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 1-866-249-6155**. If you have questions regarding the prior authorization, please contact CVS Caremark at **1-866-814-5506.** 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: _____
Request Initiated For: _____

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

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

3. What is the ICD-10 code? _____

4. The preferred product for your patient's health plan is Norditropin. Can the patient's treatment be switched to Humatrope? ***If Yes, fax a new prescription to the pharmacy.*** ❑ Yes - Norditropin ❑ No - Continue request for non-preferred product. *If No, complete this form in its entirety and State Step Therapy section.*

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

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

7. 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

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

Section A: Short Bowel Syndrome

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

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

10. 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.*

11. 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: _____

12. 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: _____

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

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

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

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

17. *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)

18. Is the patient a neonate or was the patient diagnosed with growth hormone (GH) deficiency as a neonate? ❑ Yes ❑ No *If No, skip to #20*

19. 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

20. 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

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21. 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)

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

III. SHOX Deficiency

23. 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)

24. 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
❑ None of the above ❑ Maternal, uniparental disomy in chromosome 15

25. *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)

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

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

28. 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)

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

Section C: Adult Growth Hormone Disorder

30. Has patient had any **pretreatment** pharmacologic provocative 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

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

31. Does the patient have a low **pretreatment** insulin-like growth factor-1 (IGF-1) level for age and gender? ***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:* _____

32. Does the patient have a structural abnormality of the hypothalamus or pituitary gland?
❑ Yes ❑ No *If No, skip to #34*

33. Does the patient have deficiencies of three or more pituitary hormones?
If Yes, indicate below and no further questions 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 #34*

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

35. Does the patient have a congenital abnormality of the hypothalamus or pituitary gland? ❑ Yes ❑ No

Section D: HIV-Related Wasting

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

37. 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

38. *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 #40 ❑ Yes ❑ No ❑ N/A – patient is currently on growth hormone (GH) therapy

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

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

State Step Therapy

1. Is the requested drug being used for an FDA-approved indication or an indication supported in the compendia of current literature (examples: AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)? ❑ Yes ❑ No

2. Does the prescribed quantity fall within the manufacturer's published dosing guidelines or within dosing guidelines found in the compendia of current literature (examples: package insert, AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)? ❑ Yes ❑ No

3. Does the patient reside in Maryland? ❑ Yes ❑ No *If No, skip to #7*

4. Is the alternate drug (Norditropin) FDA-approved for the medical condition being treated? ❑ Yes ❑ No

5. Has the prescriber provided proof, documented in the patient's chart notes, indicating that the requested drug was ordered for the patient in the past 180 days? ❑ Yes ❑ No *If No, skip to #7*

6. Has the prescriber provided proof, documented in the patient chart notes, that in their opinion the requested drug is effective for the patient's condition? ❑ Yes ❑ No *No further questions*

7. Are any of the following conditions met for the alternate drug (Norditropin)?
❑ The alternate drug is contraindicated
❑ The alternate drug is likely to cause an adverse reaction, physical or mental harm
❑ The alternate drug is expected to be ineffective
❑ The alternate drug was previously tried or a drug in the same class or with the same action was previously tried and was stopped due to ineffectiveness or an adverse event
❑ The alternate drug is not in the patient's best interest
❑ The alternate drug was tried while covered by the current or the previous health benefit plan
❑ None of the above

8. Is the patient stable or currently receiving a positive therapeutic outcome with the requested drug and a change in the prescription drug is expected to be ineffective or cause harm to the patient? ❑ 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 #: _____

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