Growth Hormone

CareFirst 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*

What is the ICD-10 code? _____

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

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

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Criteria Questions:

1. What is the diagnosis?

❒ Pediatric growth hormone (GH) deficiency (including panhypopituitarism), *Continue to 2*

❒ Adult growth hormone (GH) deficiency (including panhypopituitarism), *Continue to 72*

❒ Idiopathic short stature (ISS), *Continue to 144*

❒ Small for gestational age (SGA), *Continue to 2*

❒ Turner syndrome, *Continue to 2*

❒ Growth failure associated with chronic kidney disease (CKD), *Continue to 2*

❒ Noonan syndrome, *Continue to 2*

❒ Growth failure associated with cystic fibrosis, *Continue to 2*

❒ Prader-Willi syndrome, *Continue to 2*

❒ HIV-associated wasting/cachexia, *Continue to 158*

❒ Short stature homeobox-containing gene (SHOX) deficiency, *Continue to 2*

❒ Growth failure associated with congenital adrenal hyperplasia, *Continue to 2*

❒ Growth failure associated with cerebral palsy, *Continue to 2*

❒ Growth failure associated with Russell-Silver syndrome, *Continue to 2*

❒ Short bowel syndrome (SBS), *Continue to 141*

❒ Other, please specify. _____, *No further questions*

2. Is this request for continuation of therapy?

❒ Yes, *Continue to 3*

❒ No, *Continue to 5*

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

❒ Yes, *Continue to 5*

❒ No, *Continue to 4*

❒ Unknown, *Continue to 5*

4. 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

❒ Yes, *Continue to 63*

❒ No, *Continue to 63*

5. What is the patient's diagnosis?

❒ Pediatric growth hormone (GH) deficiency (includes panhypopituitarism) - Please indicate the date GH deficiency was diagnosed and the date GH therapy was initiated (if applicable) _____, *Continue to 6*

❒ Small for gestational age (SGA), *Continue to 53*

❒ Turner syndrome, *Continue to 23*

❒ Noonan syndrome, *Continue to 47*

❒ Growth failure associated with chronic kidney disease (CKD), *Continue to 36*

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❒ Growth failure associated with cystic fibrosis, *Continue to 36*

❒ Growth failure associated with congenital adrenal hyperplasia, *Continue to 36*

❒ Growth failure associated with cerebral palsy, *Continue to 36*

❒ Growth failure associated with Russell-Silver syndrome, *Continue to 36*

❒ Short stature homeobox-containing gene (SHOX) deficiency, *Continue to 28*

❒ Prader-Willi Syndrome, *Continue to 44*

6. Is the patient a neonate or was the patient diagnosed with growth hormone (GH) deficiency as a neonate?
❒ Yes, *Continue to 7*
❒ No, *Continue to 9*

7. 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, magnetic resonance imaging (MRI) results, or chart notes? ***ACTION REQUIRED***: If Yes, attach medical records. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *Continue to 8*
❒ No, *Continue to 8*

8. Is the medical record 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, or chart notes) attached?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

9. 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. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *Continue to 10*
❒ No, *Continue to 11*

10. What is the peak level? Indicate in ng/ml.
_____ ng/ml, *Continue to 14*

11. Does the patient have a pituitary or central nervous system (CNS) disorder?
❒ Yes, *Continue to 12*
❒ No, *Continue to 12*

12. What is the pituitary or CNS disorder?

❒ Transcription factor defect (PIT-1, PROP-1, LHX3/4, HESX-1, PITX-2), *Continue to 13*

❒ Growth hormone releasing hormone (GHRH) receptor gene defect, *Continue to 13*

❒ GH secretagogue receptor gene defect, *Continue to 13*

❒ GH gene defect, *Continue to 13*

❒ Optic nerve hypoplasia/septo-optic dysplasia, *Continue to 13*

❒ Agenesis of corpus callosum, *Continue to 13*

❒ Empty sella syndrome, *Continue to 13*

❒ Ectopic posterior pituitary, *Continue to 13*

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❒ Pituitary aplasia/hypoplasia, *Continue to 13*

❒ Pituitary stalk defect, *Continue to 13*

❒ Holoprosencephaly, *Continue to 13*

❒ Encephalocele, *Continue to 13*

❒ Hydrocephalus, *Continue to 13*

❒ Anencephaly or prosencephaly, *Continue to 13*

❒ Arachnoid cyst, *Continue to 13*

❒ Other mid-line facial defects (e.g., single central incisor, cleft lip/palate), *Continue to 13*

❒ Vascular malformation, *Continue to 13*

❒ CNS tumor/neoplasm (e.g., craniopharyngioma, glioma/astrocytoma, pituitary adenoma, germinoma), *Continue to 13*

❒ Cysts (Rathke cleft cyst or arachnoid cleft cyst), *Continue to 13*

❒ Surgery, *Continue to 13*

❒ Radiation, *Continue to 13*

❒ Chemotherapy, *Continue to 13*

❒ CNS infection, *Continue to 13*

❒ CNS infarction, *Continue to 13*

❒ Inflammatory process (e.g., autoimmune hypophysitis), *Continue to 13*

❒ Infiltrative process (e.g., sarcoidosis, histiocytosis, hemochromatosis), *Continue to 13*

❒ Head trauma/traumatic brain injury, *Continue to 13*

❒ Aneurysmal subarachnoid hemorrhage, *Continue to 13*

❒ Perinatal or postnatal trauma, *Continue to 13*

❒ Surgery of the pituitary or hypothalamus, *Continue to 13*

❒ Other, please specify. _____, *Continue to 13*

13. 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

❒ Yes, *Continue to 14*

❒ No, *Continue to 14*

14. 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. _____

❒ Yes, *Continue to 15*

❒ No, *Continue to 15*

15. 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. _____

❒ Yes, *Continue to 16*

❒ No, *Continue to 16*

16. What is the pretreatment age?

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❒ Less than 2.5 years of age, *Continue to 17*

❒ Greater than or equal to 2.5 years of age, *Continue to 18*

17. Does the patient have a pretreatment height of greater than 2 standard deviations (SD) below the mean for age and gender AND a slow growth velocity? ***ACTION REQUIRED***: If Yes, attach a growth chart showing pretreatment heights and growth velocity. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *Continue to 21*
❒ No, *Continue to 21*

18. Does the patient have a pretreatment height of greater than 2 standard deviations (SD) below the mean for age and gender?
❒ Yes, *Continue to 19*
❒ No, *Continue to 20*

19. 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
❒ Yes, *Continue to 21*
❒ No, *Continue to 21*

20. 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
❒ Yes, *Continue to 21*
❒ No, *Continue to 21*

21. Are the epiphyses still open?
❒ Yes, *Continue to 22*
❒ No, *Continue to 22*

22. 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?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

23. Was the diagnosis of Turner syndrome confirmed by karyotyping? ***ACTION REQUIRED***: If Yes, attach karyotype study results. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *Continue to 24*
❒ No, *Continue to 24*

24. Is the patient's pretreatment height provided? Indicate in centimeters. _____
❒ Yes, *Continue to 25*
❒ No, *Continue to 25*

25. Does the patient have a pretreatment height less than the 5th percentile for age? ***ACTION REQUIRED***: If Yes, attach a growth chart showing pretreatment height. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *Continue to 26*
❒ No, *Continue to 26*

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26. Are the epiphyses still open?
❒ Yes, *Continue to 27*
❒ No, *Continue to 27*

27. Is the diagnostic karyotype study result attached?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

28. Has the diagnosis of SHOX deficiency been confirmed by molecular or genetic analyses? ***ACTION REQUIRED***: If Yes, attach molecular/genetic test results. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *Continue to 29*
❒ No, *Continue to 29*

29. 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. _____
❒ Yes, *Continue to 30*
❒ No, *Continue to 30*

30. 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. _____
❒ Yes, *Continue to 31*
❒ No, *Continue to 31*

31. Does the patient have a pretreatment height of greater than 2 standard deviations (SD) below the mean for age and gender?
❒ Yes, *Continue to 32*
❒ No, *Continue to 33*

32. Does the patient have a pretreatment 1-year height velocity 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 growth velocity. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *Continue to 34*
❒ No, *Continue to 34*

33. Does the patient have a pretreatment 1-year height velocity greater than 2 standard deviations (SD) below the mean for age and gender? ***ACTION REQUIRED***: If Yes, attach a growth chart showing pretreatment height and growth velocity. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *Continue to 34*
❒ No, *Continue to 34*

34. Are the epiphyses still open?
❒ Yes, *Continue to 35*
❒ No, *Continue to 35*

35. Is the diagnostic molecular or genetic test result attached?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

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36. 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. _____
❒ Yes, *Continue to 37*
❒ No, *Continue to 37*

37. 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. _____
❒ Yes, *Continue to 38*
❒ No, *Continue to 38*

38. What is the pretreatment age?

❒ Less than 2.5 years of age, *Continue to 39*

❒ Greater than or equal to 2.5 years of age, *Continue to 40*

39. Does the patient have a pretreatment height of greater than 2 standard deviations (SD) below the mean for age and gender AND a slow growth velocity? ***ACTION REQUIRED***: If Yes, attach a growth chart showing pretreatment height and growth velocity. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *Continue to 43*
❒ No, *Continue to 43*

40. Does the patient have a pretreatment height of greater than 2 standard deviations (SD) below the mean for age and gender?
❒ Yes, *Continue to 41*
❒ No, *Continue to 42*

41. 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 growth velocity. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *Continue to 43*
❒ No, *Continue to 43*

42. 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 and growth velocity. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *Continue to 43*
❒ No, *Continue to 43*

43. Are the epiphyses still open?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

44. 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. _____
❒ Yes, *Continue to 45*
❒ No, *Continue to 45*

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45. Was the diagnosis of Prader-Willi syndrome confirmed by genetic testing demonstrating any of the following: A) Deletion in the chromosomal 15q11.2-q13 region, B) Maternal uniparental disomy in chromosome 15, or C) Imprinting defects, translocations, or inversions involving chromosome 15? ***ACTION REQUIRED***: If Yes, attach genetic test result. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *Continue to 46*
❒ No, *Continue to 46*

46. Is the diagnostic genetic test result attached?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

47. 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. _____
❒ Yes, *Continue to 48*
❒ No, *Continue to 48*

48. 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. _____
❒ Yes, *Continue to 49*
❒ No, *Continue to 49*

49. Does the patient have a pretreatment height of greater than 2 standard deviations (SD) below the mean for age and gender?
❒ Yes, *Continue to 50*
❒ No, *Continue to 51*

50. Does the patient have a pretreatment 1-year height velocity of more than 1 standard deviation (SD) below the mean for age and gender? ***ACTION REQUIRED***: If Yes, attach a growth chart showing pretreatment height and growth velocity. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *Continue to 52*
❒ No, *Continue to 52*

51. 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 and growth velocity. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *Continue to 52*
❒ No, *Continue to 52*

52. Are the epiphyses still open?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

53. What was the patient's gestational age at birth? Indicate in weeks.
❒ Greater than 37 weeks _____, *Continue to 55*
❒ 37 weeks or less _____, *Continue to 54*

54. Is information on the patient's birth weight provided? Indicate in grams. _____
❒ Yes, *Continue to 56*
❒ No, *Continue to 56*

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55. What was the patient's birth weight? Indicate in grams.

❒ 2500 grams or greater _____, *Continue to 56*

❒ Less than 2500 grams _____, *Continue to 59*

56. Is information on the patient's birth length provided? Indicate in centimeters. _____
❒ Yes, *Continue to 57*
❒ No, *Continue to 57*

57. Was the birth weight or length greater than or equal to 2 standard deviations (SD) below the mean for gestational age? ***ACTION REQUIRED***: If Yes, attach growth charts showing birth weight and length. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *Continue to 59*
❒ No, *Continue to 58*

58. Was the birth weight or length less than the 3rd percentile for gestational age? ***ACTION REQUIRED***: If Yes, attach growth charts showing birth weight and length. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *Continue to 59*
❒ No, *Continue to 59*

59. Is the pretreatment age 2 years of age or older? Indicate age in years and months.

_____
❒ Yes, *Continue to 60*
❒ No, *Continue to 60*

60. Is one pretreatment height provided? Indicate height in centimeters. _____
❒ Yes, *Continue to 61*
❒ No, *Continue to 61*

61. 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, attach growth chart showing pretreatment height. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *Continue to 62*
❒ No, *Continue to 62*

62. Are the epiphyses still open?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

63. Is information on the patient's current age provided? Indicate age in years and months.

_____
❒ Yes, *Continue to 64*
❒ No, *Continue to 64*

64. Is information on the patient's current height provided? Indicate height in centimeters.

_____
❒ Yes, *Continue to 65*
❒ No, *Continue to 65*

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65. What is the patient's diagnosis?

❒ Pediatric growth hormone (GH) deficiency, *Continue to 66*

❒ Turner syndrome, *Continue to 67*

❒ Short stature homeobox-containing gene (SHOX) deficiency, *Continue to 67*

❒ Noonan syndrome, *Continue to 67*

❒ Growth failure associated with chronic kidney disease (CKD), *Continue to 67*

❒ Growth failure associated with congenital adrenal hyperplasia, *Continue to 67*

❒ Growth failure associated with cerebral palsy, *Continue to 67*

❒ Growth failure associated with cystic fibrosis, *Continue to 67*

❒ Growth failure associated with Russell-Silver syndrome, *Continue to 67*

❒ Prader-Willi syndrome, *Continue to 71*

❒ Small for gestational age (SGA), *Continue to 67*

66. Is information on the date growth hormone (GH) therapy was initiated provided?

_____

❒ Yes, *Continue to 67*
❒ No, *Continue to 67*

67. Are the epiphyses still open?

❒ Yes, confirmed by X-ray, *Continue to 68*

❒ Yes, but X-ray is not available, *Continue to 68*

❒ No, *Continue to 68*

68. Is the patient growing at a rate of more than 2 cm/year? ***ACTION REQUIRED***: If Yes, attach current growth chart showing growth velocity. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *No Further Questions*
❒ No, *Continue to 69*

69. Is there a clinical reason for the lack of efficacy?
❒ Yes, *Continue to 70*
❒ No, *Continue to 70*

70. What is the clinical reason for the lack of efficacy?
❒ On treatment less than 1 year - Indicate treatment duration. _____, *No further questions*

❒ Nearing final adult height/in later stages of puberty, *No further questions*

❒ Other, please specify. _____, *No further questions*

71. Have body composition and psychomotor function improved or stabilized in response to growth hormone (GH) therapy?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

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72. Is this a request for a continuation of therapy?
❒ Yes, *Continue to 105*
❒ No, *Continue to 73*

73. Does the patient have a low pre-treatment insulin-like growth factor-1 (IGF-1) (between 0 to 2 standard deviations below the mean for age and gender 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
❒ Yes, *Continue to 74*
❒ No, *Continue to 89*

74. 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 pre-treatment provocative test results. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *Continue to 75*
❒ No, *Continue to 89*

75. What was the first agent used?

❒ Insulin tolerance test, *Continue to 76*

❒ Glucagon stimulation test, *Continue to 78*

❒ Macrilen test, *Continue to 77*

❒ None of the above, *Continue to 99*

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

❒ Less than or equal to 5 ng/mL, *Continue to 82*

❒ Greater than 5 ng/mL, *Continue to 99*

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

❒ Less than 2.8 ng/mL, *Continue to 82*

❒ Greater than or equal to 2.8 ng/mL, *Continue to 99*

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

❒ Less than 25 kg/m^2, *Continue to 80*

❒ Greater than or equal to 25 kg/m^2 but less than or equal to 30 kg/m^2, *Continue to 79*

❒ Greater than 30 kg/m^2, *Continue to 81*

79. Does the patient have a high pretest probability of growth hormone deficiency (GHD) (e.g., patient has acquired structural abnormalities)?
❒ Yes, *Continue to 80*
❒ No, *Continue to 81*

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

❒ Less than or equal to 3.0 ng/mL, *Continue to 82*

❒ Greater than 3.0 ng/mL, *Continue to 99*

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

❒ Less than or equal to 1.0 ng/mL, *Continue to 82*

❒ Greater than 1.0 ng/mL, *Continue to 99*

82. What was the second agent used?

❒ Insulin tolerance test, *Continue to 83*

❒ Glucagon stimulation test, *Continue to 85*

❒ Macrilen test, *Continue to 84*

❒ None of the above, *Continue to 99*

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

❒ Less than or equal to 5 ng/mL, *Continue to 98*

❒ Greater than 5 ng/mL, *Continue to 99*

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

❒ Less than 2.8 ng/mL, *Continue to 98*

❒ Greater than or equal to 2.8 ng/mL, *Continue to 99*

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

❒ Less than 25 kg/m^2, *Continue to 87*

❒ Greater than or equal to 25 kg/m^2 but less than or equal to 30 kg/m^2, *Continue to 86*

❒ Greater than 30 kg/m^2, *Continue to 88*

86. Does the patient have a high pretest probability (e.g., acquired structural abnormalities) of growth hormone deficiency (GHD)?

❒ Yes, *Continue to 87*

❒ No, *Continue to 88*

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

❒ Less than or equal to 3.0 ng/mL, *Continue to 98*

❒ Greater than 3.0 ng/mL, *Continue to 99*

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

❒ Less than or equal to 1.0 ng/mL, *Continue to 98*

❒ Greater than 1.0 ng/mL, *Continue to 99*

89. 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 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

❒ Yes, *Continue to 90*

❒ No, *Continue to 99*

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90. Has the patient had at least 1 pretreatment pharmacologic provocative growth hormone (GH)? ***ACTION REQUIRED***: If Yes, attach laboratory report or medical record of pre-treatment provocative test results.
ACTION REQUIRED: Submit supporting documentation
❒ Yes, *Continue to 91*
❒ No, *Continue to 99*

91. What was the agent used?

❒ Insulin tolerance test, *Continue to 92*

❒ Glucagon stimulation test, *Continue to 94*

❒ Macrilen test, *Continue to 93*

❒ None of the above, *Continue to 99*

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

❒ Less than or equal to 5 ng/mL, *Continue to 98*

❒ Greater than 5 ng/mL, *Continue to 99*

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

❒ Less than 2.8 ng/mL, *Continue to 98*

❒ Greater than or equal to 2.8 ng/mL, *Continue to 99*

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

❒ Less than 25 kg/m^2, *Continue to 96*

❒ Greater than or equal to 25 kg/m^2 but less than or equal to 30 kg/m^2, *Continue to 95*

❒ Greater than 30 kg/m^2, *Continue to 97*

95. Does the patient have a high pretest probability (e.g., acquired structural abnormalities) of growth hormone deficiency (GHD)?
❒ Yes, *Continue to 96*
❒ No, *Continue to 97*

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

❒ Less than or equal to 3.0 ng/mL, *Continue to 98*

❒ Greater than 3.0 ng/mL, *Continue to 99*

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

❒ Less than or equal to 1.0 ng/mL, *Continue to 98*

❒ Greater than 1.0 ng/mL, *Continue to 99*

98. 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?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

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

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❒ Yes, *Continue to 100*
❒ No, *Continue to 102*

100. 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. _____
❒ Yes, *Continue to 101*
❒ No, *Continue to 102*

101. Does the patient have a low pretreatment insulin-like growth factor-1 (IGF-1) more than 2 standard deviations below the mean for age and gender 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
❒ Yes, *No Further Questions*
❒ No, *Continue to 102*

102. Does the patient have a genetic or structural hypothalamic-pituitary defect (transcription factor defects [PIT-1, PROP-1, LHX3/4, HESX-1, PITX-2], GHRH receptor-gene defects, GH secretagogue receptor gene defects, GH-gene defects associated with brain structural defects, single central incisor, cleft lip/palate) or an acquired cause (perinatal insults)?
❒ Yes, *No Further Questions*
❒ No, *Continue to 103*

103. Does the patient have childhood-onset growth hormone deficiency (GHD)?
❒ Yes, *Continue to 104*
❒ No, *Continue to 104*

104. Does the patient have a congenital abnormality of the central nervous system (CNS), hypothalamus, or pituitary gland?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

105. Does the patient have a low pre-treatment insulin-like growth factor-1 (IGF-1) (between 0 to 2 standard deviations below the mean for age and gender 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
❒ Yes, *Continue to 106*
❒ No, *Continue to 123*

106. 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 pre-treatment provocative test results. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *Continue to 107*
❒ No, *Continue to 123*

107. What was the first agent used?

❒ Insulin tolerance test, *Continue to 108*

❒ Glucagon stimulation test, *Continue to 110*

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❒ Macrilen test, *Continue to 109*

❒ Other provocative GH test, *Continue to 108*

108. What was the peak growth hormone (GH) level of the insulin tolerance test or other provocative GH test?

❒ Less than or equal to 5 ng/mL, *Continue to 115*

❒ Greater than 5 ng/mL, *Continue to 123*

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

❒ Less than 2.8 ng/mL, *Continue to 115*

❒ Greater than or equal to 2.8 ng/mL, *Continue to 123*

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

❒ Less than 25 kg/m^2, *Continue to 112*

❒ Greater than or equal to 25 kg/m^2 but less than or equal to 30 kg/m^2, *Continue to 111*

❒ Greater than 30 kg/m^2, *Continue to 113*

111. Does the patient have a high pretest probability of growth hormone deficiency (e.g., patient has acquired structural abnormalities)?

❒ Yes, *Continue to 112*

❒ No, *Continue to 113*

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

❒ Less than or equal to 3.0 ng/mL, *Continue to 115*

❒ Greater than 3.0 ng/mL, *Continue to 114*

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

❒ Less than or equal to 1.0 ng/mL, *Continue to 115*

❒ Greater than 1.0 ng/mL, *Continue to 114*

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

❒ Less than or equal to 5 ng/mL, *Continue to 115*

❒ Greater than 5 ng/mL, *Continue to 123*

115. What was the second agent used?

❒ Insulin tolerance test, *Continue to 116*

❒ Glucagon stimulation test, *Continue to 118*

❒ Macrilen test, *Continue to 117*

❒ Other provocative GH test, *Continue to 116*

116. What was the peak growth hormone (GH) level of the insulin tolerance test or other provocative GH test?

❒ Less than or equal to 5 ng/mL, *Continue to 139*

❒ Greater than 5 ng/mL, *Continue to 123*

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

❒ Less than 2.8 ng/mL, *Continue to 139*

❒ Greater than or equal to 2.8 ng/mL, *Continue to 123*

118. What is the patient's body mass index (BMI)? Indicate BMI in kg/m^2.

❒ Less than 25 kg/m^2, *Continue to 120*

❒ Greater than or equal to 25 kg/m^2 but less than or equal to 30 kg/m^2, *Continue to 119*

❒ Greater than 30 kg/m^2, *Continue to 121*

119. Does the patient have a high pretest probability (e.g., acquired structural abnormalities) of growth hormone deficiency (GHD)?

❒ Yes, *Continue to 120*

❒ No, *Continue to 121*

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

❒ Less than or equal to 3.0 ng/mL, *Continue to 139*

❒ Greater than 3.0 ng/mL, *Continue to 122*

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

❒ Less than or equal to 1.0 ng/mL, *Continue to 139*

❒ Greater than 1.0 ng/mL, *Continue to 122*

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

❒ Less than or equal to 5 ng/mL, *Continue to 139*

❒ Greater than 5 ng/mL, *Continue to 123*

123. 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 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

❒ Yes, *Continue to 124*

❒ No, *Continue to 133*

124. 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 pre-treatment provocative test results. ***ACTION REQUIRED***: Submit supporting documentation

❒ Yes, *Continue to 125*

❒ No, *Continue to 133*

125. What was the agent used?

❒ Insulin tolerance test, *Continue to 126*

❒ Glucagon stimulation test, *Continue to 128*

❒ Macrilen test, *Continue to 127*

❒ Other provocative GH test., *Continue to 126*

126. What was the peak growth hormone (GH) level of the insulin tolerance test or other provocative GH test?

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❒ Less than or equal to 5 ng/mL, *Continue to 139*

❒ Greater than 5 ng/mL, *Continue to 133*

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

❒ Less than 2.8 ng/mL, *Continue to 139*

❒ Greater than or equal to 2.8 ng/mL, *Continue to 133*

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

❒ Less than 25 kg/m^2, *Continue to 130*

❒ Greater than or equal to 25 kg/m^2 but less than or equal to 30 kg/m^2, *Continue to 129*

❒ Greater than 30 kg/m^2, *Continue to 131*

129. Does the patient have a high pretest probability (e.g., acquired structural abnormalities) of growth hormone deficiency (GHD)?
❒ Yes, *Continue to 130*
❒ No, *Continue to 131*

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

❒ Less than or equal to 3.0 ng/mL, *Continue to 139*

❒ Greater than 3.0 ng/mL, *Continue to 132*

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

❒ Less than or equal to 1.0 ng/mL, *Continue to 139*

❒ Greater than 1.0 ng/mL, *Continue to 132*

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

❒ Less than or equal to 5 ng/mL, *Continue to 139*

❒ Greater than 5 ng/mL, *Continue to 133*

133. Does the patient have organic hypothalamic-pituitary disease (e.g., suprasellar mass with previous surgery and cranial irradiation)?
❒ Yes, *Continue to 134*
❒ No, *Continue to 136*

134. 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. _____
❒ Yes, *Continue to 135*
❒ No, *Continue to 136*

135. Does the patient have a low pretreatment insulin-like growth factor-1 (IGF-1) more than 2 standard deviations below the mean for age and gender 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

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❒ Yes, *Continue to 139*
❒ No, *Continue to 136*

136. Does the patient have a genetic or structural hypothalamic-pituitary defect (transcription factor defects [PIT-1, PROP-1, LHX3/4, HESX-1, PITX-2], GHRH receptor-gene defects, GH-gene defects associated with brain structural defects, single central incisor, cleft lip/palate) or an acquired cause (perinatal insults)?
❒ Yes, *Continue to 140*
❒ No, *Continue to 137*

137. Does the patient have childhood-onset growth hormone deficiency (GHD)?
❒ Yes, *Continue to 138*
❒ No, *Continue to 138*

138. Does the patient have a congenital abnormality of the central nervous system (CNS), hypothalamus, or pituitary gland?
❒ Yes, *Continue to 140*
❒ No, *Continue to 140*

139. 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?
❒ Yes, *Continue to 140*
❒ No, *Continue to 140*

140. 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. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

141. Is the patient dependent on intravenous parenteral nutrition (e.g., TPN) for nutritional support?
❒ Yes, *Continue to 142*
❒ No, *Continue to 142*

142. Will the requested product be used in conjunction with optimal management of short bowel syndrome (SBS)?
❒ Yes, *Continue to 143*
❒ No, *Continue to 143*

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

_____weeks, *No further questions*

144. Is this request for continuation of therapy?

❒ Yes, *Continue to 145*

❒ No, *Continue to 152*

145. Is information on the patient's current height and age provided? Indicate height in centimeters and age in years and months. _____

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❒ Yes, *Continue to 146*
❒ No, *Continue to 146*

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

❒ Yes, *Continue to 152*

❒ No, *Continue to 147*

❒ Unknown, *Continue to 152*

147. 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
❒ Yes, *Continue to 148*
❒ No, *Continue to 148*

148. Are the epiphyses still open?

❒ Yes, confirmed by X-ray, *Continue to 149*

❒ Yes, but X-ray is not available, *Continue to 149*

❒ No, *Continue to 149*

149. Is the patient growing at a rate of more than 2 cm/year? ***ACTION REQUIRED***: If Yes, attach growth charts showing growth velocity. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *No Further Questions*
❒ No, *Continue to 150*

150. Is there a clinical reason for lack of efficacy?
❒ Yes, *Continue to 151*
❒ No, *Continue to 151*

151. Indicate clinical reason.
❒ On treatment for less than 1 year - Indicate treatment duration. _____, *No further questions*

❒ Nearing final adult height - in later stages of puberty, *No further questions*

❒ Other, please specify. _____, *No further questions*

152. Is information on the patient's pre-treatment height and age provided? Indicate height in centimeters and age in years and months. _____
❒ Yes, *Continue to 153*
❒ No, *Continue to 153*

153. Does the patient have a pretreatment height of greater than 2.25 standard deviations (SD) below the mean for age and gender? ***ACTION REQUIRED***: If Yes, attach growth chart showing pretreatment height. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *Continue to 154*
❒ No, *Continue to 154*

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154. Does the patient have the following adult height prediction: A) Boys: Less than 5 feet, 3 inches, B) Girls: Less than 4 feet, 11 inches?
❒ Yes, *Continue to 155*
❒ No, *Continue to 155*

155. Has pediatric growth hormone deficiency (GHD) been ruled out with a provocative growth hormone test with a peak of greater than or equal to 10 ng/mL? ***ACTION REQUIRED***: If Yes, attach laboratory report or medical record of pre-treatment provocative test result. ***ACTION REQUIRED***: Submit supporting documentation
❒ Yes, *Continue to 156*
❒ No, *Continue to 156*

156. Are the epiphyses still open?
❒ Yes, *Continue to 157*
❒ No, *Continue to 157*

157. Are laboratory report of a pretreatment pharmacologic provocative test for growth hormone (GH) with a peak level greater than or equal to 10 ng/mL and growth chart with pretreatment height greater than 2.25 SD below the mean attached to the request?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

158. Is the patient on anti-retroviral therapy?
❒ Yes, *Continue to 159*
❒ No, *Continue to 159*

159. Is one pretreatment height and weight provided? Indicate height in centimeters and weight in kilograms.
_____
❒ Yes, *Continue to 160*
❒ No, *Continue to 160*

160. Is the patient's current height and weight provided? Indicate height in centimeters and weight in kilograms.
_____
❒ Yes, *Continue to 161*
❒ No, *Continue to 161*

161. Is the request for continuation of therapy?
❒ Yes, *Continue to 162*
❒ No, *Continue to 163*

162. Is the patient currently receiving growth hormone through samples or a manufacturer's patient assistance program?
❒ Yes, *Continue to 163*
❒ No, *Continue to 166*
❒ Unknown, *Continue to 163*

163. Prior to initiating growth hormone (GH) therapy, what is/was the patient's body mass index (BMI)? Indicate BMI in kg/m^2.
_____ kg/m^2, *Continue to 164*

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164. Has the patient tried and had a suboptimal response to alternative therapies (i.e., dronabinol, megestrol acetate, cyproheptadine, or testosterone if hypogonadal)?
❒ Yes, *No Further Questions*
❒ No, *Continue to 165*

165. Does the patient have a contraindication or intolerance to alternative therapies (i.e., dronabinol, megestrol acetate, cyproheptadine, or testosterone if hypogonadal)?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

166. 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
❒ Yes, *Continue to 167*
❒ No, *Continue to 167*

167. What is the current body mass index (BMI)? Indicate in kg/m^2.
❒ 27 kg/m^2 or greater _____, *No further questions*
❒ Less than 27 kg/m^2 _____, *No further questions*

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)**

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