

Saizen® Prior Authorization Request Form (Page 1 of 6)

Member Information (required)			Provider Information (required)		
Member Name:			Provider Name:		
Insurance ID#:			NPI#:		Specialty:
Date of Birth:			Office Phone:		
Street Address:			Office Fax:		
City:	State:	Zip:	Office Street Address:		
Phone:			City:	State:	Zip:
Medication Information (required)					
Medication Name:			Strength:		Dosage Form:
<input type="checkbox"/> Check if requesting brand			Directions for Use:		
<input type="checkbox"/> Check if request is for continuation of therapy					
Clinical Information (required)					
<p>Select the diagnosis below:</p> <p><input type="checkbox"/> Pediatric growth hormone deficiency</p> <p><input type="checkbox"/> Growth hormone deficiency in adults</p> <p><input type="checkbox"/> Growth hormone deficiency in transition phase adolescents</p> <p><input type="checkbox"/> Idiopathic short stature (ISS)</p> <p><input type="checkbox"/> Isolated growth hormone deficiency in adults</p> <p><input type="checkbox"/> Pediatric growth failure associated with chronic renal insufficiency</p> <p><input type="checkbox"/> Prader-W illi syndrome</p> <p><input type="checkbox"/> Short-stature homeobox (SHOX) gene deficiency</p> <p><input type="checkbox"/> Small for gestational age (SGA)</p> <p><input type="checkbox"/> Turner syndrome or Noonan syndrome</p> <p><input type="checkbox"/> Other diagnosis: _____ ICD-10 Code(s): _____</p>					
<p>Clinical Information:</p> <p>Is Saizen prescribed by or in consultation with an endocrinologist? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>For patients with chronic renal insufficiency, is Saizen prescribed by or in consultation with a nephrologist? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Select if the patient has had a trial and failure or intolerance to the following:</p> <p><input type="checkbox"/> Norditropin</p> <p><input type="checkbox"/> Nutropin AQ/Nutropin AQ Nuspin</p> <p><input type="checkbox"/> Omnitrope</p>					
<p>For pediatric growth hormone deficiency, also answer the following:</p> <p>Is the patient an infant < 4 months of age? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Does the infant have growth deficiency? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Does the patient have history of neonatal hypoglycemia associated with pituitary disease? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Does the patient have panhypopituitarism? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Is the patient's height > 2.0 standard deviations [SD] below mid-parental height? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Is the patient's height > 2.25 SD below population mean (below the 1.2 percentile for age and gender)? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Is the patient's growth velocity > 2 SD below mean for age and gender? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Does the patient have delayed skeletal maturation of > 2 SD below mean for age and gender (e.g., delayed > 2 years compared w ith chronological age)? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>					
<Continued on next page>					

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<Continuation of pediatric growth hormone deficiency>

Is the patient's bone age < 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)**

- | | |
|---|-------------------------|
| <input type="checkbox"/> Arginine | Peak value: _____ mcg/L |
| <input type="checkbox"/> Clonidine | Peak value: _____ mcg/L |
| <input type="checkbox"/> Glucagon | Peak value: _____ mcg/L |
| <input type="checkbox"/> Insulin | Peak value: _____ mcg/L |
| <input type="checkbox"/> Levodopa | Peak value: _____ mcg/L |
| <input type="checkbox"/> Growth hormone releasing hormone | Peak value: _____ mcg/L |

For patients 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)**

- | | | |
|---|----------------------------------|------------------------|
| <input type="checkbox"/> Insulin-like growth factor 1 (IGF-1/Somatomedin-C) | IGF-1/Somatomedin-C level: _____ | Reference range: _____ |
| <input type="checkbox"/> Insulin growth factor binding protein-3 (IGFBP-3) | IGFBP-3 level: _____ | Reference range: _____ |

Will pediatric growth hormone dosing be utilized as defined by the prescribing information? 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: _____

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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:

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

Does the patient have panhypopituitarism? Yes No

Will the requested medication be used in combination with aromatase inhibitors (e.g., Arimidex [anastrozole], Femara [letrozole])? Yes No

Will the requested medication be used in combination with androgens (e.g., Delatestryl [testosterone enanthate], Depo-Testosterone [testosterone cypionate])? Yes No

Will adult GH dosing be utilized as defined by the prescribing information? Yes No

Reauthorization:

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

Does the patient have panhypopituitarism? Yes No

Will the requested medication be used in combination with aromatase inhibitors (e.g., Arimidex [anastrozole], Femara [letrozole])? Yes No

Will the requested medication be used in combination with androgens (e.g., Delatestryl [testosterone enanthate], Depo -Testosterone [testosterone cypionate])? Yes No

Will adult GH dosing be utilized as defined by the prescribing information? Yes No

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For growth hormone (GH) deficiency in transition phase adolescents, also answer the following:

Will adult GH dosing be utilized as defined by the prescribing information (additional information may be found in the AACE 2 009 treatment guideline)? Yes No

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

Will adult GH dosing be utilized as defined by the prescribing information (additional information may be found in the AACE 2009 treatment guideline)? 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

Will the requested medication be used in combination with aromatase inhibitors (e.g., Arimidex [anastrozole], Femara [letrozole])? Yes No

Will the requested medication be used in combination with androgens (e.g., Delatestryl [testosterone enanthate], Depo-Testosterone [testosterone cypionate])? Yes No

Reauthorization:

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

Will the requested medication be used in combination with aromatase inhibitors (e.g., Arimidex [anastrozole], Femara [letrozole])? Yes No

Will the requested medication be used in combination with androgens (e.g., Delatestryl [testosterone enanthate], Depo-Testosterone [testosterone cypionate])? Yes No

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

Is the patient's bone age < 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: _____

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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 the patient's bone age < 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 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 \leq 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:

Previous height: _____ Date obtained: _____

Current height: _____ Date obtained: _____

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 the patient's bone age < 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:

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: _____

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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.
Please fax this form to 1-844-712-8129 to initiate a prior authorization review for the member and medication above.
Please note: plan benefits may limit or exclude coverage of specific medications including those requested on this form.

I certify, to the best of my knowledge, the statements and information provided on this form are factual and correct.

Provider/Representative (and Title): _____ Date: _____

PROACT INTERNAL USE ONLY:					
Clinical Review Decision					
	Approved, through				
	Denied (documentation attached, if necessary)				
Tracking:					
1 st Attempt		2 nd Attempt		Letter Mailed:	