

Pharmacy Prior Authorization Form

Fax completed form to: 877.974.4411 toll free, or 616.942.8206

This form applies to: Commercial (Traditional) Commercial (Individual/Optimized)

Medicaid

This request is: Urgent (life threatening) Non-Urgent (standard review)

Urgent means the standard review time may seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function.

Human Growth Hormone

Member

Last Name: _____ First Name: _____

ID #: _____ DOB: _____ Gender: _____

Primary Care Physician: _____

Requesting Provider: _____ Prov. Phone: _____ Prov. Fax: _____

Provider Address: _____

Provider NPI: _____ Contact Name: _____

Provider Signature: _____ Date: _____

Product Information

New request Continuation request

Drug product: Norditropin FlexPro*
 Genotropin cartridge
 Genotropin MiniQuick

Drug strength requested: _____

Start date (or date of next dose): _____

Date of last dose (if applicable): _____

Dosing frequency: _____

ICD code(s): _____

Non-covered services

The following conditions are not covered:

- For patients <18 years old: constitutional growth delay, idiopathic short stature, familial short stature, and those with acute or chronic catabolic illness.
- For patients ≥ 18 years old: treated during childhood without documented evidence of persistent growth hormone deficiency; physiologic reductions in growth hormone related to aging; and treatment of Turner's syndrome or cystinosis.

Note: Authorization for indications, dosing, or a route of administration not approved by the Food and Drug Administration (FDA) or recognized in CMS-accepted compendia (e.g. DrugDex, AHFS, U.S. Pharmacopeia, and also Clinical Pharmacology for oncology indications only) require supporting evidence for coverage. Please provide two published peer-reviewed literature articles supporting the appropriateness of the drug, the dosing of the drug, or the route of administration to be used for the identified indication.

Precertification Requirements – Patients < 18 years old

Before this drug is covered, the patient must meet all of the following requirements:

- Must be prescribed by a specialist in the condition being treated (e.g., pediatric endocrinologist, pediatric nephrologist)
- Must meet one of the following diagnoses and the applicable criteria for each diagnosis:

1. Growth hormone deficiency

- Must meet one of the following:
 1. Height is at least 2.5 SD below the mean for chronological age and sex, **or**
 2. Height is between 2.0 and 2.5 SDs below the mean for chronological age and sex with decreased growth rate measured as growth velocity over one year below 25th percentile, **or**
 3. Using for neonatal hypoglycemia associated with growth hormone deficiency
- Growth plates must be open
- Must meet one of the following:
 1. Documented GH deficiency via 2 growth hormone (GH) stimulation tests below 10 ng/mL; **or**
 2. GH stimulation test level below 15 ng/mL, and IGF-1 and IGF-PB3 levels below normal for bone age and gender; **or**
 3. One GH stimulation test below 10 ng/mL for children with defined CNS pathology (ex. pituitary surgery, radiation therapy, precocious puberty), **or**
 4. If using for neonatal hypoglycemia associated with GHD, one random GH level < 20 ng/mL

2. Turner's syndrome

- Growth plates must be open
- Diagnosis must be confirmed by genetic testing

3. Pre-transplant chronic renal insufficiency

- Must meet one of the following:
 1. Height is at least 2.5 SD below the mean for chronological age and sex, **or**
 2. Height is between 2.0 and 2.5 SDs below the mean for chronological age and sex with decreased growth rate measured as growth velocity over one year below 25th percentile
- Growth plates must be open
- Patient is receiving weekly dialysis or creatinine clearance is less than 75 ml/min
- No evidence of active malignancy

4. Prader-Willi Syndrome

- Growth plates must be open
- Diagnosis must be confirmed by genetic testing

5. Noonan Syndrome

- Growth plates must be open
- Diagnosis must be confirmed by genetic testing

6. Small for Gestational Age (SGA)

- Child born small for gestational age, defined as birth weight or length < 10th percentile of birth weight for gestational age
- Child fails to manifest catch up growth by age of 2 years, defined as height 2 or more SDs below the mean for age and sex
- Growth plates must be open

For a 12-month continuation, patient must have met the following requirements:

1. During first 12 months of therapy: 7.0 cm/year or more
2. If more than 12 months of therapy: 6 cm/year or more

3. Bone age for females more than 13 years: 2.5 cm/year or more; males more than 15 years: 2.5 cm/year or more
4. If not on maximum recommended dose
5. Duration of therapy is limited to (whichever comes first):
 - Growth velocity is less than 2.5 cm/year
 - Bone age in males reaches 16
 - Bone age in females reaches 14

Precertification Requirements – Patients \geq 18 years old

Before this drug is covered, the patient must meet all of the following requirements:

- Must meet one of the following diagnoses and the applicable criteria for each diagnosis:

1. Growth hormone deficiency (GHD)

- GHD documented by one of the following:
 - i. suboptimal response (less than 3 mcg/L) to a hypoglycemic challenge (if contraindicated, another acceptable method is allowed); OR
 - ii. at least 2 other pituitary-related hormone deficiencies AND an abnormally low IGF
- Patient has one of the following:
 - i. hypothalamic pituitary disease resulting from tumor or infarct
 - ii. history of cranial irradiation during childhood or adulthood resulting in GH deficiency
 - iii. Pituitary surgery resulting in GH deficiency
 - iv. Continuing treatment of childhood onset GH deficiency
 - v. History of head trauma or subarachnoid hemorrhage

2. Short bowel syndrome

- Must be receiving total parenteral nutrition (TPN)
- Must be participating in a program that manages dietary intake and hydration

For a 12-month continuation for GHD, patient must meet one of the following requirements:

- Low IGF-1 (within the past 12 months), but dose is being increased; OR
- IGF-1 (within the past 12 months) within appropriate range for age and sex

**PEDIATRICS New Request
Priority Health Precertification Documentation**

1. Does the patient have any of the following conditions?

- Constitutional growth delay
- Acute or chronic catabolic illness
- Idiopathic short stature
- Familial short stature
- None of the above

COMPLETE THE FOLLOWING INFORMATION BASED ON THE PATIENT'S CONDITION:

<input type="checkbox"/> Growth hormone deficiency	1. Child's height is 2.5 SD below the mean for chronological age and sex	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	2. Child's height is between 2.0 and 2.5 SD below the mean for chronological age and sex WITH decreased growth velocity (measured over one year) below the 25 th percentile for age and sex	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	3. Child has neonatal hypoglycemia associated with GHD	<input type="checkbox"/> Yes	<input type="checkbox"/> No
		<input type="checkbox"/> Yes	<input type="checkbox"/> No

	<p>4. Are the patient's growth plates open?</p> <p>5. Which, if any, is the patient's growth hormone deficiency related to?</p> <p><input type="checkbox"/> pituitary surgery</p> <p><input type="checkbox"/> radiation therapy</p> <p><input type="checkbox"/> precocious puberty</p> <p><input type="checkbox"/> other pituitary or sellar pathology – specify: _____</p> <p>6. Submit one of the following:</p> <p><input type="checkbox"/> Two growth hormone stimulation test results below 10 ng/mL, or</p> <p><input type="checkbox"/> Growth hormone stimulation test less than 15 ng/mL, and IGF-1 and IGF-PB3 test results showing below normal for patient's bone age and gender, or</p> <p><input type="checkbox"/> If structural cause is present (under #5), one growth hormone stimulation test result below 10 ng/mL</p> <p><input type="checkbox"/> If using for neonatal hypoglycemia associated with GHD, one random GH level < 20 ng/mL</p>
<input type="checkbox"/> Turner's syndrome	<p>1. Are the patient's growth plates open? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>2. Is the diagnosis of Turner's syndrome confirmed by genetic testing? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<input type="checkbox"/> Pre-transplant chronic renal insufficiency	<p>1. Child's height is 2.5 SD below the mean for chronological age and sex <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>2. Child's height is between 2.0 and 2.5 SD below the mean for chronological age and sex WITH decreased growth velocity (measured over one year) below 25th percentile for age and sex <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>3. Are the child's growth plates open? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>4. Is the patient receiving weekly dialysis or is the patient's CrCl < 75 mL/min? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>5. Is there evidence of active malignancy? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<input type="checkbox"/> Prader-Willi syndrome	<p>1. Are the patient's growth plates open? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>2. Is the diagnosis confirmed by appropriate genetic testing? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<input type="checkbox"/> Noonan Syndrome	<p>1. Are the patient's growth plates open? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>2. Is the diagnosis of Noonan Syndrome confirmed by genetic testing? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<input type="checkbox"/> Small for Gestational Age (SGA)	<p>1. Child's birth weight or length is less than the 10th percentile of birth weight for gestational age <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>2. Are the patient's growth plates open? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>3. Child fails to manifest catch up growth by age 2 years, defined as height 2 or more SDs below the mean for age and sex <input type="checkbox"/> Yes <input type="checkbox"/> No</p>

PEDIATRICS continuation request
Priority Health Precertification Documentation

1. How long has the patient used human growth hormone? _____ years, _____ months
2. What is the patient's bone age? _____
3. What is the patient's current growth velocity? _____ cm/year

ADULTS (age 18 or older) new request
Priority Health Precertification Documentation

A. Does the patient have any of the following conditions or contraindications?

- Treatment during childhood without documented evidence of persistent GH deficiency
- Physiologic reductions in GH related to aging
- Treatment of Turner's syndrome or cystinosis
- None of the above

B. What condition is this drug being requested for?

- Growth Hormone Deficiency (GHD)
- Short bowel syndrome (SBS)
- Other – the patient's condition is: _____

Rationale for use: _____

For Growth Hormone Deficiency

C. The patient's GHD is defined by which of the following?

- Suboptimal response (< than 3 mcg/L) to a hypoglycemic challenge
- At least 2 other pituitary-related hormone deficiencies and an abnormally low IGF
- Suboptimal response to another acceptable method (if hypoglycemic challenge contraindicated)

Please define method: _____

D. At least one of the following applies (please check all that apply):

- Hypothalamic pituitary disease resulting from tumor or infarct
- History of cranial irradiation during childhood or adulthood resulting in GH deficiency
- Pituitary surgery resulting in GH deficiency
- Continuing treatment of childhood onset GH deficiency
- History of head trauma or subarachnoid hemorrhage
- None; **Rationale for use:** _____

For Short Bowel Syndrome

E. Is the patient receiving total parenteral nutrition (TPN)?

- Yes.
- No. **Rationale for use:** _____

F. Is the patient participating in a program that manages dietary intake and hydration?

- Yes.
- No. **Rationale for use:** _____

ADULTS continuation request

Patient's Serum IGF-1: _____ Date: _____