



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Growth Hormones: Norditropin, Genotropin, Humatrope, Nutropin AQ, Omnitrope, Saizen, Zomacton	Page:	1 of 14
Effective Date:	10/1/2023	Last Review Date:	8/24/2023
Applies to:	<input type="checkbox"/> Illinois <input checked="" type="checkbox"/> Maryland <input type="checkbox"/> Michigan	<input type="checkbox"/> Florida <input type="checkbox"/> Florida Kids <input type="checkbox"/> Virginia	<input checked="" type="checkbox"/> New Jersey <input type="checkbox"/> Pennsylvania Kids <input checked="" type="checkbox"/> Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for the Growth Hormone class that includes Norditropin, Genotropin, Humatrope, Nutropin AQ, Omnitrope, Saizen, and Zomacton under the patient’s prescription drug benefit.

Description:

A. FDA-Approved Indications

1. Pediatric patients with growth failure due to any of the following:
 - a. Growth hormone (GH) deficiency
 - b. Turner syndrome
 - c. Noonan syndrome
 - d. Small for gestational age (SGA)
 - e. Prader-Willi syndrome
 - f. Chronic kidney disease (CKD)
 - g. Short stature homeobox-containing gene (SHOX) deficiency
2. Adults with childhood-onset or adult-onset GH deficiency

B. Compendial Uses

1. Human immunodeficiency virus (HIV)-associated wasting/cachexia
2. Short bowel syndrome (SBS)
3. Growth failure associated with any of the following:
 - a. Cerebral palsy
 - b. Congenital adrenal hyperplasia
 - c. Cystic fibrosis
 - d. Russell-Silver syndrome

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Preferred Agent:

Norditropin

Non-Preferred Agents:

Genotropin

Humatrope



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Growth Hormones: Norditropin, Genotropin, Humatrope, Nutropin AQ, Omnitrope, Saizen, Zomacton	Page:	2 of 14
Effective Date:	10/1/2023	Last Review Date:	8/24/2023
Applies to:	<input type="checkbox"/> Illinois <input checked="" type="checkbox"/> Maryland <input type="checkbox"/> Michigan	<input type="checkbox"/> Florida <input type="checkbox"/> Florida Kids <input type="checkbox"/> Virginia	<input checked="" type="checkbox"/> New Jersey <input type="checkbox"/> Pennsylvania Kids <input checked="" type="checkbox"/> Kentucky PRMD

Nutropin AQ
Omnitrope
Saizen
Zomacton

Policy/Guideline:

I. FORMULARY PREFERENCING

- A. The patient is unable to take Norditropin, the preferred formulary alternative for the given diagnosis, due to a trial and inadequate treatment response or intolerance, or a contraindication.

II. DOCUMENTATION

- A. **Submission of the following documentation is necessary to initiate the prior authorization review for both initial and renewal requests, where applicable:**
 - 1. Medical records supporting the diagnosis of neonatal Growth Hormone deficiency
 - 2. Pretreatment growth hormone provocative test results (laboratory report or medical record documentation)
 - 3. Growth chart
 - 4. Pretreatment and/or current IGF-1 level (laboratory report or medical record documentation)
 - 5. The following laboratory test reports must be provided:
 - a) Diagnostic karyotype results in Turner syndrome
 - b) Diagnostic genetic test results in Prader-Willi syndrome
 - c) Diagnostic molecular or genetic test results in SHOX deficiency
 - 6. The following information must be provided for all renewal requests:
 - a) Total duration of treatment (approximate duration is acceptable)
 - b) Date of last dose administered
 - c) Approving health plan/pharmacy benefit manager
 - d) Date of prior authorization/approval
 - e) Prior authorization approval letter

III. CRITERIA FOR INITIAL APPROVAL

A. Pediatric Growth Hormone Deficiency



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Growth Hormones: Norditropin, Genotropin, Humatrope, Nutropin AQ, Omnitrope, Saizen, Zomacton	Page:	3 of 14
Effective Date:	10/1/2023	Last Review Date:	8/24/2023
Applies to:	<input type="checkbox"/> Illinois <input checked="" type="checkbox"/> Maryland <input type="checkbox"/> Michigan	<input type="checkbox"/> Florida <input type="checkbox"/> Florida Kids <input type="checkbox"/> Virginia	<input checked="" type="checkbox"/> New Jersey <input type="checkbox"/> Pennsylvania Kids <input checked="" type="checkbox"/> Kentucky PRMD

Authorization may be granted to members with pediatric GH deficiency when EITHER criteria is met:

1. Member is a neonate or was diagnosed with Growth Hormone deficiency as a neonate.
 - i. Medical records must be available to support the diagnosis of neonatal GH deficiency (e.g., hypoglycemia with random GH level, evidence of multiple pituitary hormone deficiency, chart notes, or magnetic resonance imaging [MRI] results).
 2. Member meets ALL of the following:
 - i. Member has EITHER:
 - a. Two pretreatment pharmacologic provocative GH tests with both results demonstrating a peak GH level <10 ng/mL

OR

 - b. A documented pituitary or CNS disorder (refer to Appendix A) and a pretreatment IGF-1 level > 2 standard deviations (SD) below the mean
 - ii. For members < 2.5 years of age at initiation of treatment, the pretreatment height is > 2 SD below the mean and growth velocity is slow
 - iii. For members ≥ 2.5 years of age at initiation of treatment:
 - a. Pretreatment height is > 2 SD below the mean and 1-year height velocity is > 1 SD below the mean

OR

 - b. Pretreatment 1-year height velocity is > 2 SD below the mean
- iv. Epiphyses are open

B. Adult GH Deficiency

Authorization may be granted to members with adult GH deficiency when ANY of the following criteria is met:

1. Member meets both of the following:
 - i. Member has had 2 pretreatment pharmacologic provocative GH tests and both results demonstrated deficient GH responses defined as the following:



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Growth Hormones: Norditropin, Genotropin, Humatrope, Nutropin AQ, Omnitrope, Saizen, Zomacton Page: 4 of 14

Effective Date: 10/1/2023 Last Review Date: 8/24/2023

Applies to: Illinois Florida New Jersey
 Maryland Florida Kids Pennsylvania Kids
 Michigan Virginia Kentucky PRMD

- a. Insulin tolerance test (ITT) with a peak GH level ≤ 5 ng/mL
 - b. Macrilen with a peak GH level of less than 2.8 ng/mL
 - c. Glucagon stimulation test with a peak GH level ≤ 3.0 ng/mL in patients with a body mass index (BMI) ≤ 30 kg/m² and a high pretest probability of GHD (e.g., acquired structural abnormalities) OR a BMI < 25 kg/m²
 - d. Glucagon stimulation test with a peak GH level ≤ 1.0 ng/mL in patients with a BMI of ≥ 25 kg/m² and a low pretest probability of GHD (e.g., acquired structural abnormalities) OR a BMI > 30 kg/m²
- ii. Member has a low pre-treatment IGF-1 (between 0 to 2 SD below the mean for age and gender)
2. Member meets both of the following:
 - i. Member has had 1 pretreatment pharmacologic provocative GH test that demonstrated deficient GH responses defined as one of the following:
 - a. Insulin tolerance test (ITT) with a peak GH level ≤ 5 ng/mL
 - b. Macrilen with a peak GH level of less than 2.8 ng/mL
 - c. Glucagon stimulation test with a peak GH level ≤ 3.0 ng/mL in patients with a body mass index (BMI) ≤ 30 kg/m² and a high pretest probability of GHD (e.g., acquired structural abnormalities) OR a BMI < 25 kg/m²
 - d. Glucagon stimulation test with a peak GH level ≤ 1.0 ng/mL in patients with a BMI of ≥ 25 kg/m² and a low pretest probability of GHD (e.g., acquired structural abnormalities) OR a BMI > 30 kg/m²
 - ii. Member has a pretreatment IGF-1 level that is more than 2 SD below the mean for age and gender
3. Member has organic hypothalamic-pituitary disease (e.g., suprasellar mass with previous surgery and cranial irradiation) with ≥ 3 documented pituitary hormone deficiencies (refer to Appendix B) and a low pre-treatment IGF-1 more than 2 standard deviations below the mean for age and gender



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Growth Hormones: Norditropin, Genotropin, Humatrope, Nutropin AQ, Omnitrope, Saizen, Zomacton	Page:	5 of 14
Effective Date:	10/1/2023	Last Review Date:	8/24/2023
Applies to:	<input type="checkbox"/> Illinois <input checked="" type="checkbox"/> Maryland <input type="checkbox"/> Michigan	<input type="checkbox"/> Florida <input type="checkbox"/> Florida Kids <input type="checkbox"/> Virginia	<input checked="" type="checkbox"/> New Jersey <input type="checkbox"/> Pennsylvania Kids <input checked="" type="checkbox"/> Kentucky PRMD

4. Member has genetic or structural hypothalamic-pituitary defects (refer to Appendix C)
5. Member has childhood-onset GH deficiency and a congenital abnormality of the CNS, hypothalamus, or pituitary (refer to Appendix C)

C. Small for Gestational Age

Authorization may be granted to members born with SGA when ALL the following criteria are met:

1. Member meets at least one of the following:
 - a. Birth weight < 2500 g at gestational age > 37 weeks
 - b. Birth weight or length less than 3rd percentile for gestational age
 - c. Birth weight or length ≥ 2 SD below the mean for gestational age
2. Pretreatment age is ≥ 2 years
3. Member failed to manifest catch-up growth by age 2 (i.e., pretreatment height > 2 SD below the mean)
4. Epiphyses are open

D. Turner Syndrome

Authorization may be granted to members with Turner syndrome when ALL the following criteria are met:

1. Diagnosis was confirmed by karyotyping
2. Patient's pretreatment height is less than the 5th percentile for age
3. Epiphyses are open

E. Prader-Willi Syndrome

Authorization may be granted to members with Prader-Willi syndrome when the diagnosis was confirmed by genetic testing demonstrating any of the following:

1. Deletion in the chromosomal 15q11.2-q13 region
2. Maternal uniparental disomy in chromosome 15
3. Imprinting defects, translocations, or inversions involving chromosome 15

F. Noonan Syndrome

Authorization may be granted to members with Noonan syndrome when ALL the following criteria are met:



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Growth Hormones: Norditropin, Genotropin, Humatrope, Nutropin AQ, Omnitrope, Saizen, Zomacton	Page:	6 of 14
Effective Date:	10/1/2023	Last Review Date:	8/24/2023
Applies to:	<input type="checkbox"/> Illinois <input checked="" type="checkbox"/> Maryland <input type="checkbox"/> Michigan	<input type="checkbox"/> Florida <input type="checkbox"/> Florida Kids <input type="checkbox"/> Virginia	<input checked="" type="checkbox"/> New Jersey <input type="checkbox"/> Pennsylvania Kids <input checked="" type="checkbox"/> Kentucky PRMD

1. Pretreatment height is > 2 SD below the mean and 1-year height velocity is > 1 SD below the mean OR pretreatment 1-year height velocity is > 2 SD below the mean
2. Epiphyses are open

G. Short Stature Homeobox-Containing Gene Deficiency

Authorization may be granted to members with SHOX deficiency when ALL the following criteria are met:

1. The diagnosis of SHOX deficiency was confirmed by molecular or genetic analyses
2. Pretreatment height is > 2 SD below the mean and 1-year height velocity is > 1 SD below the mean OR pretreatment 1-year height velocity is > 2 SD below the mean
3. Epiphyses are open

H. Growth Failure Associated with Chronic Kidney Disease (CKD), Cerebral Palsy, Congenital Adrenal Hyperplasia, Cystic Fibrosis, and Russell-Silver Syndrome

Authorization may be granted to members with CKD, cerebral palsy, congenital adrenal hyperplasia, cystic fibrosis, or Russell-Silver syndrome when ALL of the following criteria are met:

1. For members < 2.5 years of age at initiation of treatment, the pretreatment height is > 2 SD below the mean and growth velocity is slow
2. For members ≥ 2.5 years of age at initiation of treatment:
 - a. Pretreatment height is > 2 SD below the mean and 1-year height velocity is > 1 SD below the mean, OR
 - b. Pretreatment 1-year height velocity is > 2 SD below the mean
3. Epiphyses are open

I. HIV-Associated Wasting/Cachexia

Authorization may be granted to members with HIV-associated wasting or cachexia when ALL of the following criteria are met:

1. Member has trialed and experienced a suboptimal response to alternative therapies (e.g., cyproheptadine, dronabinol, megestrol acetate or



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Growth Hormones: Norditropin, Genotropin, Humatrope, Nutropin AQ, Omnitrope, Saizen, Zomacton	Page:	7 of 14
Effective Date:	10/1/2023	Last Review Date:	8/24/2023
Applies to:	<input type="checkbox"/> Illinois <input checked="" type="checkbox"/> Maryland <input type="checkbox"/> Michigan	<input type="checkbox"/> Florida <input type="checkbox"/> Florida Kids <input type="checkbox"/> Virginia	<input checked="" type="checkbox"/> New Jersey <input type="checkbox"/> Pennsylvania Kids <input checked="" type="checkbox"/> Kentucky PRMD

- testosterone if hypogonadal) or contraindication or intolerance to alternative therapies
- Member is currently on antiretroviral therapy
 - BMI is less than 18.5 kg/m² prior to starting therapy with growth hormone (see Appendix D)

J. Short Bowel Syndrome

Authorization may be granted to members with short bowel syndrome who depend on intravenous parenteral nutrition when GH will be used in conjunction with optimal management of SBS.

IV. CRITERIA FOR CONTINUATION OF THERAPY

A. Pediatric GH Deficiency, Turner Syndrome, Noonan Syndrome, CKD, SGA, SHOX deficiency, Congenital Adrenal Hyperplasia, Cerebral Palsy, Cystic Fibrosis, and Russell-Silver Syndrome

Authorization may be granted for continuation of therapy when ALL of the following criteria are met:

- Epiphyses are open (confirmed by X-ray or X-ray is not available)
- Member's growth rate is > 2 cm/year unless there is a documented clinical reason for lack of efficacy (e.g., on treatment less than 1 year, nearing final adult height/late stages of puberty)

B. Prader-Willi Syndrome

Authorization may be granted for continuation of therapy when the member's body composition and psychomotor function have improved or stabilized in response to GH therapy.

C. Adult GH Deficiency

Authorization may be granted for continuation of therapy when ANY of the following criteria is met:

- Member meets all of the following:
 - Member has had 2 pretreatment pharmacologic provocative GH tests and both results demonstrated deficient GH responses defined as the following:
 - Insulin tolerance test (ITT) or another provocative GH test with a peak GH level ≤ 5 ng/mL



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Growth Hormones: Norditropin, Genotropin, Humatrope, Nutropin AQ, Omnitrope, Saizen, Zomacton	Page:	8 of 14
Effective Date:	10/1/2023	Last Review Date:	8/24/2023
Applies to:	<input type="checkbox"/> Illinois <input checked="" type="checkbox"/> Maryland <input type="checkbox"/> Michigan	<input type="checkbox"/> Florida <input type="checkbox"/> Florida Kids <input type="checkbox"/> Virginia	<input checked="" type="checkbox"/> New Jersey <input type="checkbox"/> Pennsylvania Kids <input checked="" type="checkbox"/> Kentucky PRMD

- b. Macrilen with a peak GH level of less than 2.8 ng/mL
 - c. Glucagon stimulation test with a peak GH level ≤ 3.0 ng/mL in patients with a body mass index (BMI) ≤ 30 kg/m² and a high pretest probability of GHD (e.g., acquired structural abnormalities) OR a BMI < 25 kg/m²
 - d. Glucagon stimulation test with a peak GH level ≤ 1.0 ng/mL in patients with a BMI of ≥ 25 kg/m² and a low pretest probability of GHD (e.g., acquired structural abnormalities) OR a BMI > 30 kg/m²
 - ii. Member has a low pre-treatment IGF-1 (between 0 to 2 SD below the mean for age and gender)
 - iii. Current IGF-1 level is not elevated for age and gender
2. Member meets all of the following:
- i. Member has had 1 pretreatment pharmacologic provocative GH test that demonstrated deficient GH responses defined as one of the following:
 - a. Insulin tolerance test (ITT) or another provocative GH test with a peak GH level ≤ 5 ng/mL
 - b. Macrilen with a peak GH level of less than 2.8 ng/mL
 - c. Glucagon stimulation test with a peak GH level ≤ 3.0 ng/mL in patients with a body mass index (BMI) ≤ 30 kg/m² and a high pretest probability of GHD (e.g., acquired structural abnormalities) OR a BMI < 25 kg/m²
 - d. Glucagon stimulation test with a peak GH level ≤ 1.0 ng/mL in patients with a BMI of ≥ 25 kg/m² and a low pretest probability of GHD (e.g., acquired structural abnormalities) OR a BMI > 30 kg/m²
 - ii. Member has a pretreatment IGF-1 level that is more than 2 SD below the mean for age and gender
 - iii. Current IGF-1 level is not elevated for age and gender
3. Member meets both of the following:
- i. Member has organic hypothalamic-pituitary disease (e.g., suprasellar mass with previous surgery and cranial irradiation) with ≥ 3 documented pituitary hormone deficiencies (refer to Appendix B) and a low pre-treatment IGF-1 more than 2 standard deviations below the mean for age and gender
 - ii. Current IGF-1 level is not elevated for age and gender



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Growth Hormones: Norditropin, Genotropin, Humatrope, Nutropin AQ, Omnitrope, Saizen, Zomacton	Page:	9 of 14
Effective Date:	10/1/2023	Last Review Date:	8/24/2023
Applies to:	<input type="checkbox"/> Illinois <input checked="" type="checkbox"/> Maryland <input type="checkbox"/> Michigan	<input type="checkbox"/> Florida <input type="checkbox"/> Florida Kids <input type="checkbox"/> Virginia	<input checked="" type="checkbox"/> New Jersey <input type="checkbox"/> Pennsylvania Kids <input checked="" type="checkbox"/> Kentucky PRMD

- Member has genetic or structural hypothalamic-pituitary defects (refer to Appendix C) and current IGF-1 level is not elevated for age and gender
- Member has childhood-onset GH deficiency and a congenital abnormality of the CNS, hypothalamus, or pituitary (refer to Appendix C) and current IGF-1 level is not elevated for age and gender

D. HIV-Associated Wasting/Cachexia

Authorization may be granted for continuation of therapy when ALL of the following criteria are met:

- Member is diagnosed with HIV-associated wasting/cachexia
- Member is currently on antiretroviral therapy.
- Member is currently receiving treatment with growth hormone excluding obtainment as samples or via manufacturer's patient assistance programs
- Current BMI is less than 27 kg/m² (see Appendix D).

V. APPENDICES

A. Appendix A: Examples of Hypothalamic/Pituitary/CNS Disorders

- Congenital genetic abnormalities
 - Transcription factor defects (PIT-1, PROP-1, LHX3/4, HESX-1, PITX-2)
 - Growth hormone releasing hormone (GHRH) receptor gene defects
 - GH secretagogue receptor gene defects
 - GH gene defects
 - GH receptor/post receptor defects
- Congenital structural abnormalities
 - Optic nerve hypoplasia/septo-optic dysplasia
 - Agenesis of corpus callosum
 - Empty sella syndrome
 - Ectopic posterior pituitary
 - Pituitary aplasia/hypoplasia
 - Pituitary stalk defect
 - Holoprosencephaly
 - Encephalocele
 - Hydrocephalus
 - Anencephaly or prosencephaly



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Growth Hormones: Norditropin, Genotropin, Humatrope, Nutropin AQ, Omnitrope, Saizen, Zomacton Page: 10 of 14

Effective Date: 10/1/2023 Last Review Date: 8/24/2023

Applies to: Illinois Florida New Jersey
 Maryland Florida Kids Pennsylvania Kids
 Michigan Virginia Kentucky PRMD

- k. Arachnoid cyst
 - l. Other mid-line defects (e.g., single central incisor, cleft lip/palate)
 - m. Vascular malformations
3. Acquired structural abnormalities (or causes of hypothalamic/pituitary damage)
- a. CNS tumors/neoplasms (e.g., craniopharyngioma, glioma/astrocytoma, pituitary adenoma, germinoma)
 - b. Cysts (Rathke cleft cyst or arachnoid cleft cyst)
 - c. Surgery
 - d. Radiation
 - e. Chemotherapy
 - f. CNS infections
 - g. CNS infarction (e.g., Sheehan's syndrome)
 - h. Inflammatory processes (e.g., autoimmune hypophysitis)
 - i. Infiltrative processes (e.g., sarcoidosis, histiocytosis, hemochromatosis)
 - j. Head trauma/traumatic brain injury
 - k. Aneurysmal subarachnoid hemorrhage
 - l. Perinatal or postnatal trauma
 - m. Surgery of the pituitary or hypothalamus

B. Appendix B: Pituitary Hormones (Other than Growth Hormone)

- 1. Adrenocorticotrophic hormone (ACTH)
- 2. Antidiuretic hormone (ADH)
- 3. Follicle stimulating hormone (FSH)
- 4. Luteinizing hormone (LH)
- 5. Thyroid stimulating hormone (TSH)
- 6. Prolactin

C. Appendix C: Requirements for GH-Stimulation Testing in Adults

- 1. Testing for adult GHD is not required
 - a. Three or more pituitary hormone deficiencies and low IGF-1
 - b. Congenital structural abnormalities
 - i. Transcription factor defects (PIT-1, PROP-1, LHX3/4, HESX-1, PITX-2)
 - ii. GHRH receptor-gene defects
 - iii. GH-receptor/post-receptor defects



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Growth Hormones: Norditropin, Genotropin, Humatrope, Nutropin AQ, Omnitrope, Saizen, Zomacton Page: 11 of 14

Effective Date: 10/1/2023 Last Review Date: 8/24/2023

Applies to: Illinois Florida New Jersey
 Maryland Florida Kids Pennsylvania Kids
 Michigan Virginia Kentucky PRMD

- iv. GH-gene defects associated with brain structural defects
- v. Single central incisor
- vi. Cleft lip/palate
- c. Acquired causes such as perinatal insults
- 2. Testing for adult GHD is required
 - a. Acquired
 - i. Skull-base lesions
 - ii. Pituitary adenoma
 - iii. Craniopharyngioma
 - iv. Rathke's cleft cyst
 - v. Meningioma
 - vi. Glioma/astrocytoma
 - vii. Neoplastic sellar and parasellar lesions
 - viii. Chordoma
 - ix. Hamartoma
 - x. Lymphoma
 - xi. Metastases
 - xii. Other brain injury
 - xiii. Traumatic brain injury
 - xiv. Sports-related head trauma
 - xv. Blast injury
 - xvi. Infiltrative/granulomatous disease
 - xvii. Langerhans cell histiocytosis
 - xviii. Autoimmune hypophysitis (primary or secondary)
 - xix. Sarcoidosis
 - xx. Tuberculosis
 - xxi. Amyloidosis
 - b. Surgery to the sella, suprasellar, and parasellar region
 - c. Cranial irradiation
 - d. Central nervous system infections (bacteria, viruses, fungi, parasites)
 - e. Infarction/hemorrhage (e.g., apoplexy, Sheehan's syndrome, subarachnoid hemorrhage, ischemic stroke, snake bite)
 - f. Empty sella



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Growth Hormones: Norditropin, Genotropin, Humatrope, Nutropin AQ, Omnitrope, Saizen, Zomacton Page: 12 of 14

Effective Date: 10/1/2023 Last Review Date: 8/24/2023

Applies to: Illinois Florida New Jersey
 Maryland Florida Kids Pennsylvania Kids
 Michigan Virginia Kentucky PRMD

- g. Hydrocephalus
- h. Idiopathic

D. Appendix D: Calculation of BMI⁴²

BMI =	$\frac{\text{Weight (pounds)} \times 703}{[\text{Height (inches)}]^2}$	OR	$\frac{\text{Weight (kg)}}{[\text{Height (m)}]^2}$
BMI classification:	Underweight		< 18.5 kg/m ²
	Normal weight		18.5 – 24.9 kg/m ²
	Overweight		25 – 29.9 kg/m ²
	Obesity (class 1)		30 – 34.9 kg/m ²
	Obesity (class 2)		35 – 39.9 kg/m ²
	Extreme obesity (class 3)		≥ 40 kg/m ²

Approval Duration and Quantity Restrictions:

- A. Initial and Renewal Approval for HIV-Associated Wasting/Cachexia: 12 weeks
- B. Short Bowel Syndrome: A lifetime total of 8 weeks
- C. Initial and Renewal Approval for all other indications: 12 months

Quantity Level Limit: Reference Formulary for drug specific quantity level limits

References:

1. Norditropin [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; February 2018.
2. Genotropin [package insert]. New York, NY: Pfizer Inc.; April 2019.
3. Humatrope [package insert]. Indianapolis, IN: Eli Lilly and Company; October 2019.
4. Nutropin AQ [package insert]. South San Francisco, CA: Genentech, Inc.; December 2016.
5. Saizen [package insert]. Rockland, MA: EMD Serono Inc.; May 2018.
6. Zomacton [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; July 2018.
7. Omnitrope [package insert]. Princeton, NJ: Sandoz Inc.; June 2019.
8. Wakeling EL, Brioude F, Lokulo-Sodipe O, et al. Diagnosis and management of Silver-Russell syndrome: first international consensus statement. Nat Rev Endocrinol. 2017;13(2):105-124.
9. Nemecek PM, Polsky B, Gottlieb MS. Treatment Guidelines for HIV-Associated Wasting. Mayo Clin Proc. 2000;75:386-394.
10. Grinspoon S, Mulligan K for the Department of Health and Human Services Working Group on the Prevention and Treatment of Wasting and Weight Loss. Weight loss and wasting in patients infected with human immunodeficiency virus. Clin Infect Dis. 2003;36(Suppl 2):S69-78.
11. Polsky B, Kotler D, Steinhart C. HIV-associated wasting in the HAART era: guidelines for assessment, diagnosis, and treatment. AIDS Patient Care STDS. 2001;15(8):411-23.



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Growth Hormones: Norditropin, Genotropin, Humatrope, Nutropin AQ, Omnitrope, Saizen, Zomacton Page: 13 of 14

Effective Date: 10/1/2023 Last Review Date: 8/24/2023

Applies to: Illinois Florida New Jersey
 Maryland Florida Kids Pennsylvania Kids
 Michigan Virginia Kentucky PRMD

12. Parekh NR, Steiger E. Criteria for the use of recombinant human growth hormone in short bowel syndrome. *Nutrition Clin Prac.* 2005;20:503-508.
13. Congilio SJ, Stevenson RD, Rogol AD. Apparent growth hormone deficiency in children with cerebral palsy. *Dev Med Child Neurol.* 1996;38(9):797-804.
14. Shim ML, Moshang T, Oppenheim WL, et al. Is treatment with growth hormone effective in children with cerebral palsy? *Dev Med Child Neurol.* 2004;46(8):569-71.
15. Gallagher MP, Levine LS, Oberfield SE. A review of the effects of therapy on growth and bone mineralization in children with congenital adrenal hyperplasia. *Growth Horm IGF Res.* 2005;15 Suppl A:S26-30.
16. Lin-Su K, Vogiatzi MG, Marshall I, et al. Treatment with growth hormone and luteinizing hormone releasing hormone analog improves final adult height in children with congenital adrenal hyperplasia. *J Clin Endocrinol Metab.* 2005;90:3318-3325.
17. 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.
18. Hardin DS, Adams-Huet B, Brown D, et al. Growth hormone treatment improves growth and clinical status in prepubertal children with cystic fibrosis: results of a multicenter randomized controlled trial. *J Clin Endocrinol Metab.* 2006; 91(12):4925-9.
19. Hardin DS, Ellis KJ, Dyson M, et al. Growth hormone improves clinical status in prepubertal children with cystic fibrosis: Results of a randomized controlled clinical trial. *J Pediatr.* 2001;139:636-42.
20. Hardin DS, Rice J, Ahn C, et al. Growth hormone treatment enhances nutrition and growth in children with cystic fibrosis receiving enteral nutrition. *J Pediatr.* 2005;146:324-8.
21. Ranke MB, Lindberg A. Growth hormone treatment of short children born small for gestational age or with Silver-Russell syndrome: Results from KIGS (Kabi International Growth Study), including the first report on final height. *Acta Paediatr Suppl.* 1996;417:18-26.
22. Gharib H, Cook DM, Saenger PH, et al. American Association of Clinical Endocrinologists Growth Hormone Task Force. Medical guidelines for clinical practice for growth hormone use in adults and children 2003 Update. *Endocr Pract.* 2003;9(1):64-76.
23. National Institute for Clinical Excellence: Guidance on the use of human growth hormone (somatotropin) for the treatment of growth failure in children. May 2010. <http://www.nice.org.uk/nicemedia/live/12992/48715/48715.pdf>. Accessed January 10, 2022.
24. Wilson TA, Rose SR, Cohen P, et al. Update of Guidelines for the Use of Growth Hormone in Children: The Lawson Wilkins Pediatric Endocrinology Society Drug and Therapeutics Committee. *J Pediatr.* 2003;143:415-421.
25. Franklin SL, Geffner ME. Growth hormone: the expansion of available products and indications. *Pediatr Clin North Am.* 2011;58:1141-1165.
26. 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,



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Growth Hormones: Norditropin, Genotropin, Humatrope, Nutropin AQ, Omnitrope, Saizen, Zomacton	Page:	14 of 14
Effective Date:	10/1/2023	Last Review Date:	8/24/2023
Applies to:	<input type="checkbox"/> Illinois <input checked="" type="checkbox"/> Maryland <input type="checkbox"/> Michigan	<input type="checkbox"/> Florida <input type="checkbox"/> Florida Kids <input type="checkbox"/> Virginia	<input checked="" type="checkbox"/> New Jersey <input type="checkbox"/> Pennsylvania Kids <input checked="" type="checkbox"/> Kentucky PRMD

idiopathic short stature, and primary insulin-like growth factor-I deficiency. *Horm Res Paediatr.* 2016;86:361-397.

27. Allen NG, Bangalore Krishna K, Lee PA. Use of gonadotropin-releasing hormone analogs in children. *Curr Opin Pediatr.* 2021;33(4):442-448.
28. Deal CL, Tony M, Hoybye C, et al. Growth Hormone Research Society workshop summary: consensus guidelines for recombinant human growth hormone therapy in Prader-Willi syndrome. *J Clin Endocrinol Metab.* 2013;98:E1072-E1087.
29. Blum WF, Crowe BJ, Quigley CA, et al. Growth hormone is effective in treatment of short stature associated with short stature homeobox-containing gene deficiency: two-year results of a randomized, controlled, multicenter trial. *J Clin Endocrinol Metab.* 2007;92:219-228.
30. Blum WF, Ross JL, Zimmermann AG, et al. GH treatment to final height produces similar height gains in patients with SHOX deficiency and Turner syndrome: results of a multicenter trial. *J Clin Endocrinol Metab.* 2013;98(8):E1383-92.
31. Cook DM, Yuen KCJ, Biller BMK, Kemp SF, Lee Vance M. American Association of Clinical Endocrinologists. Medical guidelines for clinical practice for growth hormone use in growth hormone-deficient adults and transition patients 2009 update. *Endocr Pract.* 2009;15(2):1-28.
32. Molitch ME, Clemmons DR, Malozowski S, et al. Evaluation and treatment of adult growth hormone deficiency: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2011;96:1587-1609.
33. National Institute for Clinical Excellence: Human growth hormone (somatropin) in adults with growth hormone deficiency. August 2003.
34. Deal C, Hasselmann C, Pfaffle RW, et al. Associations between pituitary imaging abnormalities and clinical and biochemical phenotypes in children with congenital growth hormone deficiency: data from an international observational study. *Horm Res Paediatr.* 2013;79:283-292.
35. National Heart, Lung, and Blood Institute. Obesity Education Initiative: The practical guide: identification, evaluation, and treatment of overweight and obesity in adults. Bethesda, MD: US Dept of Health and Human Services, National Heart, Lung, and Blood Institute; 2000. NIH Publication No. 00-4084.
36. Macrilen [package insert]. Goettingen, Germany: Allphamed Pharbil Arzneimittel GmbH; July 2021.
37. 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: 1191-1232.
38. Butler MG, Miller JL, Forster JL. Prader-Willi syndrome – clinical genetics, diagnosis and treatment approaches: An update. *Curr Pediatr Rev.* 2019;15(4):207-244.