Growth Hormone

Prior Authorization Request

CVS Caremark administers the prescription benefit plan for the patient identified. This patient's benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of the prescribed medication is necessary. **Please respond below and fax this form to CVS Caremark toll-free at 1-855-330-1720**. If you have questions regarding the prior authorization, please contact CVS Caremark at **1-888-877-0518.** For inquiries or questions related to the patient's eligibility, drug copay or medication delivery; please contact the Specialty Customer Care Team: CaremarkConnect® 1-800-237-2767.

The recipient of this fax may make a request to opt-out of receiving telemarketing fax transmissions from CVS Caremark. There are numerous ways you may opt-out: The recipient may call the toll-free number at 877-265-2711, at any time, 24 hours a day/7 days a week. The recipient may also send an opt-out request via email to do_not_call@cvscaremark.com. An opt out request is only valid if it (1) identifies the number to which the request relates, and (2) if the person/entity making the request does not, subsequent to the request, provide express invitation or permission to CVS Caremark to send facsimile advertisements to such person/entity at that particular number. CVS Caremark is required by law to honor an opt-out request within thirty days of receipt.

Patient's Name: _____ **Date**: _____
Patient's ID: _____ **Patient's Date of Birth:** _____
Physician's Name: _____
Specialty: _____ **NPI#:** _____
Physician Office Telephone: _____ **Physician Office Fax:** _____

Referring Provider Info: ❑ **Same as Requesting Provider**
Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

Rendering Provider Info: ❑ **Same as Referring Provider** ❑ **Same as Requesting Provider**
Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Required Demographic Information:

Patient Weight: _____*kg*

*Patient Height:*_____*cm*

Please indicate the place of service for the requested drug:

❑ *Ambulatory Surgical*	❑ *Home*	❑ *Off Campus Outpatient Hospital*
❑ *On Campus Outpatient Hospital*	❑ *Office*	❑ *Pharmacy*

Send completed form to: Case Review Unit CVS Caremark Specialty Programs Fax: 1-855-330-1720

Note: This fax may contain medical information that is privileged and confidential and is solely for the use of individuals named above. If you are not the intended recipient you hereby are advised that any dissemination, distribution, or copying of this communication is prohibited. If you have received the fax in error, please immediately notify the sender by telephone and destroy the original fax message. Growth Hormone SGM – 07/2021.

Criteria Questions:

1. What drug is being prescribed? ❑ Genotropin ❑ Humatrope ❑ Norditropin ❑ Nutropin AQ
   ❑ Omnitrope ❑ Saizen ❑ Zomacton ❑ Other _____

2. What is the diagnosis?
   ❑ Pediatric growth hormone deficiency (includes panhypopituitarism)
   ❑ Adult growth hormone deficiency (includes panhypopituitarism)
   ❑ Small for gestational age (SGA)
   ❑ Growth failure associated with cerebral palsy (CP)
   ❑ Growth failure associated with cystic fibrosis (CF)
   ❑ Growth failure associated with chronic kidney disease (CKD)
   ❑ Growth failure associated with congenital adrenal hyperplasia (CAH)
   ❑ Growth failure associated with Russell-Silver syndrome (RSS)
   ❑ Other _____
   ❑ Turner syndrome (TS)
   ❑ Noonan syndrome (NS)
   ❑ HIV-associated wasting/cachexia
   ❑ Short bowel syndrome (SBS)
   ❑ Prader-Willi syndrome (PWS)
   ❑ Idiopathic short stature (ISS)
   ❑ SHOX deficiency (SHOXD)

3. What is the ICD-10 code? _____ *If diagnosis is SBS, skip to section A.*

4. Is this request for continuation of therapy? ❑ Yes ❑ No *If No, skip to diagnosis section.*

5. Is the patient currently receiving growth hormone through samples or a manufacturer's patient assistance program?
   ❑ Yes ❑ No ❑ Unknown *If Yes or Unknown, skip to diagnosis section.*

6. Please indicate/attach the following information provided by the prescriber. ***ACTION REQUIRED: Attach medical records.***
   A) Total duration of treatment (approximate duration is acceptable): _____
   B) Date of the last dose administered: _____
   C) Approving health plan/pharmacy benefit manager: _____
   D) Date of the prior authorization/approval: _____
   E) **Attach** authorization approval letter

Complete the following section based on patient's diagnosis, if applicable.

Section A: Short Bowel Syndrome

7. Is the patient dependent on intravenous parenteral nutrition (e.g. TPN)? ❑ Yes ❑ No

8. Will the requested product be used in conjunction with optimal management of short bowel syndrome (SBS)?
   ❑ Yes ❑ No

9. How many weeks of growth hormone (GH) therapy has the patient received in their lifetime? _____ weeks

Section B: Pediatric Disorders *Please complete the following sub-section, if applicable.*

10. Indicate patient's **pretreatment** height and age ***(two measurements taken 6-18 months apart)***:
    ACTION REQUIRED: Attach a growth chart showing pretreatment heights and growth velocity.
    a) Height: _____ cm Age: _____ years, _____ months Date: _____
    b) Height: _____ cm Age: _____ years, _____ months Date: _____

11. Has patient had any **pretreatment** pharmacologic provocative tests?
    ACTION REQUIRED: If Yes, attach laboratory report or medical record of pre-treatment provocative test results. ❑ Yes, ***How many?*** _____ ❑ No
    ❑ Agent: _____ Peak Level: _____ ng/mL Date: _____
    ❑ Agent: _____ Peak Level: _____ ng/mL Date: _____

12. What is the **pretreatment** 1-year height velocity? ***ACTION REQUIRED: Attach a growth chart showing growth velocity.*** _____ cm/year

13. Does the patient have a **pretreatment** slow growth velocity? ***ACTION REQUIRED: Attach a growth chart showing growth velocity.*** ❑ Yes ❑ No

14. Are the epiphyses still open? ❑ Yes ❑ No ❑ X-ray not available

Send completed form to: Case Review Unit CVS Caremark Specialty Programs Fax: 1-855-330-1720

Note: This fax may contain medical information that is privileged and confidential and is solely for the use of individuals named above. If you are not the intended recipient you hereby are advised that any dissemination, distribution, or copying of this communication is prohibited. If you have received the fax in error, please immediately notify the sender by telephone and destroy the original fax message. Growth Hormone SGM – 07/2021.

15. Indicate patient's **current**: Height: _____ cm Age: _____ years, _____ months

16. *If currently on therapy*, is the patient growing at a rate of more than 2 cm/year? ***ACTION REQUIRED: If yes, collect current growth chart showing growth velocity.*** ❑ Yes ❑ No
    Indicate therapy start date:_____
    If No, indicate clinical reason for the lack of efficacy: _____

I. *Pediatric GHD (includes panhypopituitarism)*

17. Is the patient a neonate or was the patient diagnosed with growth hormone (GH) deficiency as a neonate?
    ❑ Yes ❑ No *If No, skip to #19*

18. Are medical records available to support the diagnosis of neonatal growth hormone (GH) deficiency such as hypoglycemia with random GH level, evidence of multiple pituitary hormone deficiencies, MRI results, or chart notes? ***ACTION REQUIRED: If Yes, attach medical records.*** ❑ Yes ❑ No

19. Does patient have a pituitary or CNS disorder?
    ❑ Known mutation in GH-releasing hormone receptor, GH gene, GH receptor, or pituitary transcription factors
    ❑ CNS tumor/neoplasm (e.g., craniopharyngioma, glioma, pituitary adenoma)
    ❑ Optic nerve hypoplasia/septo-optic dysplasia
    ❑ Empty sella syndrome
    ❑ Ectopic posterior pituitary
    ❑ Pituitary aplasia/hypoplasia
    ❑ Pituitary stalk defect
    ❑ Anencephaly or prosencephaly
    ❑ Other mid-line defect
    ❑ Vascular malformation
    ❑ Surgery
    ❑ Aneurysmal subarachnoid hemorrhage
    ❑ Agenesis of corpus callosum
    ❑ Cyst (Rathke cleft cyst or arachnoid cleft cyst)
    ❑ Radiation
    ❑ Chemotherapy
    ❑ CNS infection
    ❑ CNS infarction (e.g., Sheehan's syndrome)
    ❑ Inflammatory lesion (e.g., autoimmune hypophysitis)
    ❑ Infiltrative lesion (e.g., sarcoidosis, histiocytosis)
    ❑ Head trauma/traumatic brain injury
    ❑ Other _____
    ❑ No pituitary or CNS disorder

20. Does the patient have a **pretreatment** insulin-like growth factor-1 (IGF-1) level greater than 2 standard deviations (SD) below the mean? ***ACTION REQUIRED: If Yes, attach laboratory report or medical record of pretreatment IGF-1 level.*** ❑ Yes ❑ No
    *Indicate patient's **pretreatment** IGF-1 level: _____ Range: _____*

II. *Turner Syndrome (TS)*

21. Was the diagnosis of Turner syndrome confirmed by karyotyping?
    ACTION REQUIRED: If Yes, attach karyotype study result. ❑ Yes ❑ No

III. *SHOX Deficiency*

22. Has the diagnosis of SHOX deficiency been confirmed by molecular or genetic analyses?
    ACTION REQUIRED: If Yes, attach molecular/genetic test results. ❑ Yes ❑ No

IV. *Prader-Willi Syndrome (PWS)*

23. Was the diagnosis of Prader-Willi syndrome confirmed by genetic testing demonstrating any of the following?
    ACTION REQUIRED: If Yes, attach genetic test result.
    ❑ Deletion in 15q11.2-q13 region
    ❑ Imprinting defects/translocations involving chromosome 15
    ❑ Maternal, uniparental disomy in chromosome 15
    ❑ None of the above

24. *If currently on therapy*, have body composition and psychomotor function improved or stabilized in response to growth hormone (GH) therapy? ❑ Yes ❑ No ❑ N/A, not currently on therapy

V. *Small for Gestational Age (SGA)*

25. What was the patient's gestational age at birth? _____ weeks _____ days

26. What was the patient's: Birth Weight? _____ grams AND Birth Length? _____ cm
    ACTION REQUIRED: Attach growth charts showing birth weight and length.

Send completed form to: Case Review Unit CVS Caremark Specialty Programs Fax: 1-855-330-1720

Note: This fax may contain medical information that is privileged and confidential and is solely for the use of individuals named above. If you are not the intended recipient you hereby are advised that any dissemination, distribution, or copying of this communication is prohibited. If you have received the fax in error, please immediately notify the sender by telephone and destroy the original fax message. Growth Hormone SGM – 07/2021.

27. Did the patient fail to manifest catch-up growth by age two as demonstrated by **pretreatment** height greater than 2 standard deviations (SD) below the mean for age and gender? ***ACTION REQUIRED: If yes, collect growth chart showing pretreatment height.*** ❑ Yes ❑ No

VI. *Idiopathic Short Stature (ISS)*

28. What is the patient's **pretreatment** predicted adult height? _____ feet, _____ inches

Section C: Adult Growth Hormone Disorder

29. Does the patient have a low pre-treatment IGF-1 (between 0 to 2 standard deviations below the mean)? ***Action Required: If 'Yes', collect laboratory report or medical record of pretreatment IGF-1 level.***
❑ Yes ❑ No *If No, skip to #33*

30. Has patient had any **pretreatment** pharmacologic provocative growth hormone (GH) tests or a pretreatment test with the agent Macrilen? ***ACTION REQUIRED: If Yes, attach laboratory report or medical record of pre-treatment provocative test results.*** ❑ Yes, ***How many?*** ___ ❑ No *If No, skip to #33*

❑ Agent: _____ Peak Level: _____ ng/mL Date: _____
❑ Agent: _____ Peak Level: _____ ng/mL Date: _____
❑ Agent: _____ Peak Level: _____ ng/mL Date: _____

31. What is the patient's body mass index (BMI)? _____ kg/m^2 , *If less than 25 kg/m^2 or greater than 30 kg/m^2 skip to #33*

32. Does the patient have a high pre-test probability of growth hormone deficiency (e.g., patient has acquired structural abnormalities)? ❑ Yes ❑ No

33. Does the patient have a pretreatment insulin-like growth factor-1 (IGF-1) more than 2 standard deviations below the mean? ***Action Required: If 'Yes', collect laboratory report or medical record of pretreatment IGF-1 level.***
❑ Yes ❑ No

34. Does the patient have organic hypothalamic-pituitary disease (e.g., suprasellar mass with previous surgery and cranial irradiation)? ❑ Yes ❑ No *If No, skip to #37*

35. Does the patient have deficiencies of three or more pituitary hormones?
If Yes, indicate below or mark "No deficiencies of pituitary hormones."
❑ Growth hormone ❑ Adrenocorticotropic hormone (ACTH)
❑ Antidiuretic hormone (ADH) ❑ Follicle stimulating hormone (FSH)
❑ Luteinizing hormone (LH) ❑ Thyroid stimulating hormone (TSH)
❑ Prolactin ❑ Other _____
❑ No deficiencies of pituitary hormones, *continue to #37*

36. Does the patient have a pretreatment insulin-like growth factor-1 (IGF-1) more than 2 standard deviations below the mean for age and gender***?*** ***Action Required: If 'Yes', collect laboratory report or medical record of pretreatment IGF-1 level.*** *If yes, no further questions* ❑ Yes ❑ No

37. Does the patient have a genetic or structural hypothalamic-pituitary defect (e.g., transcription factor defects, GHRH receptor-gene defects, GH-receptor/post-receptor defects, GH-gene defects associated with brain structural defects, single central incisor, cleft lip/palate)? *If initation and yes, no further questions. If continuation and yes, skip to #40* ❑ Yes ❑ No

38. Did the patient have childhood-onset growth hormone deficiency (GHD)? ❑ Yes ❑ No

39. Does the patient have a congenital abnormality of the CNS, hypothalamus, or pituitary gland?
❑ Yes ❑ No *If initation and yes, no further questions. If continuation and yes, continue to #40*

40. Is the patient's current IGF-1 elevated for age and gender? ***Action Required: If 'Yes', collect laboratory report or medical record of current IGF-1 level.*** ❑ Yes ❑ No

Note: This fax may contain medical information that is privileged and confidential and is solely for the use of individuals named above. If you are not the intended recipient you hereby are advised that any dissemination, distribution, or copying of this communication is prohibited. If you have received the fax in error, please immediately notify the sender by telephone and destroy the original fax message. Growth Hormone SGM – 07/2021.

Section D: HIV-Related Wasting

41. Is the patient on anti-retroviral therapy? ❑ Yes ❑ No

42. Indicate the following:
    Pretreatment: Height: _____ cm Weight: _____ lbs / kg body mass index (BMI): _____ kg/m^2
    Current: Height: _____ cm Weight: _____ lbs / kg body mass index (BMI): _____ kg/m^2

43. *If new to growth hormone (GH) therapy*, has the patient tried and had a suboptimal response to alternative therapies (i.e., dronabinol, megesterol, cyproheptadine, or testosterone if hypogonadal)?
    If Yes, skip to #39 ❑ Yes ❑ No ❑ N/A – patient is currently on growth hormone (GH) therapy

44. Did the patient have a contraindication or intolerance to alternative therapies (i.e., dronabinol, megesterol, cyproheptadine, or testosterone if hypogonadal)? ❑ Yes ❑ No

45. Has the patient received treatment with growth hormone? ❑ Yes ❑ No

****Please attach the most recent clinical notes or supporting documentation****

I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by CVS Caremark or the benefit plan sponsor.

X_____
Prescriber or Authorized Signature **Date (mm/dd/yy)**

Please complete the following contact information in case additional information is needed.

Office Contact Person:_____ Contact Phone:_____ Ext #: _____

Send completed form to: Case Review Unit CVS Caremark Specialty Programs Fax: 1-855-330-1720

Note: This fax may contain medical information that is privileged and confidential and is solely for the use of individuals named above. If you are not the intended recipient you hereby are advised that any dissemination, distribution, or copying of this communication is prohibited. If you have received the fax in error, please immediately notify the sender by telephone and destroy the original fax message. Growth Hormone SGM – 07/2021.