Saizen® Prior Authorization Request Form (Page 1 of 4)

<table>
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<tr>
<th>Member Information (required)</th>
<th>Provider Information (required)</th>
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<td>Member Name:</td>
<td>Provider Name:</td>
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<td>Insurance ID#:</td>
<td>NPI#:</td>
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<td>Date of Birth:</td>
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Medication Information (required)

- Medication Name: 
- Strength: 
- Dosage Form: 
- Directions for Use: 
  - Check if requesting **brand**
  - Check if request is for **continuation of therapy**

Clinical Information (required)

Select the diagnosis below:
- Pediatric growth hormone deficiency
- Growth hormone deficiency in adults
- Growth hormone deficiency in transition phase adolescents
- Idiopathic short stature (ISS)
- Isolated growth hormone deficiency in adults
- Pediatric growth failure associated with chronic renal insufficiency
- Prader-Willi syndrome
- Short-stature homeobox (SHOX) gene deficiency
- Small for gestational age (SGA)
- Turner syndrome or Noonan syndrome
- Other diagnosis: ____________________________________________ ICD-10 Code(s): __________________________________

**Clinical Information:**
- Select if the requested medication is prescribed by or in consultation with one of the following specialists:
  - Endocrinologist
  - Nephrologist
- Select if the patient has had a trial and failure or intolerance to the following:
  - Norditropin (somatropin)
  - Nutropin AQ/Nutropin AQ Nuspip (somatropin)
  - Omnitrope (somatropin)

**For pediatric growth hormone deficiency, also answer the following:**
- Is the patient an infant < 4 months of age?  Yes  No
- Does the infant have growth deficiency?  Yes  No
- Does the patient have history of neonatal hypoglycemia associated with pituitary disease?  Yes  No
- Does the patient have panhypopituitarism?  Yes  No
- Select if the diagnosis of pediatric GH deficiency is confirmed by the patient’s height as documented by the following (utilizing age and gender growth charts related to height):
  - Height > 2.0 standard deviations [SD] below mid-parental height
  - Height > 2.25 SD below population mean (below the 1.2 percentile for age and gender)
- Is the patient’s growth velocity > 2 SD below mean for age and gender?  Yes  No

<continued on the next page>
<continuation of pediatric growth hormone deficiency>

Does the patient have delayed skeletal maturation of > 2 SD below mean for age and gender (e.g., delayed > 2 years compared with chronological age)?  □ Yes □ No

Is there documentation the patient's bone age is < 16 years for males or < 14 years for females?  □ Yes □ No

Select if the patient has undergone provocative GH stimulation tests with the following:  (Document the GH response)

- Arginine  Peak value: ___________ mcg/L
- Clonidine  Peak value: ___________ mcg/L
- Glucagon  Peak value: ___________ mcg/L
- Insulin  Peak value: ___________ mcg/L
- Levodopa  Peak value: ___________ mcg/L
- Growth hormone releasing hormone  Peak value: ___________ mcg/L

For patients less than 1 year of age, select if the following is below the age and gender adjusted normal range as provided by the physician's lab:  (Document the specified lab value and reference range)

- Insulin-like growth factor 1 (IGF-1/Somatedin-C)  IGF-1/Somatedin-C level: ___________ Reference range: ___________
- Insulin growth factor binding protein-3 (IGFBP-3)  IGFBP-3 level: ___________ Reference range: ___________

Reauthorization:

Please document that the patient has had a height increase of at least 2 cm/year over the previous year of treatment below:

- Previous height: ______________________  Date obtained: ______________________
- Current height: ______________________  Date obtained: ______________________

Has the expected adult height been reached?  □ Yes □ No

Document the expected adult height goal: ______________________

For growth hormone (GH) deficiency in adults, also answer the following:

Are there clinical records supporting a diagnosis of childhood-onset GH deficiency?  □ Yes □ No

Does the patient have adult-onset GH deficiency?  □ Yes □ No

Are there clinical records documenting that hormone deficiency is a result of hypothalamic-pituitary disease from organic or known causes (e.g., damage from surgery, cranial irradiation, head trauma, or subarachnoid hemorrhage)?  □ Yes □ No

Select if the patient has undergone one of the following GH stimulation tests to confirm adult GH deficiency and the peak GH value is as follows:

- Insulin tolerance test (ITT) ≤ 5 mcg/L
- Arginine & GH-releasing hormone (GHRH+ARG) ≤ 11 mcg/L if body mass index (BMI) is < 25 kg/m²; ≤ 8 mcg/L if BMI is ≥ 25 and < 30 kg/m²; ≤ 4 mcg/L if BMI is ≥ 30 kg/m²
- Glucagon ≤ 3 mcg/L
- Arginine (ARG) ≤ 0.4 mcg/L

Select if there is documentation the patient has deficiency of the following anterior pituitary hormones:

- Adrenocorticotropic hormone (ACTH)  □ Prolactin
- Follicle-stimulating hormone/luteinizing hormone (FSH/LH)  □ Thyroid stimulating hormone (TSH)

Does the patient have an IGF-1/Somatedin-C level below the age and gender adjusted normal range as provided by the physician's lab?  □ Yes □ No

Reauthorization:

Is there evidence of ongoing monitoring as demonstrated by documentation within the past 12 months of an IGF-1/Somatedin-C level?  □ Yes □ No

For isolated growth hormone deficiency in adults, also answer the following:

Is there documentation the patient has deficiency of GH defined by a failure to produce a peak serum GH level of > 5 mcg/L after provocative pharmacologic stimulation by two of the following tests:  Insulin, L-arginine, and/or glucagon?  □ Yes □ No

Reauthorization:

Is there evidence of ongoing monitoring as demonstrated by documentation within the past 12 months of an IGF-1/Somatedin-C level?  □ Yes □ No
For growth hormone (GH) deficiency in transition phase adolescents, also answer the following:

Has the expected adult height been reached?  □ Yes  □ No
Are the patient's epiphyses closed on bone radiograph?  □ Yes  □ No
Select if there is documentation the patient has high risk of GH deficiency due to GH deficiency in childhood from one of the following:
□ Embryopathic/congenital defects  □ Irreversible structural hypothalamic-pituitary disease
□ Genetic mutations  □ Panhypopituitarism
□ Deficiency of three or more of the following anterior pituitary hormones: ACTH, TSH, Prolactin, FSH/LH

Does the patient have an IGF-1/Somatomedin-C level below the age and gender adjusted normal range as provided by the physician’s lab?  □ Yes  □ No

Is the patient at low risk of severe GH deficiency (e.g., due to isolated and/or idiopathic deficiency)?  □ Yes  □ No
Has GH therapy been discontinued for at least 1 month?  □ Yes  □ No
Select if the patient has undergone one of the following GH stimulation tests after discontinuation of therapy for at least 1 month and the peak GH value is as follows:
□ Insulin tolerance test (ITT) ≤ 5 mcg/L
□ Arginine & GH-releasing hormone (GHRH+ARG) ≤ 11 mcg/L if body mass index (BMI) is < 25 kg/m²; ≤ 8 mcg/L if BMI is ≥ 25 and < 30 kg/m²; ≤ 4 mcg/L if BMI is ≥ 30 kg/m²
□ Glucagon ≤ 3 mcg/L
□ Arginine (ARG) ≤ 0.4 mcg/L

Reauthorization:
Is there evidence the patient has had a positive response to therapy (e.g., increase in total lean body mass, exercise capacity or IGF-1 and IGFBP-3 levels)?  □ Yes  □ No

For pediatric growth failure associated with chronic renal insufficiency, also answer the following:

Is there documentation the patient's bone age is < 16 years for males or < 14 years for females?  □ Yes  □ No

Reauthorization:
Please document that the patient has had a height increase of at least 2 cm/year over the previous year of treatment below:

| Previous height: ____________________ | Date obtained: ____________________ |
| Current height: ____________________  | Date obtained: ____________________ |

Has the expected adult height been reached?  □ Yes  □ No

Document the expected adult height goal: ____________________

For Prader-Willi syndrome, also answer the following:

Reauthorization:
Is there evidence the patient has had a positive response to therapy (e.g., increase in total lean body mass, decrease in fat mass)?  □ Yes  □ No

Please document that the patient has had a height increase of at least 2 cm/year over the previous year of treatment below:

| Previous height: ____________________ | Date obtained: ____________________ |
| Current height: ____________________  | Date obtained: ____________________ |

Has the expected adult height been reached?  □ Yes  □ No

Document the expected adult height goal: ____________________

For short-stature homeobox (SHOX) gene deficiency, also answer the following:

Does the patient have a diagnosis of pediatric growth failure with short stature homeobox (SHOX) gene deficiency as confirmed by genetic testing?  □ Yes  □ No
Is there documentation the patient’s bone age is < 16 years for males or < 14 years for females?  □ Yes  □ No

Reauthorization:
Please document that the patient has had a height increase of at least 2 cm/year over the previous year of treatment below:

| Previous height: ____________________ | Date obtained: ____________________ |
| Current height: ____________________  | Date obtained: ____________________ |

Has the expected adult height been reached?  □ Yes  □ No

Document the expected adult height goal: ____________________

This document and others if attached contain information that is privileged, confidential and/or may contain protected health information (PHI). The Provider named above is required to safeguard PHI by applicable law. The information in this document is for the sole use of OptumRx. Proper consent to disclose PHI between these parties has been obtained. If you received this document by mistake, please know that sharing, copying, distributing or using information in this document is against the law. If you are not the intended recipient, please notify the sender immediately.

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For small for gestational age (SGA), also answer the following:
Select if the diagnosis of SGA is based on demonstration of catch up growth failure in the first 24 months of life using a 0-36 month growth chart as confirmed by one of the following:
- Patient’s birth weight was below the 3rd percentile for gestational age (> 2 SD below population mean)
- Patient’s birth length was below the 3rd percentile for gestational age (> 2 SD below population mean)
Does patient’s height remain ≤ the 3rd percentile (> 2 SD below population mean)?  □ Yes  □ No

Reauthorization:
Please document that the patient has had a height increase of at least 2 cm/year over the previous year of treatment below:

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Has the expected adult height been reached?  □ Yes  □ No
Document the expected adult height goal: _______________________

For Turner syndrome (gonadal dysgenesis) or Noonan syndrome, also answer the following:
Is there documentation the patient’s bone age is < 16 years for males or < 14 years for females?  □ Yes  □ No
Is the patient's height below the 5th percentile on growth charts for age and gender?  □ Yes  □ No

Reauthorization:
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Has the expected adult height been reached?  □ Yes  □ No
Document the expected adult height goal: _______________________

Are there any other comments, diagnoses, symptoms, medications tried or failed, and/or any other information the physician feels is important to this review?
________________________________________________________________________________
________________________________________________________________________________

Please note: This request may be denied unless all required information is received.
For urgent or expedited requests please call 1-800-711-4555.
This form may be used for non-urgent requests and faxed to 1-800-527-0531.