Growth Hormone
Genotropin (somatropin)
Humatrope (somatropin)
Norditropin (somatropin)
Nutropin AQ (somatropin)
Omnitrope (somatropin)
Saizen (somatropin)
Zomactan (somatropin)
Skytrofa (lonapegsomatropin-tcgd)
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

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

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

Note: Skytrofa is only FDA approved for pediatric growth hormone deficiency.

Coverage Guidelines

Authorization may be reviewed for members new to AllWays Health Partners who are currently receiving treatment with the requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

Pediatric Growth Hormone (GH) Deficiency

Member meets ONE of the following:

1. Member is a neonate or was diagnosed with GH deficiency as a neonate. 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:
    a. Member has EITHER:
        i. Two pretreatment pharmacologic provocative GH tests with both results demonstrating a peak GH level < 10 ng/mL, OR
        ii. A documented pituitary or CNS disorder (refer to Appendix A) and a pretreatment IGF-1 level > 2 standard deviations (SD) below the mean
    b. 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
    c. For members ≥ 2.5 years of age at initiation of treatment:
        i. Pretreatment height is > 2 SD below the mean and 1-year height velocity is > 1 SD below the mean, OR
        ii. Pretreatment 1-year height velocity is > 2 SD below the mean
    d. Epiphyses are open

Small for Gestational Age

Member meets ALL of the following:

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

Turner Syndrome

Member meets ALL of the following:

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

Growth Failure associated with Chronic Kidney Disease, Cerebral Palsy, Congenital Adrenal Hyperplasia, Cystic Fibrosis, and Russell-Silver Syndrome

Member meets ALL of the following:

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

Prader-Willi Syndrome

Diagnosis of Prader-Willi Syndrome is confirmed by ONE of the following:

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

Noonan Syndrome

Member meets ALL of the following:

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

Short Stature Homeobox-Containing Gene Deficiency (SHOX)

Member meets ALL of the following:

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 > 2SD below the mean
3. Epiphyses are open

Adult GH Deficiency

Member meets ONE of the following:

1. Member has had 2 pretreatment pharmacologic provocative GH tests and both results demonstrated GH levels < 5 ng/mL, unless the agent is Macrilen in which case a GH level of less than 2.8 ng/ml confirms the presence of adult GHD
2. Member has had 1 pretreatment pharmacologic provocative GH test that demonstrated a GH level < 5 ng/mL AND has a pretreatment IGF-1 level that is low for age and gender, unless the agent is Macrilen in which case a GH level of less than 2.8 ng/ml confirms the presence of adult GHD
3. Member has a structural abnormality of the hypothalamus or pituitary (refer to Appendix A) and ≥ 3 documented pituitary hormone deficiencies (refer to Appendix B)
4. Member has childhood-onset GH deficiency and a congenital abnormality of the hypothalamus or pituitary (refer to Appendix A)

HIV-Associated Wasting/Cachexia

Member meets ALL of the following:

1. Member has trialed and experienced a suboptimal response to alternative therapies (e.g., cyproheptadine, dronabinol, megestrol acetate or testosterone if hypogonadal) or contraindication or intolerance to alternative therapies
2. Member is currently on antiretroviral therapy
3. BMI is less than 18.5 kg/m^2 prior to starting therapy with growth hormone (see Appendix C)

Short Bowel Syndrome

Member meets ALL of the following:

1. Member depends on intravenous (IV) parenteral nutrition
2. GH will be used in conjunction with optimal management of SBS

Continuation of Therapy

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

1. **For Pediatric GHD, Turner Syndrome, Noonan Syndrome, CDK, SGA, SHOX deficiency, Congenital Adrenal Hyperplasia, Cerebral Palsy, Cystic Fibrosis and Russel-Silver Syndrome:**
    a. Epiphyses are open (confirmed by X-ray or X-ray is not available)
    b. 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)
2. **Prader-Willi Syndrome (PWS):** documentation indicating member's body composition and psychomotor function have improved or stabilized in response to GH therapy.
3. **For Adult GHD:** Initial criteria is met
4. **HIV-Associated Wasting/Cachexia:**
    a. Member is diagnosed with HIV-associated wasting/cachexia
    b. Member is currently on antiretroviral therapy.
    c. Member is currently receiving treatment with growth hormone excluding obtainment as samples or via manufacturer's patient assistance programs
    d. Current BMI is less than 27 kg/m^2 (see Appendix C).

Limitations

1. Initial approvals will be varied based on the treatment:
    a. **For Short Bowel Syndrome,** approvals will be for up to 8 weeks
    b. **For HIV-Associated Wasting/Cachexia,** approvals will be for up to 12 weeks.
    c. **For ALL other indications,** approvals will be for up to 12 months.
2. Reauthorizations will be varied based on the treatment:
    a. **For HIV-Associated Wasting/Cachexia,** approvals will be for up to 12 weeks.
    b. **For ALL other indications,** approvals will be for up to 12 months.
    c. Treatment for Short Bowel Syndrome past 8 weeks has not been studied and will be reviewed on a case by case basis.

Appendix

Appendix A: Examples of Hypothalamic/Pituitary/CNS Disorders

1. Congenital genetic abnormalities
    a. Known mutations in growth-hormone-releasing hormone (GHRH) receptor, GH gene, GH receptor, or pituitary transcription factors
2. Congenital structural abnormalities
    a. Optic nerve hypoplasia/septo-optic dysplasia
    b. Agenesis of corpus callosum
    c. Empty sella syndrome
    d. Ectopic posterior pituitary
    e. Pituitary aplasia/hypoplasia
    f. Pituitary stalk defect
    g. Anencephaly or prosencephaly
    h. Other mid-line defects
    i. Vascular malformations
3. Acquired structural abnormalities (or causes of hypothalamic/pituitary damage)
    a. CNS tumors/neoplasms (e.g., craniopharyngioma, glioma, pituitary adenoma)
    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 lesions (e.g., autoimmune hypophysitis)
    i. Infiltrative lesions (e.g., sarcoidosis, histiocytosis)
    j. Head trauma/traumatic brain injury
    k. Aneurysmal subarachnoid hemorrhage

Appendix B: Pituitary Hormones (Other than Growth Hormone)

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

Appendix C: Calculation of BMI

$$\text{BMI} = \frac{\text{Weight (pounds)} \times 703}{[\text{Height (inches)}]^2} \quad \text{OR} \quad \frac{\text{Weight (kg)}}{[\text{Height (m)}]^2}$$

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	≥ 40 kg/m^2

References

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

05/18/2022 – Created and Reviewed for May P&T; switched from CVS SGM to custom. Effective 07/01/2022

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.