Growth Hormone
Genotropin, Humatrope, Norditropin, Nutropin AQ, Omnitrope, Saizen, Zomacton, Zorbtive
Effective 01/01/21

Plan	☐ MassHealth ☒ Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	This medication has 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

Recombinant human growth hormone (GH) is the primary treatment for short stature due to GH deficiency, as well as additional indications in children and adolescents; including idiopathic short stature and short stature associated with small for gestational age (SGA), chronic kidney disease, Turner syndrome, Prader-Willi syndrome, mutations in the SHOX gene, and Noonan syndrome. Recombinant GH is also a treatment for indications in adult; including adult GH deficiency and HIV wasting.

Preferred Medications	Non-Preferred Medications
Omnitrope	Humatrope
Genotropin	Norditropin
Nutropin AQ	Saizen
	Serostim
	Zomacton
	Zorbtive

Coverage Guidelines

Authorization may be granted for members new to AllWays Health Partners who are currently receiving treatment with a Growth Hormone product for any indication listed below, excluding when the product is obtained as samples or via manufacturer's patient assistance program.

OR

Authorization may be granted for members for the following indications when all the criteria has been met and documentation has been provided.

Pediatric GH Deficiency

1. Member has a diagnosis of GH deficiency and meets ONE of the following:
    a. 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)
    b. Member meets ALL the following:
        i. Member has ONE of the following:
            A. Two pretreatment pharmacologic provocative GH tests with both results demonstrating a peak GH level < 10 ng/mL
            B. A documented pituitary or CNS disorder (refer to Appendix A) and a pretreatment IGF-1 level > 2 standard deviations (SD) below the mean
        i. 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
        ii. For members ≥ 2.5 years of age at initiation of treatment; meet ONE of the following:
            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 > 2 SD below the mean
            C. Epiphyses are open
2. Authorization for Humatrope, Norditropin, Saizen, and Zomacton may be approved when the member has had an inadequate response, intolerance, and/or contraindication to Omnitrope, Genotropin, AND Nutropin AQ

Small for Gestational Age

1. Member has a diagnosis of born small for gestational age (SGA) when the following criteria are met:
    a. Member meets at least one of the following:
        i. Birth weight < 2500 g at gestational age > 37 weeks
        ii. Birth weight or length less than 3rd percentile for gestational age
        iii. Birth weight or length ≥ 2 SD below the mean for gestational age
    b. Pretreatment age is ≥ 2 years
    c. Member failed to manifest catch-up growth by age 2 (i.e., pretreatment height > 2 SD below the mean)
    d. Epiphyses are open
2. Authorization for Humatrope, Norditropin, and Zomacton may be approved when the member has had an inadequate response, intolerance, and/or contraindication to Omnitrope AND Genotropin.

Turner Syndrome

1. Member has a diagnosis of Turner Syndrome when the following criteria are met:
2. A laboratory test showing a diagnostic karyotype for Turner Syndrome
3. Patient's pretreatment height is less than the 5th percentile for age
4. Epiphyses are open
5. Authorization for Humatrope, Norditropin, and Zomacton may be approved when the member has had an inadequate response, intolerance, and/or contraindication to Omnitrope, Genotropin, AND Nutropin AQ

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

1. Member has a diagnosis of Growth Failure associated with CKD, cerebral palsy, congenital adrenal hyperplasia, cystic fibrosis, or Russell-Silver syndrome
2. 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
3. For members ≥ 2.5 years of age at initiation of treatment, member meets ONE of the following:
    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 > 2 SD below the mean
4. Epiphyses are open
5. Authorization for Humatrope, Norditropin, Saizen, and Zomacton may be approved when the member has had an inadequate response, intolerance, and/or contraindication to Omnitrope, Genotropin, AND Nutropin AQ

Prader-Willi Syndrome (Humatrope, Norditropin, and Zomacton)
1. Member has a diagnosis of Prader-Willi Syndrome
2. Diagnosis was confirmed by ONE of the following genetic testing:
    a. Deletion in the chromosomal 15q11.2-q13 region
    b. Maternal uniparental disomy in chromosome 15
    c. Imprinting defects or translocations involving chromosome 15

Noonan Syndrome (Norditropin ONLY)
1. Member has a diagnosis of short stature associated with Noonan syndrome
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

Short Stature Homeobox-Containing Gene (SHOX) Deficiency (Humatrope and Zomacton)
1. Member has a diagnosis of short stature or growth failure associated with SHOX deficiency
2. The diagnosis is confirmed by molecular or genetic analyses
3. 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
4. Epiphyses are open

Adult GH Deficiency
1. Member has a diagnosis of adult GH deficiency
2. 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
3. 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
4. Member has a structural abnormality of the hypothalamus or pituitary (refer to Appendix A) and ≥ 3 documented pituitary hormone deficiencies (refer to Appendix B)
5. Member has childhood-onset GH deficiency and a congenital abnormality of the hypothalamus or pituitary (refer to Appendix A)
6. Authorization for Humatrope, Norditropin, Saizen and Zomacton may be approved when the member has had an inadequate response, intolerance, and/or contraindication to Omnitrope, Genotropin, AND Nutropin AQ

HIV-Associated Wasting/Cachexia (Serostim ONLY)
1. Member has a diagnosis of HIV associated wasting and/or cachexia
2. Member has tried and had a suboptimal response to alternative therapies (e.g., cyproheptadine, dronabinol, megestrol acetate or testosterone if hypogonadal) unless the member has a contraindication or intolerance to alternative therapies
3. Member is currently on antiretroviral therapy
4. Pretreatment BMI is < 18.5 kg/m2 (see Appendix C)

Short Bowel Syndrome (Zorbtive ONLY)
1. Member has a diagnosis of short bowel syndrome
2. Member depends on intravenous (IV) parenteral nutrition
3. GH medication will be used in conjunction with optimal management of SBS

Continuation of Therapy

Reauthorization requires physician attestation of continuation of therapy and positive response to therapy. For the diagnosis below the documentation of the additional clinical information is also required:
1. Pediatric GH Deficiency, Turner Syndrome, Noonan Syndrome, CKD, SGA, SHOX deficiency, Congenital Adrenal Hyperplasia, Cerebral Palsy, Cystic Fibrosis, and Russell-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: The member's body composition and psychomotor function have improved or stabilized in response to GH therapy.
3. Adult GH Deficiency: All initial criteria are met
4. HIV-Associated Wasting/Cachexia
    a. Member is currently on antiretroviral therapy.
    b. Current BMI is < 27 kg/m2 (see Appendix C).

Limitations

1. Initial authorization will be granted for 12 months for all indications listed above, except of short bowel syndrome.
    - For short bowel syndrome, authorization will be granted for a lifetime total of 8 weeks.
2. Reauthorizations will be granted for 12 months when diagnosis-specific criteria have been met.

Appenices

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

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

BMI classification:
Underweight < 18.5 kg/m2
Normal weight 18.5 – 24.9 kg/m2
Overweight 25 – 29.9 kg/m2
Obesity (class 1) 30 – 34.9 kg/m2
Obesity (class 2) 35 – 39.9 kg/m2
Extreme obesity ≥ 40 kg/m2

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6. Saizen (somatropin) [prescribing information]. Rockland, MA: EMD Serono Inc; August 2020.
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Review History

11/18/2020- Updated: moved criteria from SGM to custom template, added preferred drug strategies, Nov P&T review; references updated. Effective 01/01/21

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.