



PRIOR AUTHORIZATION REQUEST

Omnitrope

Patient Information:

Name:	
Member ID:	
Address:	
City, State, Zip:	
Date of Birth:	

Prescriber Information:

Name:	
NPI:	
Phone Number:	
Fax Number:	
Address:	
City, State, Zip:	

Requested Medication

Rx Name:	
Rx Strength:	
Rx Quantity:	
Rx Frequency:	
Rx Route of Administration:	
Diagnosis and ICD Code:	

Your patient's prescription benefit requires that we review certain requests for coverage with the prescriber. You have prescribed a medication for your patient that requires Prior Authorization before benefit coverage or coverage of additional quantities can be provided. Please complete the following questions then fax this form to the toll-free number listed below. Upon receipt of the completed form, prescription benefit coverage will be determined based on the plan's rules.

SECTION A: Please note that supporting clinical documentation is required for ALL PA requests. Pharmacy prior authorization reviews can be subject to trial with additional medications that are not listed within the criteria. The policies are subject to change based on COMAR requirements, MDH transmittals and updates to treatment guidelines.

- | | | |
|---|---|-------------|
| 1 | What is the patient's age?
<input type="checkbox"/> Less than 12 years of age (If checked, go to 3)

<input type="checkbox"/> Greater than or equal to 12 years of age (If checked, go to 2) | |
| 2 | Does the physician certify that growth hormone (somatropin) is not being used for anti-aging, longevity, cosmetic, or enhancement of athletic performance/body building purposes?
[If no, no further questions.] | Yes No |

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- 3 Is the patient a child or an adolescent whose epiphyses are still open AND who has not reached their mid-parental height?
[NOTE: If the adolescent who was previously on growth hormone has stopped growing, the epiphyses are closed, or mid-parental height has been attained, they may be reviewed as a transition adolescent or as an adult with growth hormone deficiency OR as an adult with Prader Willi syndrome. Transition adolescents will nearly always have had a diagnosis of growth hormone deficiency. The transition period is the time from late puberty to establishment of adult muscle and bone composition and encompasses attainment of adult height.]

☐ Child or adolescent (If checked, go to 4)

☐ Adult or transition adolescent (If checked, go to 5)

- 4 What is the diagnosis or indication?

☐ Growth hormone deficiency (If checked, go to 8)

☐ Previous radiation to the brain or tumor resection of a child (If checked, go to 9)

☐ Congenital hypopituitarism (If checked, go to 10)

☐ Panhypopituitarism [Note: GHD may occur in combination with other pituitary hormone deficiencies and is referred to as hypopituitarism, panhypopituitarism, or multiple pituitary hormone deficiency.] (If checked, go to 11)

☐ Hypophysectomy (surgical removal of pituitary gland) (If checked, go to 12)

☐ Non-growth hormone deficient short stature (idiopathic short stature) (If checked, go to 13)

☐ Patients with short stature associated with Turner syndrome (If checked, go to 14)

☐ SHOX (short stature homeobox-containing gene) deficiency (If checked, go to 15)

☐ Growth failure in child or adolescent with chronic kidney disease (CKD) (If checked, go to 16)

☐ Prader-Willi syndrome (If checked, go to 17)

☐ Children born small for gestational age (SGA) or with intrauterine growth restriction (retardation) (IUGR) including those with Silver-Russell syndrome (If checked, go to 18)

☐ Noonan syndrome (If checked, go to 19)

☐ Short bowel syndrome (If checked, go to 6)

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- ☐ Acute critical illness due to complications following surgery, multiple accidental trauma, or with acute respiratory failure (If checked, no further questions)
- ☐ Enhancement of athletic ability (If checked, no further questions)
- ☐ Central precocious puberty (If checked, no further questions)
- ☐ Chronic fatigue syndrome (If checked, no further questions)
- ☐ Congenital adrenal hyperplasia (CAH) (If checked, no further questions)
- ☐ Constitutional delay of growth and puberty (If checked, no further questions)
- ☐ Corticosteroid-induced short stature, including a variety of chronic glucocorticoid-dependent conditions, such as asthma, Crohn's disease, juvenile rheumatoid arthritis, as well as after renal, heart, liver, or bone marrow transplantation (If checked, no further questions)
- ☐ Fibromyalgia (If checked, no further questions)
- ☐ HIV-infected patients with alterations in body fat distribution (for example, increased abdominal girth, lipodystrophy and excess abdominal fat, buffalo hump) (If checked, no further questions)
- ☐ Infertility (If checked, no further questions)
- ☐ Obesity (If checked, no further questions)
- ☐ Other (If checked, no further questions)

- 5 What is the diagnosis or indication?
- ☐ Childhood onset growth hormone (GH) deficiency OR adult onset GH deficiency that, in the adult, results from one of the following: GH deficiency alone or multiple hormone deficiencies (hypopituitarism) resulting from pituitary disease, hypothalamic disease, pituitary surgery, cranial radiation therapy, tumor treatment, traumatic brain injury, or subarachnoid hemorrhage (If checked, go to 20)
 - ☐ Prader-Willi syndrome (If checked, go to 22)
 - ☐ Short bowel syndrome in an adult (If checked, go to 6)
 - ☐ Acute critical illness due to complications following surgery, multiple accidental trauma, or with acute respiratory failure (If checked, no further questions)
 - ☐ Aging (that is, antiaging); to improve functional status in elderly patients; and somatopause (If checked, no further questions)

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- ☐ Enhancement of athletic ability (If checked, no further questions)
- ☐ Central precocious puberty (If checked, no further questions)
- ☐ Chronic fatigue syndrome (If checked, no further questions)
- ☐ Congenital adrenal hyperplasia (CAH) (If checked, no further questions)
- ☐ Constitutional delay of growth and puberty (If checked, no further questions)
- ☐ Corticosteroid-induced short stature, including a variety of chronic glucocorticoid-dependent conditions, such as asthma, Crohn's disease, juvenile rheumatoid arthritis, as well as after renal, heart, liver, or bone marrow transplantation (If checked, no further questions)
- ☐ Fibromyalgia (If checked, no further questions)
- ☐ HIV-infected patients with alterations in body fat distribution (e.g., increased abdominal girth, lipodystrophy and excess abdominal fat, buffalo hump) (If checked, no further questions)
- ☐ Infertility (If checked, no further questions)
- ☐ Obesity (If checked, no further questions)
- ☐ Osteoporosis (If checked, no further questions)
- ☐ Other (If checked, no further questions)

6	Is the patient greater than or equal to 18 years of age? [If no, no further questions.]	Yes	No
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7	Is the request for a second course of therapy with growth hormone (somatropin)? [NOTE: Examples of growth hormone medications: Genotropin, Humatrope, Norditropin, Nutropin AQ, Omnitrope, Saizen, Zorbtive, Zomacton.] [If yes, skip to question 23.] [If no, skip to question 24.]	Yes	No
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8	Does the patient have any of the following indications? <input type="checkbox"/> Previous radiation to the brain or tumor resection of a child (If checked, go to 9) <input type="checkbox"/> Congenital hypopituitarism (If checked, go to 10) <input type="checkbox"/> Panhypopituitarism (If checked, go to 11) <input type="checkbox"/> Hypophysectomy (surgical removal of pituitary gland) (If checked, go to 12) <input type="checkbox"/> None of the above (If checked, go to 25)		
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- 9 Is this request for initial therapy or for a continuation of therapy with growth hormone (somatropin)?
[NOTE: IF the patient has been established on growth hormone (somatropin) for more than or equal to 10 months select "Continuation" or else select "Initial."]
☐ Continuation (If checked, go to 26)

☐ Initial (If checked, go to 27)
- 10 Is this request for initial therapy or for a continuation of therapy with growth hormone (somatropin)?
[NOTE: IF the patient has been established on growth hormone (somatropin) for more than or equal to 10 months select "Continuation" or else select "Initial."]
☐ Continuation (If checked, go to 26)

☐ Initial (If checked, go to 28)
- 11 Is this request for initial therapy or for a continuation of therapy with growth hormone (somatropin)?
[NOTE: IF the patient has been established on growth hormone (somatropin) for more than or equal to 10 months select "Continuation" or else select "Initial."]
☐ Continuation (If checked, go to 26)

☐ Initial (If checked, go to 29)
- 12 Is this request for initial therapy or for a continuation of therapy with growth hormone (somatropin)?
[NOTE: If the patient has been established on growth hormone (somatropin) for more than or equal to 10 months select "Continuation" or else select "Initial."]
☐ Continuation (If checked, go to 26)

☐ Initial (If checked, no further questions)
- 13 Is this request for initial therapy or for a continuation of therapy with growth hormone (somatropin)?
[NOTE: Patients continuing growth hormone must have received at least 6 months of therapy.]
☐ Continuation (If checked, go to 30)

☐ Initial (If checked, go to 31)
- 14 Is this request for initial therapy or for a continuation of therapy with growth hormone (somatropin)?
[NOTE: IF the patient has been established on growth hormone (somatropin) for more than or equal to 10 months select "Continuation" or else select "Initial."]
☐ Continuation (If checked, go to 33)

☐ Initial (If checked, no further questions)

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|----|---|------------|-----------|
| 15 | <p>Is this request for initial therapy or for a continuation of therapy with growth hormone (somatropin)?</p> <p>[NOTE: IF the patient has been established on growth hormone (somatropin) for more than or equal to 10 months select "Continuation" or else select "Initial."]</p> <p><input type="checkbox"/> Continuation (If checked, go to 33)</p> <p><input type="checkbox"/> Initial (If checked, go to 34)</p> | | |
| 16 | <p>Is this request for initial therapy or for a continuation of therapy with growth hormone (somatropin)?</p> <p>[NOTE: IF the patient has been established on growth hormone (somatropin) for more than or equal to 10 months select "Continuation" or else select "Initial."]</p> <p><input type="checkbox"/> Continuation (If checked, go to 32)</p> <p><input type="checkbox"/> Initial (If checked, go to 35)</p> | | |
| 17 | <p>Is this request for initial therapy or for a continuation of therapy with growth hormone (somatropin)?</p> <p>[NOTE: IF the patient has been established on growth hormone (somatropin) for more than or equal to 10 months select "Continuation" or else select "Initial."]</p> <p><input type="checkbox"/> Continuation (If checked, go to 36)</p> <p><input type="checkbox"/> Initial (If checked, go to 37)</p> | | |
| 18 | <p>Is this request for initial therapy or for a continuation of therapy with growth hormone (somatropin)?</p> <p>[NOTE: IF the patient has been established on growth hormone (somatropin) for more than or equal to 10 months select "Continuation" or else select "Initial."]</p> <p><input type="checkbox"/> Continuation (If checked, go to 26)</p> <p><input type="checkbox"/> Initial (If checked, go to 38)</p> | | |
| 19 | <p>Is this request for initial therapy or for a continuation of therapy with growth hormone (somatropin)?</p> <p>[NOTE: IF the patient has been established on growth hormone (somatropin) for more than or equal to 10 months select "Continuation" or else select "Initial."]</p> <p><input type="checkbox"/> Continuation (If checked, go to 33)</p> <p><input type="checkbox"/> Initial (If checked, go to 39)</p> | | |
| 20 | <p>Is documentation being provided to confirm that the patient has childhood onset growth hormone (GH) deficiency OR adult onset GH deficiency that, in the adult, results from one of the following: GH deficiency alone or multiple hormone deficiencies (hypopituitarism) resulting from pituitary disease, hypothalamic disease, pituitary surgery, cranial radiation therapy, tumor treatment, traumatic brain injury, or subarachnoid hemorrhage? ACTION REQUIRED: Submit supporting documentation.</p> <p>[If no, no further questions.]</p> | <p>Yes</p> | <p>No</p> |

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- | | | | |
|----|---|-----|----|
| 21 | Has the patient been evaluated by an endocrinologist?
[If yes, skip to question 41.]
[If no, no further questions.] | Yes | No |
| 22 | Is this request for initial therapy or for a continuation of therapy with growth hormone (somatropin)?
[NOTE: IF the patient has been established on growth hormone (somatropin) for more than or equal to 10 months select "Continuation" or else select "Initial."]
<input type="checkbox"/> Continuation (If checked, go to 42)

<input type="checkbox"/> Initial (If checked, go to 62) | | |
| 23 | Has the patient responded to growth hormone (somatropin) therapy with a decrease in the requirement for specialized nutritional support according to the prescriber?
[No further questions.] | Yes | No |
| 24 | Is the patient receiving specialized nutritional support (defined as a high carbohydrate, low-fat diet that is adjusted for individual patient requirements and preferences)?
[No further questions.] | Yes | No |
| 25 | Is this request for initial therapy or for a continuation of therapy with growth hormone (somatropin)?
[NOTE: IF the patient has been established on growth hormone (somatropin) for more than or equal to 10 months select "Continuation" or else select "Initial."]
<input type="checkbox"/> Continuation (If checked, go to 26)

<input type="checkbox"/> Initial (If checked, go to 40) | | |
| 26 | What is the patient's age?
<input type="checkbox"/> Less than 12 years of age (If checked, go to 60)

<input type="checkbox"/> Greater than or equal to 12 years to less than or equal to 18 years of age (If checked, go to 52)

<input type="checkbox"/> Greater than 18 years of age (If checked, go to 50) | | |
| 27 | Has the patient been evaluated by an endocrinologist?
[If yes, skip to question 44.]
[If no, no further questions.] | Yes | No |
| 28 | Has the patient been evaluated by an endocrinologist?
[If yes, skip to question 45.]
[If no, no further questions.] | Yes | No |
| 29 | Does the patient have pituitary stalk agenesis, empty sella, sellar or supra-sellar | Yes | No |

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mass lesion, or ectopic posterior pituitary "bright spot" on magnetic resonance image or computed tomography?

[If yes, skip to question 49.]

[If no, skip to question 46.]

30 How long has the patient been receiving growth hormone?

[NOTE: Patients starting growth hormone must have received at least 6 months of therapy in order to evaluate for response. Examples of growth hormone medications: Genotropin, Humatrope, Norditropin, Nutropin AQ, Omnitrope, Saizen. After the first 6-month trial, patients who respond are reviewed every 12 months.]

☐ 6 months (or less than 12 months if started with a different insurance) (If checked, go to 51)

☐ At least 10 months (If checked, go to 47)

31 Is the patient greater than or equal to 5 years of age?

Yes

No

[If yes, skip to question 53.]

[If no, no further questions.]

32 Has the patient's height increased by greater than or equal to 2 cm/year in the most recent year AND the patient's epiphyses are still open?

Yes

No

[No further questions.]

33 Has the patient's height increased by greater than or equal to 2.5 cm/year in the most recent year AND the patient's epiphyses are still open?

Yes

No

[No further questions.]

34 Has short stature homeobox-containing gene (SHOX) deficiency been demonstrated by chromosome analysis?

Yes

No

[If yes, skip to question 54.]

[If no, no further questions.]

35 Does the patient have or has had chronic kidney disease (CKD) as defined by abnormal creatinine clearance?

Yes

No

[If yes, skip to question 55.]

[If no, no further questions.]

36 Has the patient's height increased by greater than or equal to 2.5 cm/year in the most recent year AND the patient's epiphyses are still open?

Yes

No

[NOTE: When the epiphyses are closed and/or the height velocity is less than 2.5 cm/year, the patient can be reviewed for continuation of therapy as an adult with Prader-Willi syndrome.]

[No further questions.]

37 Has the patient been evaluated by an endocrinologist?

Yes

No

[No further questions.]

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38	<p>Is the patient greater than or equal to 2 years of age? [If yes, skip to question 56.] [If no, no further questions.]</p>	Yes	No
39	<p>Has the patient been evaluated by an endocrinologist? [If yes, skip to question 57.] [If no, no further questions.]</p>	Yes	No
40	<p>Has the patient had TWO growth hormone (GH) stimulation tests performed with ANY of the following agents: A) levodopa, B) insulin-induced hypoglycemia, C) arginine, D) clonidine, or E) glucagon AND both tests show an inadequate response as defined by a peak GH response which is below the normal reference range as determined by the testing laboratory? [NOTE: Some children will achieve stimulated growth hormone concentrations in the normal range as determined by the testing laboratory and could be reviewed for authorization under non-growth hormone deficient short stature (idiopathic short stature).] [If yes, skip to question 62.] [If no, skip to question 43.]</p>	Yes	No
41	<p>Is the patient an adult or transition adolescent who has known mutations, embryopathic lesions, congenital or genetic defects, or structural hypothalamic-pituitary defects? [If yes, skip to question 66.] [If no, skip to question 67.]</p>	Yes	No
42	<p>Has the patient been evaluated by an endocrinologist or in consultation with an endocrinologist? [No further questions.]</p>	Yes	No
43	<p>Has the patient had one growth hormone (GH) stimulation test performed with any of the following agents: levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND the test shows an inadequate response as defined by a peak GH response which is below the normal reference range as determined by the testing laboratory? [NOTE: Some children will achieve stimulated growth hormone concentrations in the normal range as determined by the testing laboratory and could be reviewed for authorization under non-growth hormone deficient short stature (idiopathic short stature).] [If yes, skip to question 58.] [If no, no further questions.]</p>	Yes	No
44	<p>Has the patient had one growth hormone stimulation test with any of the following agents: levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND the test shows an inadequate response as defined by a peak GH response which is below the normal reference range as determined by the testing laboratory; OR the patient has a deficiency in at least one other pituitary hormone (that is, adrenocorticotrophic hormone (ACTH), thyroid-stimulating hormone (TSH),</p>	Yes	No

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gonadotropin deficiency (luteinizing hormone [LH] and/or follicle stimulating hormone [FSH] deficiency are counted as one deficiency), or prolactin)?
[No further questions.]

- | | | | |
|-----------|--|-----|----|
| 45 | <p>Has the patient had one growth hormone stimulation test with any of the following agents: levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND the test shows an inadequate response as defined by a peak GH response which is below the normal reference range as determined by the testing laboratory; OR the patient has a deficiency in at least one other pituitary hormone (that is, adrenocorticotrophic hormone (ACTH), thyroid-stimulating hormone (TSH), gonadotropin deficiency (luteinizing hormone [LH] and/or follicle stimulating hormone [FSH] deficiency are counted as one deficiency), or prolactin) and/or the patient has the imaging triad of ectopic posterior pituitary and pituitary hypoplasia with abnormal pituitary stalk?
[No further questions.]</p> | Yes | No |
| 46 | <p>Does the patient have three or more of the following pituitary hormone deficiencies: somatotropin (growth hormone), adrenocorticotrophic hormone (ACTH), thyroid stimulating hormone (TSH), gonadotropin deficiency (luteinizing hormone [LH] and/or follicle stimulating hormone [FSH] deficiency are counted as one deficiency), and prolactin?
[If yes, skip to question 49.]
[If no, skip to question 48.]</p> | Yes | No |
| 47 | <p>What is the patient's age?
 <input type="checkbox"/> Greater than or equal to 5 years to less than 12 years of age (If checked, go to 60)

 <input type="checkbox"/> Greater than or equal to 12 years to less than or equal to 18 years of age (If checked, go to 52)

 <input type="checkbox"/> Greater than 18 years of age (If checked, go to 50)

 <input type="checkbox"/> Less than 5 years of age (If checked, no further questions)</p> | | |
| 48 | <p>Has the patient had one growth hormone stimulation test with any of the following agents: levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND the test shows an inadequate response as defined by a peak GH response which is below the normal reference range as determined by the testing laboratory?
[If no, no further questions.]</p> | Yes | No |
| 49 | <p>Has the patient been evaluated by an endocrinologist?
[No further questions.]</p> | Yes | No |
| 50 | <p>Has the patient attained his/her mid-parental height?
[NOTE: Mid-parental height is the father's height plus the mother's height divided by 2, plus 2.5 inches if male or minus 2.5 inches if female.]</p> | Yes | No |

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[If yes, skip to question 52.]
[If no, no further questions.]

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|----|---|-----|----|
| 51 | What is the patient's age?
<input type="checkbox"/> 5 years of age or older (If checked, go to 59)

<input type="checkbox"/> Less than 5 years of age (If checked, no further questions) | | |
| 52 | Are the patient's epiphyses still open?
[If yes, skip to question 60.]
[If no, no further questions.] | Yes | No |
| 53 | Does the patient have constitutional delay of growth and puberty (CDGP)?
[If yes, no further questions.]
[If no, skip to question 61.] | Yes | No |
| 54 | Has the patient been evaluated by an endocrinologist?
[If yes, skip to question 63.]
[If no, no further questions.] | Yes | No |
| 55 | Has the patient been evaluated by an endocrinologist or a nephrologist?
[No further questions.] | Yes | No |
| 56 | Has the patient been evaluated by an endocrinologist?
[If yes, skip to question 64.]
[If no, no further questions.] | Yes | No |
| 57 | At baseline, is the patient's height less than the 5th percentile using a growth chart for children without Noonan syndrome?
[No further questions.] | Yes | No |
| 58 | Does the patient have at least one risk factor for growth hormone deficiency?
[NOTE: For example, the height for age curve has deviated downward across two major height percentiles [for example, from above the 25th percentile to below the 10th percentile]; the child's growth rate is less than the expected normal growth rate based on age and gender; low IGF-1 and/or IGFBP-3 levels; the child has a very low peak growth hormone level on provocative testing as defined by the prescribing physician; the child's growth velocity is less than the 10th percentile for age and gender [height velocity percentile is NOT the same as height-for-age percentile]; the patient is status post craniopharyngioma resection; the patient has optic nerve hypoplasia; the patient has a growth hormone gene deletion.]
[If yes, skip to question 62.]
[If no, no further questions.] | Yes | No |
| 59 | After the initial 6 months of therapy, did the patient have an adequate clinical response defined as an annualized growth rate that doubled in comparison to the previous year?
[NOTE: For example, if the growth velocity was 3 cm/year for the year prior to | Yes | No |

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treatment, then the growth velocity must be at least 3 cm in 6 months (baseline velocity was 1.5 cm/6 months). Another example would be if the growth velocity was 2 cm/year for the year prior to treatment, then after 6 months of somatropin therapy, the growth velocity must be at least 2 cm in 6 months (1 cm/6 months baseline).]

[No further questions.]

60	Has the patient's height increased by greater than or equal to 4 cm/year in the most recent year? [No further questions.]	Yes	No
61	Are the patient's epiphyses still open? [If yes, skip to question 74.] [If no, no further questions.]	Yes	No
62	Has the patient been evaluated by an endocrinologist? [No further questions.]	Yes	No
63	Are the patient's epiphyses still open? [If yes, skip to question 78.] [If no, no further questions.]	Yes	No
64	Was the patient's birth weight and/or birth length greater than 2 standard deviations (SD) below the mean for gestational age and gender AND the patient did not have sufficient catch-up growth before age 2 to 4 years? [If no, no further questions.]	Yes	No
65	At baseline, is the patient's height less than the 5th percentile for age and gender? [No further questions.]	Yes	No
66	Is documentation being provided to confirm that the adult or transition adolescent has known mutations, embryopathic lesions, congenital or genetic defects, or structural hypothalamic-pituitary defects? ACTION REQUIRED: Submit supporting documentation. [No further questions.]	Yes	No
67	Does the adult or transition adolescent have three or more of the following pituitary hormone deficiencies: adrenocorticotrophic hormone (ACTH), thyroid stimulating hormone (TSH), gonadotropin deficiency (luteinizing hormone [LH] and/or follicle stimulating hormone [FSH] deficiency are counted as one deficiency), and prolactin? [If no, skip to question 72.]	Yes	No
68	Is documentation being provided to confirm that the adult or transition adolescent has three or more of the following pituitary hormone deficiencies: adrenocorticotrophic hormone (ACTH), thyroid stimulating hormone (TSH), gonadotropin deficiency (luteinizing hormone [LH] and/or follicle stimulating hormone [FSH] deficiency are counted as one deficiency), and prolactin? ACTION	Yes	No

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REQUIRED: Submit supporting documentation.
[If no, no further questions.]

- | | | | |
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| 69 | Is the age and gender adjusted serum IGF-1 below the lower limits of the normal reference range for the reporting laboratory?
[If no, skip to question 72.] | Yes | No |
| 70 | Is documentation being provided to confirm that the patient has an age and gender adjusted serum IGF-1 below the lower limits of the normal reference range for the reporting laboratory? ACTION REQUIRED: Submit supporting documentation.
[If no, no further questions.] | Yes | No |
| 71 | Have other causes of low serum IGF-1 been excluded (for example, malnutrition, prolonged fasting, poorly controlled diabetes mellitus, hypothyroidism, hepatic insufficiency, oral estrogen therapy)?
[If yes, no further questions.] | Yes | No |
| 72 | Is the patient an adult OR a transition adolescent with childhood onset growth hormone deficiency who is transitioning from growth hormone therapy in childhood to adulthood (the transition period is the time from late puberty to establishment of adult muscle and bone composition, and encompasses attainment of adult height)?
<input type="checkbox"/> Transition adolescent (If checked, go to 73)

<input type="checkbox"/> Adult (If checked, go to 80) | Yes | No |
| 73 | As a transition adolescent, has the patient been off somatropin therapy (growth hormone) for at least one month before being retested with a growth hormone stimulation test?
[If yes, skip to question 79.]
[If no, no further questions.] | Yes | No |
| 74 | At baseline, is the patient's height less than the 1.2 percentile (standard deviation score (SDS) less than -2.25) for age and gender?
[If no, no further questions.] | Yes | No |
| 75 | Without growth hormone therapy, is the patient's predicted adult height less than 160 cm (63 inches) if male or less than 150 cm (59 inches) if female?
[If no, no further questions.] | Yes | No |
| 76 | What is the patient's pretreatment growth (height) velocity (growth rate) measured in cm/year?
<input type="checkbox"/> 4 cm/year or greater (If checked, go to 77)

<input type="checkbox"/> Less than 4cm/year (If checked, no further questions) | | |
| 77 | Based on age, gender, and at least 6 months of growth data, in what percentile is | | |

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the patient's pretreatment growth (height) velocity (growth rate)?

[NOTE: Height velocity percentile is NOT the same as height for age percentile.]

☐ At or above the 10th percentile (If checked, no further questions)

☐ Below the 10th percentile (If checked, no further questions)

- | | | | |
|-----------|---|-----|----|
| 78 | At baseline, is the patient's height less than the 3rd percentile for age and gender?
[No further questions.] | Yes | No |
| 79 | Is documentation being provided to confirm that as a transition adolescent, the patient has been off somatropin therapy (growth hormone) for at least one month before being retested with a growth hormone stimulation test? ACTION REQUIRED: Submit supporting documentation.
[If yes, skip to question 97.]
[If no, no further questions.] | Yes | No |
| 80 | Has the adult patient had a negative response to one of the following standard growth hormone stimulation tests?
<input type="checkbox"/> Insulin tolerance test (If checked, go to 81)

<input type="checkbox"/> Glucagon stimulation test (If checked, go to 83)

<input type="checkbox"/> Macrilen (macimorelin) test (If checked, go to 93)

<input type="checkbox"/> Arginine alone test (If checked, go to 96)

<input type="checkbox"/> No (If checked, no further questions) | | |
| 81 | Has the adult patient had a peak response of 5 micrograms per liter or less with the insulin tolerance test?
[If no, no further questions.] | Yes | No |
| 82 | Is documentation being provided to confirm that the adult patient has had an insulin tolerance test (obtaining at least 3 growth hormone levels in at least a 60 minute timeframe [not including a level at timeframe zero], with adequate hypoglycemia being achieved) with a peak response of 5.0 micrograms per liter or less? ACTION REQUIRED: Submit supporting documentation.
[No further questions.] | Yes | No |
| 83 | What is the adult patient's body mass index (BMI)?
<input type="checkbox"/> Greater than 30 kg/m2 (If checked, go to 84)

<input type="checkbox"/> Greater than or equal to 25 kg/m2 and less than or equal to 30 kg/m2 (If checked, go to 86)

<input type="checkbox"/> Less than 25 kg/m2 (If checked, go to 85) | | |
| 84 | Has the adult patient had a peak response of 1.0 micrograms/liter or less with the | Yes | No |

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glucagon stimulation test?
 [If yes, skip to question 91.]
 [If no, no further questions.]

- | | | | |
|----|---|------|----|
| 85 | Has the adult patient had a peak response of 3.0 micrograms/liter or less with the glucagon stimulation test?
[If yes, skip to question 92.]
[If no, no further questions.] | 1Yes | No |
| 86 | According to the prescriber, does the patient have a high pretest probability of GH deficiency or a low pretest probability of GH deficiency?
<input type="checkbox"/> High pretest probability of GH deficiency (If checked, go to 87)

<input type="checkbox"/> Low pretest probability of GH deficiency (If checked, go to 88) | | |
| 87 | Has the adult patient had a peak response of 3.0 micrograms/liter or less with the glucagon stimulation test?
[If yes, skip to question 89.]
[If no, no further questions.] | Yes | No |
| 88 | Has the adult patient had a peak response of 1.0 micrograms/liter or less with the glucagon stimulation test?
[If yes, skip to question 90.]
[If no, no further questions.] | Yes | No |
| 89 | Is documentation being provided to confirm that the adult patient with body mass index (BMI) greater than or equal to 25 kg/m ² and less than or equal to 30 kg/m ² with, according to the prescriber, a high pretest probability of GH deficiency had a glucagon stimulation test (obtaining at least 3 growth hormone levels in at least 180 minute timeframe [not including a level at timeframe zero]) with a peak response of 3.0 micrograms per liter or less? ACTION REQUIRED: Submit supporting documentation.
[No further questions.] | Yes | No |
| 90 | Is documentation being provided to confirm that the adult patient with body mass index (BMI) greater than or equal to 25 kg/m ² and less than or equal to 30 kg/m ² , with a low pretest probability according to the prescriber, had a glucagon stimulation test (obtaining at least 3 growth hormone levels in at least 180 minute timeframe [not including a level at timeframe zero]) with a peak response of 1.0 micrograms per liter or less? ACTION REQUIRED: Submit supporting documentation.
[No further questions.] | Yes | No |
| 91 | Is documentation being provided to confirm that the adult patient with body mass index (BMI) greater than 30 kg/m ² had a glucagon stimulation test (obtaining at least 3 growth hormone levels in at least 180 minute timeframe [not including a level at timeframe zero]) with a peak response of 1.0 micrograms per liter or less? ACTION REQUIRED: Submit supporting documentation. | Yes | No |

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[No further questions.]

- | | | | |
|----|---|-----|----|
| 92 | <p>Is documentation being provided to confirm that the adult patient with body mass index (BMI) less than 25 kg/m² had a glucagon stimulation test (obtaining at least 3 growth hormone levels in at least 180 minute timeframe [not including a level at timeframe zero]) with a peak response of 3.0 micrograms per liter or less?
 ACTION REQUIRED: Submit supporting documentation.
 [No further questions.]</p> | Yes | No |
| 93 | <p>What is the adult patient's body mass index (BMI)?
 <input type="checkbox"/> Greater than 40 kg/m² (If checked, no further questions)

 <input type="checkbox"/> Less than or equal to 40 kg/m² (If checked, go to 94)</p> | | |
| 94 | <p>Has the adult patient had a Macrilen (macimorelin) test with a peak response of less than 2.8 nanograms/milliliter (2.8 micrograms/liter)?
 [If no, no further questions.]</p> | Yes | No |
| 95 | <p>Is documentation being provided to confirm that the adult patient with body mass index (BMI) less than or equal to 40 kg/m² had a Macrilen (macimorelin) test (obtaining at least 4 growth hormone levels in at least a 90 minute timeframe [not including a level at timeframe zero]) with a peak response of less than 2.8 micrograms per liter? ACTION REQUIRED: Submit supporting documentation.
 [No further questions.]</p> | Yes | No |
| 96 | <p>Has the adult patient had a peak response of 0.4 micrograms/liter or less with the arginine alone test? ACTION REQUIRED: Submit supporting documentation.
 [No further questions.]</p> | Yes | No |
| 97 | <p>Has the transition adolescent patient had a negative response to one of the following standard growth hormone stimulation tests?
 <input type="checkbox"/> Insulin tolerance test (If checked, go to 98)

 <input type="checkbox"/> Glucagon stimulation test (If checked, go to 100)

 <input type="checkbox"/> Arginine alone test (If checked, go to 110)

 <input type="checkbox"/> Macrilen (macimorelin) test (If checked, go to 114)

 <input type="checkbox"/> No (If checked, no further questions)</p> | | |
| 98 | <p>Has the transition adolescent patient had a peak response of 5 micrograms per liter or less with the insulin tolerance test?
 [If no, no further questions.]</p> | Yes | No |
| 99 | <p>Is documentation being provided to confirm that the transition adolescent patient had an insulin tolerance test (obtaining at least 3 growth hormone levels in at least a 60 minute timeframe [not including a level at timeframe zero], with adequate</p> | Yes | No |

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hypoglycemia being achieved) with a peak response of 5.0 micrograms per liter or less? ACTION REQUIRED: Submit supporting documentation.

[No further questions.]

100 What is the transition adolescent patient's body mass index (BMI)?

☐ Less than 25 kg/m² (If checked, go to 102)

☐ Greater than or equal to 25 kg/m² and less than or equal to 30 kg/m² (If checked, go to 103)

☐ Greater than 30 kg/m² (If checked, go to 101)

101 Has the transition adolescent patient had a peak response of 1.0 micrograms/liter or less with the glucagon stimulation test?

Yes

No

[If yes, skip to question 109.]

[If no, no further questions.]

102 Has the transition adolescent patient had a peak response of 3.0 micrograms/liter or less with the glucagon stimulation test?

Yes

No

[If yes, skip to question 108.]

[If no, no further questions.]

103 According to the prescriber, does the patient have a high pretest probability of GH deficiency or a low pretest probability of GH deficiency?

☐ High pretest probability of GH deficiency (If checked, go to 105)

☐ Low pretest probability of GH deficiency (If checked, go to 104)

104 Has the transition adolescent patient had a peak response of 1.0 micrograms/liter or less with the glucagon stimulation test?

Yes

No

[If yes, skip to question 106.]

[If no, no further questions.]

105 Has the transition adolescent patient had a peak response of 3.0 micrograms/liter or less with the glucagon stimulation test?

Yes

No

[If yes, skip to question 107.]

[If no, no further questions.]

106 Is documentation being provided to confirm that the transition adolescent patient with body mass index (BMI) greater than or equal to 25 kg/m² and less than or equal to 30 kg/m², with low pretest probability according to the prescriber, had a glucagon stimulation test (obtaining at least 3 growth hormone levels in at least 180 minute timeframe [not including a level at timeframe zero]) with a peak response of 1.0 micrograms per liter or less? ACTION REQUIRED: Submit supporting documentation.

Yes

No

[No further questions.]

107 Is documentation being provided to confirm that the transition adolescent patient

Yes

No

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with body mass index (BMI) greater than or equal to 25 kg/m² and less than or equal to 30 kg/m², with a high pretest probability according to the prescriber, had a glucagon stimulation test (obtaining at least 3 growth hormone levels in at least 180 minute timeframe [not including a level at timeframe zero]) with a peak response of 3.0 micrograms per liter or less? ACTION REQUIRED: Submit supporting documentation.
[No further questions.]

108	Is documentation being provided to confirm that the transition adolescent patient with body mass index (BMI) less than 25 kg/m ² had a glucagon stimulation test (obtaining at least 3 growth hormone levels in at least 180 minute timeframe [not including a level at timeframe zero]) with a peak response of 3.0 micrograms per liter or less? ACTION REQUIRED: Submit supporting documentation. [No further questions.]	Yes	No
109	Is documentation being provided to confirm that the transition adolescent patient with body mass index (BMI) greater than 30 kg/m ² had a glucagon stimulation test (obtaining at least 3 growth hormone levels in at least 180 minute timeframe [not including a level at timeframe zero]) with a peak response of 1.0 micrograms per liter or less? ACTION REQUIRED: Submit supporting documentation. [No further questions.]	Yes	No
110	Are both the Insulin tolerance test and the glucagon stimulation test contraindicated? [If no, no further questions.]	Yes	No
111	Is documentation being provided to confirm that the transition adolescent patient has contraindications to both the insulin tolerance test and the glucagon stimulation test? ACTION REQUIRED: Submit supporting documentation. [If no, no further questions.]	Yes	No
112	Has the transition adolescent patient had a peak response of 0.4 micrograms/liter or less with the arginine alone test? [If no, no further questions.]	Yes	No
113	Is documentation being provided to confirm that the transition adolescent patient had an arginine alone test obtaining at least 3 growth hormone levels in at least 120 minute timeframe [not including a level at timeframe zero] with a peak response of 0.4 micrograms/liter or less? ACTION REQUIRED: Submit supporting documentation. [No further questions.]	Yes	No
114	Has the transition adolescent patient had a Macrilen (macimorelin) test with a peak response of less than 2.8 nanograms/milliliter (2.8 micrograms/liter)? ACTION REQUIRED: Submit supporting documentation.	Yes	No



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Please document the diagnoses, symptoms, and/or any other information important to this review:

SECTION B: Physician Signature

PHYSICIAN SIGNATURE

DATE

FAX COMPLETED FORM TO: 1-833-896-0656

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