PA Request Criteria

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This fax machine is located in a secure location as required by HIPAA regulations. Fax complete signed and dated forms to CVS/Caremark at . Please contact CVS/Caremark at 1-888-413-2723 with questions regarding the prior authorization process. When conditions are met, we will authorize the coverage of the medication.

Patient Name: _____ **Date:** 6/13/2025
Patient ID: _____ **Patient Date Of Birth:**
Patient Group No: _____ **Patient Phone:** _____ **Physician Name:**
NPI#: **Specialty:**
Physician Office Address: _____ **Physician Office Telephone:**

Drug Name (specify drug) _____

Quantity: _____ **Frequency:** _____ **Strength:** _____

Route of Administration: _____ **Expected Length of Therapy:** _____

Diagnosis: _____ **ICD Code:** _____

Comments: _____

Please check the appropriate answer for each applicable question.

1. What is the diagnosis?
   - Pediatric growth hormone (GH) deficiency (including panhypopituitarism) (If checked, go to 2) ☐
   - Adult growth hormone (GH) deficiency (including panhypopituitarism) (If checked, go to 29) ☐
   - Other, please specify. (If checked, no further questions) ☐

   _____

2. Is the request for continuation of therapy of the requested drug, or another growth hormone product indicated for pediatric growth hormone (GH) deficiency? **Y** ☐ **N** ☐

3. Is the patient currently receiving growth hormone through samples or a manufacturer's patient assistance program?
   - Yes (If checked, go to 13) ☐
   - No (If checked, go to 4) ☐
   - Unknown (If checked, go to 13) ☐

4. Has the patient been previously approved for prior authorization for growth hormone under a health plan or pharmacy benefit manager? **Y** ☐ **N** ☐

5. Is the following information provided by the prescriber: 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, and E) Prior authorization approval letter? ACTION REQUIRED: If Yes, attach medical records. ACTION REQUIRED: Submit supporting documentation **Y** ☐ **N** ☐

6. Is information on the patient's current age provided? Indicate age in years and months. **Y** ☐ **N** ☐

   _____

7. Is information on the patient's current height provided? Indicate height in centimeters. **Y** ☐ **N** ☐

   _____

8. Is information on the date growth hormone therapy was initiated provided? **Y** ☐ **N** ☐

   _____

9. Are epiphyses still open?

Yes, confirmed by X-ray (If checked, go to 10) ☐

Yes, but X-ray not available (If checked, go to 10) ☐

No (If checked, no further questions) ☐

10. Is the patient growing at a rate of more than 2 cm/year? ACTION REQUIRED: If Yes, attach current growth chart showing growth velocity. **Y** ☐ **N** ☐
    ACTION REQUIRED: Submit supporting documentation

11. Is there a clinical reason for the lack of efficacy? **Y** ☐ **N** ☐

12. What is the clinical reason for the lack of efficacy?

    On treatment less than 1 year - Indicate treatment duration (If checked, no further questions) ☐

    _____

    Nearing final adult height or in later stages of puberty (If checked, no further questions) ☐

    Other, please specify. (If checked, no further questions) ☐

    _____

13. Is the patient 2.5 years of age or older? **Y** ☐ **N** ☐

14. Was the patient diagnosed with growth hormone (GH) deficiency as a neonate? **Y** ☐ **N** ☐

15. Is there documentation to support the diagnosis of neonatal growth hormone (GH) deficiency (such as hypoglycemia with random GH level, evidence of multiple pituitary hormone deficiencies, magnetic resonance imaging [MRI] results)? ACTION REQUIRED: If Yes, attach medical documentation, laboratory report, or imaging report. **Y** ☐ **N** ☐
    ACTION REQUIRED: Submit supporting documentation

16. Is the documentation supporting the diagnosis of neonatal growth hormone (GH) deficiency (such as hypoglycemia with random GH level, evidence of multiple pituitary hormone deficiencies, magnetic resonance imaging [MRI] results) attached? **Y** ☐ **N** ☐

17. Does the patient have 2 pretreatment pharmacologic provocative tests for growth hormone (GH)? ACTION REQUIRED: If Yes, attach laboratory report or medical record of pre-treatment provocative test results. **Y** ☐ **N** ☐
    ACTION REQUIRED: Submit supporting documentation

18. What is the peak level? Indicate in ng/mL.

    Less than 10 ng/mL (If checked, go to 22) ☐

    _____

    Greater than or equal to 10 ng/mL (If checked, go to 19) ☐

    _____

19. Does the patient have a pituitary or central nervous system (CNS) disorder? **Y** ☐ **N** ☐

20. What is the pituitary or central nervous system (CNS) disorder?

    Transcription factor defect (PIT-1, PROP-1, LHX3/4, HESX-1, PITX-2) (If checked, go to 21) ☐

    Growth hormone releasing hormone (GHRH) receptor gene defect (If checked, go to 21) ☐

    GH secretagogue receptor gene defect (If checked, go to 21) ☐

    GH gene defect (If checked, go to 21) ☐

    Optic nerve hypoplasia/septo-optic dysplasia (If checked, go to 21) ☐

    Agenesis of corpus callosum (If checked, go to 21) ☐

    Empty sella syndrome (If checked, go to 21) ☐

    Ectopic posterior pituitary (If checked, go to 21) ☐

    Pituitary aplasia/hypoplasia (If checked, go to 21) ☐

Pituitary stalk defect (If checked, go to 21) ☐

Holoprosencephaly (If checked, go to 21) ☐

Encephalocele (If checked, go to 21) ☐

Hydrocephalus (If checked, go to 21) ☐

Anencephaly or prosencephaly (If checked, go to 21) ☐

Arachnoid cyst (If checked, go to 21) ☐

Other mid-line facial defects (e.g., single central incisor, cleft lip/palate) (If checked, go to 21) ☐

Vascular malformation (If checked, go to 21) ☐

CNS tumor/neoplasm (e.g., craniopharyngioma, glioma/astrocytoma, pituitary adenoma, germinoma) (If checked, go to 21) ☐

Cyst (Rathke cleft cyst or arachnoid cleft cyst) (If checked, go to 21) ☐

Surgery (If checked, go to 21) ☐

Radiation (If checked, go to 21) ☐

Chemotherapy (If checked, go to 21) ☐

CNS infection (If checked, go to 21) ☐

CNS infarction (If checked, go to 21) ☐

Inflammatory process (e.g., autoimmune hypophysitis) (If checked, go to 21) ☐

Infiltrative process (e.g., sarcoidosis, histiocytosis, hemochromatosis) (If checked, go to 21) ☐

Head trauma/traumatic brain injury (If checked, go to 21) ☐

Aneurysmal subarachnoid hemorrhage (If checked, go to 21) ☐

Perinatal or postnatal trauma (If checked, go to 21) ☐

Surgery of the pituitary or hypothalamus (If checked, go to 21) ☐

Other, please specify. (If checked, no further questions) ☐

_____

21. Does the patient have a pretreatment insulin-like growth factor-1 (IGF-1) level greater than 2 standard deviations (SD) below the mean based on the laboratory reference range? ACTION REQUIRED: If Yes, attach laboratory report or medical record of pretreatment IGF-1 level.
    ACTION REQUIRED: Submit supporting documentation
    Y ☐ **N** ☐

22. Is one pretreatment height and the patient's age at the time the height was recorded provided? Indicate height in centimeters and age in years and months.
    Y ☐ **N** ☐
    _____

23. Is a second pretreatment height and the patient's age at the time the height was recorded provided? Indicate height in centimeters and age in years and months.
    Y ☐ **N** ☐
    _____

24. Does the patient have a pretreatment height of greater than 2 standard deviations (SD) below the mean for age and gender? ACTION REQUIRED: If Yes, attach a growth chart showing pretreatment height.
    ACTION REQUIRED: Submit supporting documentation
    Y ☐ **N** ☐

25. Does the patient have a pretreatment 1-year height velocity of greater than 1 standard deviation (SD) below the mean for age and gender? ACTION REQUIRED: If Yes, attach a growth chart showing pretreatment height and height velocity.
    ACTION REQUIRED: Submit supporting documentation
    Y ☐ **N** ☐

26. Does the patient have a pretreatment 1-year height velocity of greater than 2 standard deviations (SD) below the mean for age and gender? ACTION REQUIRED: If Yes, attach a growth chart showing pretreatment height velocity.
    ACTION REQUIRED: Submit supporting documentation
    Y ☐ **N** ☐

27. Are the epiphyses still open?
    Y ☐ **N** ☐

28. Are the laboratory reports or medical record documentation of the pretreatment provocative tests for growth hormone (GH), pretreatment insulin-like growth factor-1 (IGF-1) levels, and growth chart attached, if applicable? **Y** ☐ **N** ☐

29. Is the request for continuation of therapy of the requested drug, or another growth hormone product indicated for adult growth hormone (GH) deficiency? **Y** ☐ **N** ☐

30. Is the patient currently receiving growth hormone through samples or a manufacturer's patient assistance program?

- ☐ Yes (If checked, go to 32)
- ☐ No (If checked, go to 31)
- ☐ Unknown (If checked, go to 32)

31. Has the patient been previously approved for prior authorization for growth hormone under a health plan or pharmacy benefit manager? **Y** ☐ **N** ☐

32. What is the patient's pretreatment insulin-like growth factor-1 (IGF-1)? ACTION REQUIRED: Attach laboratory report or medical record of pretreatment IGF-1 level.

- ☐ 0 to 2 standard deviation(s) (SD) below the mean for age and gender based on laboratory reference range (If checked, go to 33)
- ☐ Greater than 2 standard deviations (SD) below the mean for age and gender based on laboratory reference range (If checked, go to 48)
- ☐ Other or unknown (If checked, go to 59)

ACTION REQUIRED: Submit supporting documentation

33. Has the patient had at least 2 pretreatment pharmacologic provocative growth hormone (GH) tests? ACTION REQUIRED: If Yes, attach laboratory report or medical record of pretreatment provocative test results. **Y** ☐ **N** ☐

ACTION REQUIRED: Submit supporting documentation

34. What was the first agent used?

- ☐ Insulin tolerance test (If checked, go to 35)
- ☐ Glucagon stimulation test (If checked, go to 37)
- ☐ Macrilen test (If checked, go to 36)
- ☐ None of the above (If checked, go to 59)

35. What was the peak growth hormone (GH) level of the insulin tolerance test?

- ☐ Less than or equal to 5 ng/mL (If checked, go to 41)
- ☐ Greater than 5 ng/mL (If checked, go to 59)

36. What was the peak growth hormone (GH) level of the Macrilen test?

- ☐ Less than 2.8 ng/mL (If checked, go to 41)
- ☐ Greater than or equal to 2.8 ng/mL (If checked, go to 59)

37. What is the patient's body mass index (BMI)?

- ☐ Less than 25 kg/m^2 (If checked, go to 39)
- ☐ Greater than or equal to 25 kg/m^2 but less than or equal to 30 kg/m^2 (If checked, go to 38)
- ☐ Greater than 30 kg/m^2 (If checked, go to 40)

38. Does the patient have a high pretest probability of growth hormone deficiency (e.g., patient has acquired structural abnormalities)? **Y** ☐ **N** ☐

39. What was the peak growth hormone level with the glucagon stimulation test?

- ☐ Less than or equal to 3.0 ng/mL (If checked, go to 41)
- ☐ Greater than 3.0 ng/mL (If checked, go to 59)

40. What was the peak growth hormone level with the glucagon stimulation test?
- Less than or equal to 1.0 ng/mL (If checked, go to 41) ☐
- Greater than 1.0 ng/mL (If checked, go to 59) ☐

41. What was the second agent used?
- Insulin tolerance test (If checked, go to 42) ☐
- Glucagon stimulation test (If checked, go to 44) ☐
- Macrilen test (If checked, go to 43) ☐
- None of the above (If checked, go to 59) ☐

42. What was the peak growth hormone (GH) level of the insulin tolerance test?
- Less than or equal to 5 ng/mL (If checked, go to 56) ☐
- Greater than 5 ng/mL (If checked, go to 59) ☐

43. What was the peak growth hormone (GH) level of the Macrilen test?
- Less than 2.8 ng/mL (If checked, go to 56) ☐
- Greater than or equal to 2.8 ng/mL (If checked, go to 59) ☐

44. What is the patient's body mass index (BMI)?
- Less than 25 kg/m^2 (If checked, go to 46) ☐
- Greater than or equal to 25 kg/m^2 but less than or equal to 30 kg/m^2 (If checked, go to 45) ☐
- Greater than 30 kg/m^2 (If checked, go to 47) ☐

45. Does the patient have a high pretest probability (e.g., acquired structural abnormalities) of growth hormone deficiency (GHD)? **Y** ☐ **N** ☐

46. What was the peak growth hormone level with the glucagon stimulation test?
- Less than or equal to 3.0 ng/mL (If checked, go to 56) ☐
- Greater than 3.0 ng/mL (If checked, go to 59) ☐

47. What was the peak growth hormone level with the glucagon stimulation test?
- Less than or equal to 1.0 ng/mL (If checked, go to 56) ☐
- Greater than 1.0 ng/mL (If checked, go to 59) ☐

48. Has the patient had at least 1 pretreatment pharmacologic provocative growth hormone (GH) test? ACTION REQUIRED: If Yes, attach laboratory report or medical record of pretreatment provocative test results. **Y** ☐ **N** ☐
ACTION REQUIRED: Submit supporting documentation

49. What was the agent used?
- Insulin tolerance test (If checked, go to 50) ☐
- Glucagon stimulation test (If checked, go to 52) ☐
- Macrilen test (If checked, go to 51) ☐
- None of the above (If checked, go to 57) ☐

50. What was the peak growth hormone (GH) level of the insulin tolerance test?
- Less than or equal to 5 ng/mL (If checked, go to 56) ☐
- Greater than 5 ng/mL (If checked, go to 57) ☐

51. What was the peak growth hormone (GH) level of the Macrilen test?

Less than 2.8 ng/mL (If checked, go to 56) ☐

Greater than or equal to 2.8 ng/mL (If checked, go to 57) ☐

52. What is the patient's body mass index (BMI)?

Less than 25 kg/m^2 (If checked, go to 54) ☐

Greater than or equal to 25 kg/m^2 but less than or equal to 30 kg/m^2 (If checked, go to 53) ☐

Greater than 30 kg/m^2 (If checked, go to 55) ☐

53. Does the patient have a high pretest probability (e.g., acquired structural abnormalities) of growth hormone deficiency (GHD)? **Y** ☐ **N** ☐

54. What was the peak growth hormone level with the glucagon stimulation test?

Less than or equal to 3.0 ng/mL (If checked, go to 56) ☐

Greater than 3.0 ng/mL (If checked, go to 57) ☐

55. What was the peak growth hormone level with the glucagon stimulation test?

Less than or equal to 1.0 ng/mL (If checked, go to 56) ☐

Greater than 1.0 ng/mL (If checked, go to 57) ☐

56. Are the laboratory reports or medical records of the pretreatment provocative tests for growth hormone (GH) and pretreatment insulin-like growth factor-1 (IGF-1) levels attached, if applicable? **Y** ☐ **N** ☐

57. Does the patient have organic hypothalamic-pituitary disease (e.g., suprasellar mass with previous surgery and cranial irradiation)? **Y** ☐ **N** ☐

58. Does the patient have documented deficiencies in at least three of the following pituitary hormones: A) Growth hormone, B) Adrenocorticotropic hormone (ACTH), C) Antidiuretic hormone (ADH), D) Follicle stimulating hormone (FSH), E) Luteinizing hormone (LH), F) Thyroid stimulating hormone (TSH), and G) Prolactin? If Yes, indicate deficient pituitary hormones. **Y** ☐ **N** ☐

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59. Does the patient have one of the following genetic or congenital structural hypothalamic-pituitary defects: A) Transcription factor defects (PIT-1, PROP-1, LHX3/4, HESX-1, PITX-2), B) GHRH receptor-gene defects, C) GH secretagogue receptor gene defects, D) GH-gene defects associated with brain structural defects, E) Single central incisor, or F) cleft lip/palate, OR have an acquired cause (perinatal insults)? **Y** ☐ **N** ☐

60. Does the patient have childhood-onset growth hormone deficiency (GHD)? **Y** ☐ **N** ☐

61. Does the patient have a congenital abnormality of the central nervous system (CNS), hypothalamus, or pituitary gland? **Y** ☐ **N** ☐

62. Is the following information provided by the prescriber: 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, and E) Prior authorization approval letter? ACTION REQUIRED: If Yes, attach medical records. **Y** ☐ **N** ☐

63. Does the patient have organic hypothalamic-pituitary disease (e.g., suprasellar mass with previous surgery and cranial irradiation)? **Y** ☐ **N** ☐

64. Does the patient have documented deficiencies in at least three of the following pituitary hormones: A) Growth hormone, B) Adrenocorticotropic hormone (ACTH), C) Antidiuretic hormone (ADH), D) Follicle stimulating hormone (FSH), E) Luteinizing hormone (LH), F) Thyroid stimulating hormone (TSH), and G) Prolactin? If Yes, indicate deficient pituitary hormones. **Y** ☐ **N** ☐

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65. Does the patient have one of the following genetic or congenital structural hypothalamic-pituitary defects: A) Transcription factor defects (PIT-1, PROP-1, LHX3/4, HESX-1, PITX-2), B) GHRH receptor-gene defects, C) GH secretagogue receptor gene defects, D) GH-gene defects associated with brain structural defects, E) Single central incisor, or F) cleft lip/palate, OR have an acquired cause (perinatal insults)? **Y** ☐ **N** ☐

66. Does the patient have childhood-onset growth hormone deficiency (GHD)? **Y** ☐ **N** ☐

67. Does the patient have a congenital abnormality of the central nervous system (CNS), hypothalamus, or pituitary gland? **Y** ☐ **N** ☐

68. Is the patient's current insulin-like growth factor-1 (IGF-1) elevated for age and gender based on the laboratory reference range? ACTION REQUIRED: If No, attach laboratory report or medical record of current IGF-1 level. **Y** ☐ **N** ☐
    ACTION REQUIRED: Submit supporting documentation

I attest that the medication requested is medically necessary for this patient. I further attest that the information provided is accurate and true, and that the documentation supporting this information is available for review if requested by the claims processor, the health plan sponsor, or, if applicable a state or federal regulatory agency.

_____

Prescriber (Or Authorized) Signature and Date