Prescriber Criteria Form

Growth Hormone 2024 PA Fax 101-A v1 010124.docx Growth Hormone (GH)*

Genotropin, Humatrope, Norditropin, Nutropin AQ, Omnitrope, Saizen, Zomacton (Somatropin)

*Serostim and Zorbtive are not approved for growth hormone deficiency

Coverage Determination

This fax machine is located in a secure location as required by HIPAA regulations.

Complete/review information, sign and date. Fax signed forms to CVS Caremark at **1-855-633-7673**.

Please contact CVS Caremark at **1-866-785-5714** with questions regarding the prior authorization process.

When conditions are met, we will authorize the coverage of Growth Hormone (GH)*.

Drug Name (select from list of drugs shown):

| Patient | Name: | | | | | |
|--------------|---|--------------------|------------------|--------|-----|----|
| Patient | ID: | | | | | |
| Patient DOB: | | Patient Phone: | | | | |
| Prescri | ber Name: | | | | | |
| Prescri | ber Address: | | | | | |
| City: | | State: | Zip: | | | |
| Prescri | ber Phone: | Prescriber Fax: | | | | |
| Diagno | sis: | ICD Code(s): | | | | |
| Please | e circle the appropriate answer for each que | estion. | | | | |
| 1 | Does the patient have a diagnosis of adult growth hormone deficiency? [If no, then skip to question 4.] | | | Yes | No | |
| 2 | Does the patient meet ANY of the following: (GH) stimulation tests, B) Failed 1 pre-treatn treatment insulin-like growth factor-1 (IGF-1) | nent GH stimulatio | n test AND had a | a pre- | Yes | No |

Note: Stimulation tests include: A) insulin tolerance test (ITT) (peak GH less than or equal to 5 ng/ml), B) Macrilen-stimulation test (peak GH level less than 2.8 ng/ml), C) glucagon-stimulation test (GST) (peak GH level less than or equal to 3 ng/ml) for pt with a body mass index (BMI) 25-30 kg/m2 and high pretest probability of growth hormone deficiency (GHD) (e.g., acquired structural abnormalities) or BMI less than 25 kg/m2, and D) GST (peak GH level less than or equal to 1 ng/ml) in pt with BMI 25-30 kg/m2 and low pretest

Does the patient have ANY of the following: A) Organic hypothalamic-pituitary disease

(e.g., suprasellar mass with previous surgery and cranial irradiation) with 3 or more pituitary hormone deficiencies AND a pre-treatment insulin-like growth factor-1 (IGF-1)

level more than 2 standard deviations below the mean, B) Genetic or structural hypothalamic-pituitary defects, C) Childhood-onset growth hormone deficiency with

Yes

No

probability of GHD or BMI greater than 30 kg/m2.

[If yes, then skip to question 20.]

3

| | congenital (genetic or structural) abnormality of the hypothalamus/pituitary/central nervous system? | | |
|----|---|-----|----|
| | [If yes, then skip to question 20.] | | |
| | [If no, then no further questions.] | | |
| 4 | Does the patient have a diagnosis of growth failure associated with chronic kidney disease (CKD)? | Yes | No |
| | [If yes, then skip to question 18.] | | |
| 5 | Does the patient have a diagnosis of pediatric growth hormone deficiency? [If no, then skip to question 9.] | Yes | No |
| | | | |
| 6 | Is the patient a neonate OR was the patient diagnosed with growth hormone deficiency as a neonate? | Yes | No |
| | [If yes, then skip to question 18.] | | |
| 7 | Does the patient meet ANY of the following conditions: A) Patient is younger than 2.5 years of age with a pre-treatment height more than 2 standard deviations below the mean and a slow growth velocity, B) Patient is 2.5 years of age or older with a pre-treatment 1 year height velocity more than 2 standard deviations below the mean OR a pre-treatment height more than 2 standard deviations below the mean plus a 1 year height velocity more than 1 standard deviation below the mean? [If no, then no further questions.] | | No |
| 8 | Does the patient meet ANY of the following conditions: A) Patient has failed 2 pretreatment growth hormone stimulation tests (peak level below 10 nanogram per milliliter), B) Patient has a pituitary or central nervous system disorder (e.g., genetic defect, acquired structural abnormality, congenital structural abnormality) AND a pre-treatment insulin-like growth factor-1 (IGF-1) level more than 2 standard deviations below the mean? [If yes, then skip to question 18.] [If no, then no further questions.] | | No |
| 9 | Does the patient have a diagnosis of Noonan syndrome? [If yes, then skip to question 18.] | | No |
| 10 | Does the patient have a diagnosis of idiopathic short stature? [If yes, then skip to question 18.] | | No |
| 11 | Does the patient have a diagnosis of Prader-Willi syndrome? [If yes, then skip to question 18.] | | No |
| 12 | Does the patient have a diagnosis of born small for gestational age (SGA)? [If no, then skip to question 14.] | | No |
| 13 | Does the patient meet ALL of the following conditions: A) Patient is 2 years of age or older, B) Patient has a birth weight less than 2500 grams at gestational age more than 37 weeks OR a birth weight or length below the 3rd percentile for gestational age or at least 2 standard deviations below the mean for gestational age, C) Patient did not manifest catch-up growth by age 2? | | No |

| | [If yes, then skip to question 18.] | | |
|----|--|-----|----|
| | [If no, then no further questions.] | | |
| 14 | Does the patient have a diagnosis of short stature homeobox-containing gene (SHOX) deficiency? | Yes | No |
| | [If yes, then skip to question 18.] | | |
| 15 | Does the patient have a diagnosis of Turner syndrome? | Yes | No |
| | [If no, then no further questions.] | | |
| 16 | Was the diagnosis confirmed by karyotyping? | Yes | No |
| | [If no, then no further questions.] | | |
| 17 | Is the patient's pre-treatment height less than the 5th percentile for their age? | Yes | No |
| | [If no, then no further questions.] | | |
| 18 | Does the patient have open epiphyses? | Yes | No |
| | [If no, then no further questions.] | | |
| 19 | Is the request for any of the following diagnoses: A) Pediatric growth hormone deficiency, | Yes | No |
| | B) Turner Syndrome, C) Patient born small for gestational age? | | |
| | [If no, then skip to question 22.] | | |
| 20 | Is the patient currently receiving the requested drug? | Yes | No |
| | [If no, then skip to question 22.] | | |
| 21 | Is the patient experiencing improvement of their condition with the requested drug? | Yes | No |
| | [If no, then no further questions.] | | |
| 22 | Is the requested drug being prescribed by or in consultation with any of the following | Yes | No |
| | specialists: A) Endocrinologist, B) Geneticist, C) Nephrologist, D) Infectious disease | | |
| | specialist, E) Gastroenterologist, F) Nutritional support specialist? | | |

| By signing this form, I attest that the information provided is accurate and t | |
|--|----------|
| documentation supporting this information is available for review if request | <u> </u> |
| Prescriber (or Authorized) Signature: | Date: |