MC-Rx
Powered by ProCare Rx

**Saizen®**

**Ticket #:** _____ **Request Date:** _____ **Request Time:** _____

# Saizen® Prior Authorization Request Form (Page 1 of 5)

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| **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: |
|---|---|---|
| ❑ Check if requesting **brand** | Directions for Use: | |
| ❑ 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:**

Is Saizen prescribed by or in consultation with an endocrinologist? ❑ **Yes** ❑ **No**

For patients with chronic renal insufficiency, is Saizen prescribed by or in consultation with a nephrologist? ❑ **Yes** ❑ **No**

Select if the patient has had a trial and failure or intolerance to the following:

- ❑ Norditropin
- ❑ Nutropin AQ/Nutropin AQ Nuspin
- ❑ Omnitrope

**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**

Is the patient's height > 2.0 standard deviations [SD] below mid-parental height? ❑ **Yes** ❑ **No**

**<Continued on next page>**

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**<Continuation of pediatric growth hormone deficiency>**

Is the patient's height > 2.25 SD below population mean (below the 1.2 percentile for age and gender)? ❑ **Yes** ❑ **No**

Is the patient's growth velocity > 2 SD below mean for age and gender? ❑ **Yes** ❑ **No**

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 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)***

- ❑ 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 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/Somatomedin-C) IGF-1/Somatomedin-C level: _____ Reference range: _____
- ❑ 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: _____

**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/m$^2$ ; ≤ **8 mcg/L** if BMI is ≥ 25 and < 30 kg/m$^2$; ≤ **4 mcg/L** if BMI is ≥ 30 kg/m$^2$
- ❑ 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)
- ❑ Follicle-stimulating hormone/luteinizing hormone (FSH/LH)
- ❑ Prolactin
- ❑ Thyroid stimulating hormone (TSH)

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**

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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**

**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 2009 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
- ❑ Genetic mutations
- ❑ Irreversible structural hypothalamic-pituitary disease
- ❑ 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/m$^2$ ; ≤ **8 mcg/L** if BMI is ≥ 25 and < 30 kg/m$^2$; ≤ **4 mcg/L** if BMI is ≥ 30 kg/m$^2$
- ❑ 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 ≤ 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: _____

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

_____

_____

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| **Authorized Medical Signature:** | |
|---|---|
| **Telephone:** | **Date:** |

**When Completed Return To:**

MC-Rx Clinical Division, 1267 Professional Parkway, Gainesville, GA 30507
1-866-965-Drug (3784) / Fax # 866-999-7736

***Please note: This request may be denied unless all required information is received.***