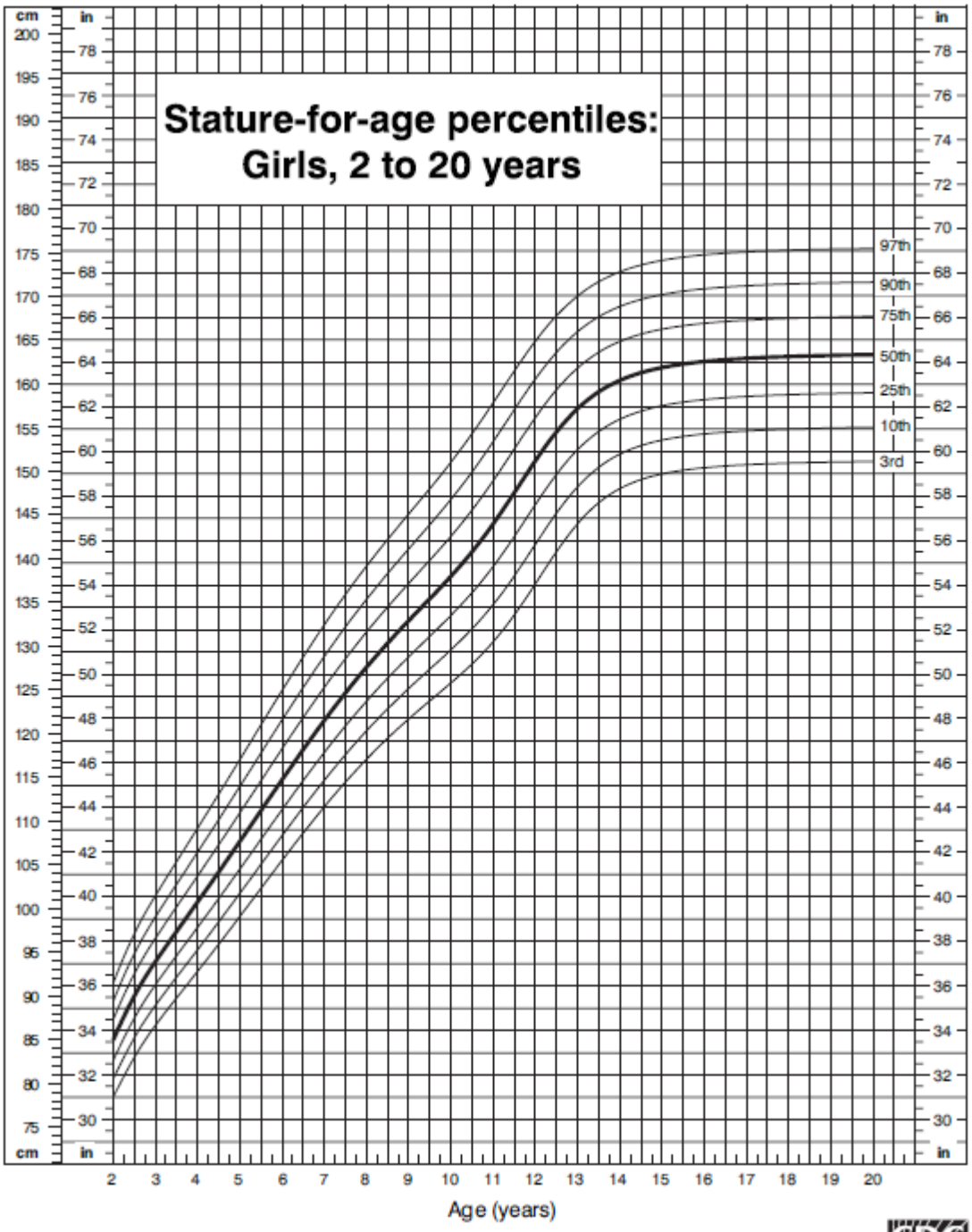
allways[sm]
HEALTH PARTNERS

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).

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References

1. Genotropin® (somatropin, rDNA origin, for injection) [package insert on the internet]. New York (NY): Pfizer, Inc.; 2019 Apr.
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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
05/18/2022 – Reviewed and updated for May P&T; Matched MH UPPL. Added Skytrofa (lonapegsomatropin-tcgd) as a non-preferred growth hormone product. Updated references. Added to Appendix: "Clinical Rationale for Non-preferred Growth Hormone Products". Effective 7/1/22.

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