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Scope: Medicaid

SPECIALTY GUIDELINE MANAGEMENT

NORDITROPIN (somatropin)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no contraindications or exclusions to the prescribed therapy.

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. Idiopathic short stature (ISS)
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. Short stature homeobox-containing gene (SHOX) deficiency
 - b. Cerebral palsy
 - c. Congenital adrenal hyperplasia
 - d. Cystic fibrosis
 - e. Russell-Silver syndrome

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

II. PRESCRIBER SPECIALTIES

For all diagnoses excluding HIV-associated wasting/cachexia, therapy must be prescribed by or in consultation with any of the following specialists:

- A. Endocrinologist
- B. Pediatric endocrinologist

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- C. Geneticist
- D. Pediatric nephrologist (CKD only)

III. INITIAL CRITERIA FOR APPROVAL

Growth charts are required for pediatric patients with the following indications: Growth hormone (GH) deficiency, Turner syndrome, Noonan syndrome, Small for gestational age (SGA), Prader-Willi syndrome, chronic kidney disease (CKD), Short stature homeobox-containing gene (SHOX) deficiency, Idiopathic short stature (ISS), or growth failure associated with any of the following: Cerebral Palsy, Congenital adrenal hyperplasia, Cystic Fibrosis, or Russell-Silver Syndrome

A. Pediatric GH Deficiency

Authorization of 12 months may be granted to members with documentation of pediatric GH deficiency when the following criteria is met:

1. Documentation that the member 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 of the following:
 - i. Member has EITHER:
 1. Two pretreatment pharmacologic provocative GH tests with both results demonstrating a peak GH level < 10 ng/mL, OR
 2. 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:
 1. Pretreatment height is > 2 SD below the mean and 1-year height velocity is > 1 SD below the mean, OR
 2. Pretreatment 1-year height velocity is > 2 SD below the mean
 - iv. Epiphyses are open

B. Idiopathic Short Stature (ISS)

Authorization of 12 months may be granted to members with documentation of ISS when ALL of the following criteria are met:

1. Documentation that the pretreatment height is > 2.25 SD below the mean
2. Documentation that the predicted adult height is $< 5'3''$ for boys and $< 4'11''$ for girls
3. Documentation that the pediatric GH deficiency has been ruled out with a provocative GH test (peak GH level ≥ 10 ng/mL)
4. Documentation that the epiphyses are open

C. Small for Gestational Age (SGA)

Authorization of 12 months may be granted to members with documentation of being born with SGA when ALL of the following criteria are met:

1. Documentation that the member meets at least one of the following:

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- 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. Documentation that the pretreatment age is ≥ 2 years
3. Documentation that the member failed to manifest catch-up growth by age 2 (i.e., pretreatment height > 2 SD below the mean)
4. Documentation that the epiphyses are open

D. Turner Syndrome

Authorization of 12 months may be granted to members with documentation of Turner syndrome when ALL of the following criteria are met:

1. Documentation that the diagnosis was confirmed by karyotyping
2. Documentation that the patient's pretreatment height is less than the 5th percentile for age
3. Documentation that the epiphyses are open

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

Authorization of 12 months may be granted to members with documentation of CKD, cerebral palsy, congenital adrenal hyperplasia, cystic fibrosis, or Russell-Silver syndrome when ALL of the following criteria are met (documentation provided):

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

F. Prader-Willi Syndrome

Authorization of 12 months may be granted to members with documentation of Prader-Willi syndrome when the diagnosis was confirmed by genetic testing demonstrating any of the following (documentation provided):

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

G. Noonan Syndrome

Authorization of 12 months may be granted to members with documentation of Noonan syndrome when ALL of the following criteria are met:

1. Documentation that the 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. Documentation that the epiphyses are open

H. Short Stature Homeobox-Containing Gene Deficiency

Authorization of 12 months may be granted to members with documentation of SHOX deficiency when ALL of the following criteria are met (documentation provided):

1. The diagnosis of SHOX deficiency was confirmed by molecular or genetic analyses

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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

I. Adult GH Deficiency

Authorization of 12 months may be granted to members with documentation of adult GH deficiency when ANY of the following criteria is met:

1. Documentation that the member meets both of the following:
 - a. Member has had 2 pretreatment pharmacologic provocative GH tests and both results demonstrated deficient GH responses defined as the following:
 - i. Insulin tolerance test (ITT) with a peak GH level ≤ 5 ng/mL
 - ii. Macrilen in which case a GH level of less than 2.8 ng/mL
 - iii. 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 (e.g., acquired structural abnormalities) OR a BMI < 25 kg/m²
 - iv. 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
 - b. Member has a low pre-treatment IGF-1 (between 0 to 2 SD below the mean for age and gender)
2. Documentation that the member meets both of the following:
 - a. Member has had 1 pretreatment pharmacologic provocative GH test that demonstrated deficient GH responses defined as one of the following:
 - i. Insulin tolerance test (ITT) with a peak GH level ≤ 5 ng/mL
 - ii. Macrilen with a peak GH level less than 2.8 ng/mL
 - iii. 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
 - iv. 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
 - b. Member has a pretreatment IGF-1 level that is more than 2 SD below the mean for age and gender
3. Documentation that the 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
4. Documentation that the member has genetic or structural hypothalamic-pituitary defects (refer to Appendix C)
5. Documentation that the member has childhood-onset GH deficiency and a congenital abnormality of the CNS, hypothalamus or pituitary (refer to Appendix C)

J. HIV-Associated Wasting/Cachexia

Authorization of 12 weeks may be granted to members with documentation of HIV-associated wasting or cachexia when ALL of the following criteria are met (documentation provided):

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1. Member 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 was less than 18.5 kg/m² prior to initiating therapy with growth hormone (see Appendix D)

K. Short Bowel Syndrome

Authorization of a lifetime total of 8 weeks may be granted to members with documentation of short bowel syndrome who depend on intravenous parenteral nutrition for nutritional support when GH will be used in conjunction with optimal management of SBS.

IV. CONTINUATION OF THERAPY

For all indications listed below, documentation of the member's diagnosis and growth charts for all pediatric indications must be provided.

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

Authorization of 12 months may be granted for continuation of therapy when ALL of the following criteria are met:

1. Documentation that the epiphyses are open (confirmed by X-ray or X-ray is not available)
2. Documentation that the 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 of 12 months 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 (documentation provided).

C. Adult GH Deficiency

Authorization of 12 months may be granted for continuation of therapy when ANY of the following criteria is met:

1. Documentation that the member meets all of the following:
 - a. Member has had 2 pretreatment pharmacologic provocative GH tests and both results demonstrated deficient GH responses defined as the following:
 - i. Insulin tolerance test (ITT) or another provocative GH test with a peak GH level ≤ 5 ng/mL
 - ii. Macrilen with a peak GH level of less than 2.8 ng/mL
 - iii. 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 (e.g., acquired structural abnormalities) OR a BMI < 25 kg/m²
 - iv. 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
 - b. Member has a low pre-treatment IGF-1 (between 0 to 2 SD below the mean)

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- c. Current IGF-1 level is not elevated for age and gender
- 2. Documentation that the member meets all of the following:
 - a. Member has had 1 pretreatment pharmacologic provocative GH test that demonstrated deficient GH responses defined as one of the following:
 - i. Insulin tolerance test (ITT) or another provocative GH test with a peak GH level ≤ 5 ng/mL
 - ii. Macrilen with a peak GH level less than 2.8 ng/mL
 - iii. 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
 - iv. 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
 - b. Member has a pretreatment IGF-1 level that is more than 2 SD below the mean
 - c. Current IGF-1 level is not elevated for age and gender
- 3. Documentation that the member meets both of the following:
 - a. 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
 - b. Current IGF-1 level is not elevated for age and gender
- 4. Documentation that the member has genetic or structural hypothalamic-pituitary defects (refer to Appendix C) and current IGF-1 level is not elevated for age and gender
- 5. Documentation that the 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 of 12 weeks may be granted for continuation of therapy when ALL of the following criteria are met:

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

V. APPENDICES

A. 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
 - b. Perinatal insults
- 2. Congenital structural abnormalities
 - a. Optic nerve hypoplasia/septo-optic dysplasia
 - b. Agenesis of corpus callosum

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- 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

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
 - 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)
- f. Empty sella
- g. Hydrocephalus
- h. Idiopathic

D. Appendix D: 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

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