

## **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.

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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), <i>Continue to 72</i>
☐ Idiopathic short stature (ISS), Continue to 144
☐ Small for gestational age (SGA), <i>Continue to 2</i>
☐ Turner syndrome, <i>Continue to 2</i>
☐ Growth failure associated with chronic kidney disease (CKD), Continue to 2
☐ Noonan syndrome, <i>Continue to 2</i>
☐ Growth failure associated with cystic fibrosis, <i>Continue to 2</i>
☐ Prader-Willi syndrome, <i>Continue to 2</i>
☐ HIV-associated wasting/cachexia, Continue to 158
☐ Short stature homeobox-containing gene (SHOX) deficiency, <i>Continue to 2</i>
☐ Growth failure associated with congenital adrenal hyperplasia, <i>Continue to 2</i>
☐ Growth failure associated with cerebral palsy, <i>Continue to 2</i>
☐ Growth failure associated with Russell-Silver syndrome, <i>Continue to 2</i>
☐ Short bowel syndrome (SBS), Continue to 141
☐ Other, please specify, No further questions
2. Is this request for continuation of therapy?  ☐ Yes, <i>Continue to 3</i> ☐ No, <i>Continue to 5</i>
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? <i>ACTION REQUIRED</i> : If Yes, attach medical records. <i>ACTION REQUIRED</i> : 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), <i>Continue to 53</i>
☐ Turner syndrome, Continue to 23
☐ Noonan syndrome, Continue to 47
☐ Growth failure associated with chronic kidney disease (CKD), Continue to 36

☐ 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?  Tyes, 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? <i>ACTION REQUIRED</i> : If Yes, attach medical records. <i>ACTION REQUIRED</i> : Submit supporting documentation  Yes, <i>Continue to 8</i> No, <i>Continue to 8</i>
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?  The example of the properties of the prop
9. Does the patient have 2 pretreatment pharmacologic provocative tests for growth hormone (GH)? <i>ACTION REQUIRED</i> : If Yes, attach laboratory report or medical record of pre-treatment provocative test results. <i>ACTION REQUIRED</i> : Submit supporting documentation ☐ Yes, <i>Continue to 10</i> ☐ No, <i>Continue to 11</i>
10. What is the peak level? Indicate in ng/mlng/ml, Continue to 14
<ul> <li>11. Does the patient have a pituitary or central nervous system (CNS) disorder?</li> <li>☐ Yes, Continue to 12</li> <li>☐ No, Continue to 12</li> </ul>
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, <i>Continue to 13</i>
☐ 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, <i>Continue to 13</i>
☐ Ectopic posterior pituitary, Continue to 13

☐ 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, <i>Continue to 13</i>
☐ Arachnoid cyst, Continue to 13
☐ Other mid-line facial defects (e.g., single central incisor, cleft lip/palate), Continue to 13
☐ Vascular malformation, <i>Continue to 13</i> ☐ CNS tumor/neoplasm (e.g., craniopharyngioma, glioma/astrocytoma, pituitary adenoma, germinoma), <i>Continue to 13</i>
☐ 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, <i>Continue to 13</i>
☐ Surgery of the pituitary or hypothalamus, <i>Continue to 13</i>
□ 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? <i>ACTION REQUIRED</i> : If Yes, attach laboratory report or medical record of pretreatment IGF-1 level. <i>ACTION REQUIRED</i> : Submit supporting documentation  Yes, <i>Continue to 14</i> No, <i>Continue to 14</i>
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  \square\$ 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?

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

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☐ Less than 2.5 years of age, <i>Continue to 17</i> ☐ Greater than or equal to 2.5 years of age, <i>Continue to 18</i>
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? <i>ACTION REQUIRED</i> : If Yes, attach a growth chart showing pretreatment heights and growth velocity. <i>ACTION REQUIRED</i> : Submit supporting documentation ☐ Yes, <i>Continue to 21</i> ☐ No, <i>Continue to 21</i>
18. Does the patient have a pretreatment height of greater than 2 standard deviations (SD) below the mean for age and gender?  Test, 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? <i>ACTION REQUIRED</i> : If Yes, attach a growth chart showing pretreatment height and height velocity. <i>ACTION REQUIRED</i> : Submit supporting documentation ☐ Yes, <i>Continue to 21</i> ☐ No, <i>Continue to 21</i>
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? <i>ACTION REQUIRED</i> : If Yes, attach a growth chart showing pretreatment height velocity. <i>ACTION REQUIRED</i> : Submit supporting documentation ☐ Yes, <i>Continue to 21</i> ☐ No, <i>Continue to 21</i>
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, <i>No Further Questions</i> No, <i>No Further Questions</i>
23. Was the diagnosis of Turner syndrome confirmed by karyotyping? <i>ACTION REQUIRED</i> : If Yes, attach karyotype study results. <i>ACTION REQUIRED</i> : Submit supporting documentation ☐ Yes, <i>Continue to 24</i> ☐ No, <i>Continue to 24</i>
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? <i>ACTION REQUIRED</i> : If Yes, attach a growth chart showing pretreatment height. <i>ACTION REQUIRED</i> : Submit supporting documentation ☐ Yes, <i>Continue to 26</i> ☐ No, <i>Continue to 26</i>

26. Are the epiphyses still open?  ☐ Yes, Continue to 27  ☐ No, Continue to 27
27. Is the diagnostic karyotype study result attached?  ☐ Yes, <i>No Further Questions</i> ☐ No, <i>No Further Questions</i>
28. Has the diagnosis of SHOX deficiency been confirmed by molecular or genetic analyses? <i>ACTION REQUIRED</i> : If Yes, attach molecular/genetic test results. <i>ACTION REQUIRED</i> : Submit supporting documentation  ☐ Yes, <i>Continue to 29</i> ☐ No, <i>Continue to 29</i>
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.
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.
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? <i>ACTION REQUIRED</i> : If Yes, attach a growth chart showing pretreatment height and growth velocity. <i>ACTION REQUIRED</i> : Submit supporting documentation ☐ Yes, <i>Continue to 34</i> ☐ No, <i>Continue to 34</i>
33. Does the patient have a pretreatment 1-year height velocity greater than 2 standard deviations (SD) below the mean for age and gender? <i>ACTION REQUIRED</i> : If Yes, attach a growth chart showing pretreatment height and growth velocity. <i>ACTION REQUIRED</i> : Submit supporting documentation ☐ Yes, <i>Continue to 34</i> ☐ No, <i>Continue to 34</i>
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

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? <i>ACTION REQUIRED</i> : If Yes, attach a growth chart showing pretreatment height and growth velocity. <i>ACTION REQUIRED</i> : Submit supporting documentation ☐ Yes, <i>Continue to 43</i> ☐ No, <i>Continue to 43</i>
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? <i>ACTION REQUIRED</i> : If Yes, attach a growth chart showing pretreatment height and growth velocity. <i>ACTION REQUIRED</i> : Submit supporting documentation ☐ Yes, <i>Continue to 43</i> ☐ No, <i>Continue to 43</i>
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? <i>ACTION REQUIRED</i> : If Yes, attach a growth chart showing pretreatment height and growth velocity. <i>ACTION REQUIRED</i> : Submit supporting documentation ☐ Yes, <i>Continue to 43</i> ☐ No, <i>Continue to 43</i>
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 Test, Continue to 45 ☐ No, Continue to 45

A) Deletion in the chromosomal 15q11.2	ndrome confirmed by genetic testing demonstrating any of the following: -q13 region, B) Maternal uniparental disomy in chromosome 15, or C) ersions involving chromosome 15? <i>ACTION REQUIRED</i> : If Yes, attach D: Submit supporting documentation
46. Is the diagnostic genetic test result at  ☐ Yes, No Further Questions ☐ No, No Further Questions	tached?
47. Is one pretreatment height and the pa in centimeters and age in years and mont ☐ Yes, Continue to 48 ☐ No, Continue to 48	tient's age at the time the height was recorded provided? Indicate height hs
	he patient's age at the time the height was recorded provided? Indicate d months.
49. Does the patient have a pretreatment and gender?  ☐ Yes, <i>Continue to 50</i> ☐ No, <i>Continue to 51</i>	height of greater than 2 standard deviations (SD) below the mean for age
	1-year height velocity of more than 1 standard deviation (SD) below the <b>QUIRED</b> : If Yes, attach a growth chart showing pretreatment height and Submit supporting documentation
	1-year height velocity of greater than 2 standard deviations (SD) below <b>REQUIRED</b> : If Yes, attach a growth chart showing pretreatment height <b>ED</b> : Submit supporting documentation
52. Are the epiphyses still open? ☐ Yes, No Further Questions ☐ No, No Further Questions	
53. What was the patient's gestational age	e 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 w  ☐ Yes, Continue to 56  ☐ No, Continue to 56	reight provided? Indicate in grams

55. What was the patient's birth weight? Indicate in gram	IS.
☐ 2500 grams or greater	
☐ Less than 2500 grams	, Continue to 59
56. Is information on the patient's birth length provided?  ☐ Yes, <i>Continue to 57</i> ☐ No, <i>Continue to 57</i>	Indicate in centimeters
57. Was the birth weight or length greater than or equal to gestational age? <i>ACTION REQUIRED</i> : If Yes, attach grame <i>REQUIRED</i> : Submit supporting documentation ☐ Yes, <i>Continue to 59</i> ☐ No, <i>Continue to 58</i>	
58. Was the birth weight or length less than the 3rd perceattach growth charts showing birth weight and length. At □ Yes, Continue to 59 □ No, Continue to 59	
59. Is the pretreatment age 2 years of age or older? Indic	ate age in years and months.
☐ Yes, Continue to 60 ☐ No, Continue to 60	
60. Is one pretreatment height provided? Indicate height ☐ Yes, <i>Continue to 61</i> ☐ No, <i>Continue to 61</i>	in centimeters.
61. Did the patient fail to manifest catch-up growth by as than 2 standard deviations (SD) below the mean for age growth chart showing pretreatment height. <i>ACTION RE</i> Yes, <i>Continue to 62</i>	and gender? ACTION REQUIRED: If Yes, attach
62. Are the epiphyses still open? ☐ Yes, <i>No Further Questions</i> ☐ No, <i>No Further Questions</i>	
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 provide	d? Indicate height in centimeters.
☐ Yes, Continue to 65 ☐ No, Continue to 65	

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, <i>Continue to 67</i>
☐ 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, <i>Continue to 68</i>
□ No, Continue to 68
68. Is the patient growing at a rate of more than 2 cm/year? <i>ACTION REQUIRED</i> : If Yes, attach current growth chart showing growth velocity. <i>ACTION REQUIRED</i> : Submit supporting documentation ☐ Yes, <i>No Further Questions</i> ☐ No, <i>Continue to 69</i>
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.
☐ Nearing final adult height/in later stages of puberty, <i>No further questions</i>
☐ 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 Ouestions

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)? <i>ACTION REQUIRED</i> : If Yes, attach laboratory report or medical record of pretreatment IGF-1 level. <i>ACTION REQUIRED</i> : Submit supporting documentation  Yes, <i>Continue to 74</i> No, <i>Continue to 89</i>
74. Has the patient had at least 2 pretreatment pharmacologic provocative growth hormone (GH) tests? <i>ACTION REQUIRED</i> : If Yes, attach laboratory report or medical record of pre-treatment provocative test results. <i>ACTION REQUIRED</i> : 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, <i>Continue to 80</i> Greater than or equal to 25 kg/m^2 but less than or equal to 30 kg/m^2, <i>Continue to 79</i> Greater than 30 kg/m^2, <i>Continue to 81</i>
79. Does the patient have a high pretest probability of growth hormone deficiency (GHD) (e.g., patient has acquired structural abnormalities)?  Test, 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, <i>Continue to 82</i> □ Greater than 3.0 ng/mL, <i>Continue to 99</i>

81. What was the peak growth hormone level with the glucagon stimulation test?  □ Less than or equal to 1.0 ng/mL, <i>Continue to 82</i> □ Greater than 1.0 ng/mL, <i>Continue to 99</i>
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, <i>Continue to 98</i> □ Greater than 5 ng/mL, <i>Continue to 99</i>
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, <i>Continue to 98</i> ☐ Greater than 1.0 ng/mL, <i>Continue to 99</i>
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? <i>ACTION REQUIRED</i> : If Yes, attach laboratory report or medical record of pretreatment IGF-1 level. <i>ACTION REQUIRED</i> : Submit supporting documentation  Yes, <i>Continue to 90</i> No, <i>Continue to 99</i>

90. Has the patient had at least 1 pretreatment pharmacologic provocative growth hormone (GH)? <i>ACTION REQUIRED</i> : If Yes, attach laboratory report or medical record of pre-treatment provocative test results. <i>ACTION REQUIRED</i> : Submit supporting documentation ☐ Yes, <i>Continue to 91</i> ☐ No, <i>Continue to 99</i>
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, <i>Continue to 98</i> ☐ Greater than 5 ng/mL, <i>Continue to 99</i>
93. What was the peak growth hormone (GH) level of the Macrilen test?  ☐ Less than 2.8 ng/mL, <i>Continue to 98</i> ☐ Greater than or equal to 2.8 ng/mL, <i>Continue to 99</i>
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, <i>Continue to 98</i> ☐ Greater than 3.0 ng/mL, <i>Continue to 99</i>
97. What was the peak growth hormone level with the glucagon stimulation test?  ☐ Less than or equal to 1.0 ng/mL, <i>Continue to 98</i> ☐ Greater than 1.0 ng/mL, <i>Continue to 99</i>
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)?

☐ 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? <i>ACTION REQUIRED</i> : If Yes, attach laboratory report or medical record of pretreatment IGF-1 level. <i>ACTION REQUIRED</i> : Submit supporting documentation  Yes, <i>No Further Questions</i> No, <i>Continue to 102</i>
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)? <i>ACTION REQUIRED</i> : If Yes, attach laboratory report or medical record of pretreatment IGF-1 level. <i>ACTION REQUIRED</i> : Submit supporting documentation  Yes, <i>Continue to 106</i> No, <i>Continue to 123</i>
106. Has the patient had at least 2 pretreatment pharmacologic provocative growth hormone (GH) tests? <i>ACTION REQUIRED</i> : If Yes, attach laboratory report or medical record of pre-treatment provocative test results. <i>ACTION REQUIRED</i> : Submit supporting documentation  Yes, <i>Continue to 107</i> No, <i>Continue to 123</i>
107. What was the first agent used?
☐ Insulin tolerance test, Continue to 108
☐ Glucagon stimulation test, Continue to 110

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. CareFirst Growth Hormone with ISS SGM 1741-A – 08/2024.

☐ 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, <i>Continue to 115</i> ☐ Greater than 5 ng/mL, <i>Continue to 123</i>
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)?  Tes, 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, <i>Continue to 115</i> ☐ Greater than 3.0 ng/mL, <i>Continue to 114</i>
113. What was the peak growth hormone level with the glucagon stimulation test?  ☐ Less than or equal to 1.0 ng/mL, <i>Continue to 115</i> ☐ Greater than 1.0 ng/mL, <i>Continue to 114</i>
114. What was the peak growth hormone level with the glucagon stimulation test?  ☐ Less than or equal to 5 ng/mL, <i>Continue to 115</i> ☐ Greater than 5 ng/mL, <i>Continue to 123</i>
<ul> <li>115. What was the second agent used?</li> <li>☐ Insulin tolerance test, Continue to 116</li> <li>☐ Glucagon stimulation test, Continue to 118</li> <li>☐ Macrilen test, Continue to 117</li> <li>☐ Other provocative GH test, Continue to 116</li> </ul>
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, <i>Continue to 139</i> ☐ Greater than 5 ng/mL, <i>Continue to 123</i>

117. What was the peak growth hormone (GH) level of the Macrilen test?  ☐ Less than 2.8 ng/mL, <i>Continue to 139</i> ☐ Greater than or equal to 2.8 ng/mL, <i>Continue to 123</i>
118. What is the patient's body mass index (BMI)? Indicate BMI in kg/m <sup>2</sup> . ☐ Less than 25 kg/m <sup>2</sup> , <i>Continue to 120</i> ☐ Greater than or equal to 25 kg/m <sup>2</sup> but less than or equal to 30 kg/m <sup>2</sup> , <i>Continue to 119</i> ☐ Greater than 30 kg/m <sup>2</sup> , <i>Continue to 121</i>
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, <i>Continue to 139</i> ☐ Greater than 3.0 ng/mL, <i>Continue to 122</i>
121. What was the peak growth hormone level with the glucagon stimulation test?  ☐ Less than or equal to 1.0 ng/mL, <i>Continue to 139</i> ☐ Greater than 1.0 ng/mL, <i>Continue to 122</i>
122. What was the peak growth hormone level with the glucagon stimulation test?  ☐ Less than or equal to 5 ng/mL, <i>Continue to 139</i> ☐ Greater than 5 ng/mL, <i>Continue to 123</i>
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? <i>ACTION REQUIRED</i> : If Yes, attach laboratory report or medical record of pretreatment IGF-1 level. <i>ACTION REQUIRED</i> : Submit supporting documentation  ☐ Yes, <i>Continue to 124</i> ☐ No, <i>Continue to 133</i>
124. Has the patient had at least 1 pretreatment pharmacologic provocative growth hormone (GH) test? <i>ACTION REQUIRED</i> : If Yes, attach laboratory report or medical record of pre-treatment provocative test results. <i>ACTION REQUIRED</i> : Submit supporting documentation ☐ Yes, <i>Continue to 125</i> ☐ No, <i>Continue to 133</i>
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?

☐ 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)?  Test, 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, <i>Continue to 139</i> ☐ Greater than 3.0 ng/mL, <i>Continue to 132</i>
131. What was the peak growth hormone level with the glucagon stimulation test?  ☐ Less than or equal to 1.0 ng/mL, <i>Continue to 139</i> ☐ Greater than 1.0 ng/mL, <i>Continue to 132</i> 132. What was the peak growth hormone level with the glucagon stimulation test?  ☐ Less than or equal to 5 ng/mL, <i>Continue to 139</i> ☐ Greater than 5 ng/mL, <i>Continue to 133</i>
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 Proposition of the patient pituitary hormones Proposition of the following pituitary hormones: A) Growth hormone (ADH), D) Follicle stimulating hormone (TSH), and G) Prolactin? If Yes, indicate deficient pituitary hormones Proposition of the following pituitary hormones: A) Growth hormone, B) Adrenocorticotropic hormone (ACTH), C) Antidiuretic hormone (ADH), D) Follicle stimulating hormone (TSH), and G) Prolactin? If Yes, indicate deficient pituitary hormones Proposition of the following pituitary hormone (ADH), D) Follicle stimulating hormone (TSH), and G) Prolactin? If Yes, indicate deficient pituitary hormones Proposition of the following pituitary hormone (ADH), D) Follicle stimulating hormone (TSH), and G) Prolactin? If Yes, Continue to 135
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? <i>ACTION REQUIRED</i> : It Yes, attach laboratory report or medical record of pretreatment IGF-1 level. <i>ACTION REQUIRED</i> : Submit

supporting documentation

☐ 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? <i>ACTION REQUIRED</i> : If No, attach laboratory report or medical record of current IGF-1 level. <i>ACTION REQUIRED</i> : Submit supporting documentation ☐ Yes, <i>No Further Questions</i> ☐ No, <i>No Further Questions</i>
141. Is the patient dependent on intravenous parenteral nutrition (e.g., TPN) for nutritional support? ☐ Yes, <i>Continue to 142</i> ☐ No, <i>Continue to 142</i>
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, <i>No further questions</i>
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.

□ 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? <i>ACTION REQUIRED</i> : If Yes, attach medical records. <i>ACTION REQUIRED</i> : Submit supporting documentation Yes, <i>Continue to 148</i>
148. Are the epiphyses still open?
☐ Yes, confirmed by X-ray, Continue to 149
☐ Yes, but X-ray is not available, <i>Continue to 149</i>
□ No, Continue to 149
149. Is the patient growing at a rate of more than 2 cm/year? <i>ACTION REQUIRED</i> : If Yes, attach growth charts showing growth velocity. <i>ACTION REQUIRED</i> : Submit supporting documentation ☐ Yes, <i>No Further Questions</i> ☐ No, <i>Continue to 150</i>
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
☐ Nearing final adult height - in later stages of puberty, <i>No further questions</i>
☐ 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
153. Does the patient have a pretreatment height of greater than 2.25 standard deviations (SD) below the mean for age and gender? <i>ACTION REQUIRED</i> : If Yes, attach growth chart showing pretreatment height. <i>ACTION REQUIRED</i> : Submit supporting documentation ☐ Yes, <i>Continue to 154</i> ☐ No, <i>Continue to 154</i>

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? <i>ACTION REQUIRED</i> : If Yes, attach laboratory report or medical record of pre-treatment provocative test result. <i>ACTION REQUIRED</i> : Submit supporting documentation ☐ Yes, <i>Continue to 156</i> ☐ No, <i>Continue to 156</i>
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
<ul> <li>161. Is the request for continuation of therapy?</li> <li>☐ Yes, Continue to 162</li> <li>☐ No, Continue to 163</li> </ul>
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 <sup>2</sup> , Continue to 164

Prescriber or Authorized Signature	Date (mm/dd/yy)
X	
	and true, and that documentation supporting this quested by CVS Caremark or the benefit plan sponsor.
Less than 27 kg/m^2	, No further questions
☐ 27 kg/m <sup>2</sup> or greater	
167. What is the current body mass index (E	BMI)? Indicate in kg/m^2.
duration is acceptable), B) Date of the last d manager, D) Date of the prior authorization/	by the prescriber: A) Total duration of treatment (approximate ose administered, C) Approving health plan/pharmacy benefit (approval, and E) Prior authorization approval letter? <i>ACTION</i> is <i>ACTION REQUIRED</i> : Submit supporting documentation
165. Does the patient have a contraindicatio acetate, cyproheptadine, or testosterone if hy ☐ Yes, No Further Questions ☐ No, No Further Questions	n or intolerance to alternative therapies (i.e., dronabinol, megestrol ypogonadal)?
164. Has the patient tried and had a subopting acetate, cyproheptadine, or testosterone if hy ☐ Yes, <i>No Further Questions</i> ☐ No, <i>Continue to 165</i>	mal response to alternative therapies (i.e., dronabinol, megestrol ypogonadal)?