PriorityHealth

# 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.



**All fields must be complete and legible for review. Your office will receive a response via fax.** No changes made since 01/2019
Last reviewed 01/2021

## 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 25$^{th}$ 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 25$^{th}$ 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


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**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

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## Precertification Requirements – Patients ≥ 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

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## 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


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

| | | | |
|---|---|---|---|
| ☐ **Growth hormone deficiency** | 1. Child's height is 2.5 SD below the mean for chronological age and sex | ☐ Yes | ☐ 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 25th percentile for age and sex | ☐ Yes | ☐ No |
| | 3. Child has neonatal hypoglycemia associated with GHD | ☐ Yes | ☐ No |
| | 4. Are the patient's growth plates open? | ☐ Yes | ☐ No |
| | 5. Which, if any, is the patient's growth hormone deficiency related to?<br>☐ pituitary surgery<br>☐ radiation therapy<br>☐ precocious puberty<br>☐ other pituitary or sellar pathology – specify:<br>_____ | | |
| | 6. Submit one of the following:<br>☐ Two growth hormone stimulation test results below 10 ng/mL, or<br>☐ 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<br>☐ If structural cause is present (under #5), one growth hormone stimulation test result below 10 ng/mL<br>☐ If using for neonatal hypoglycemia associated with GHD, one random GH level < 20 ng/mL | | |
| ☐ **Turner's syndrome** | 1. Are the patient's growth plates open? | ☐ Yes | ☐ No |
| | 2. Is the diagnosis of Turner's syndrome confirmed by genetic testing? | ☐ Yes | ☐ No |
| ☐ **Pre-transplant chronic renal insufficiency** | 1. Child's height is 2.5 SD below the mean for chronological age and sex | ☐ Yes | ☐ 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 25th percentile for age and sex | ☐ Yes | ☐ No |
| | 3. Are the child's growth plates open? | ☐ Yes | ☐ No |
| | 4. Is the patient receiving weekly dialysis or is the patient's CrCl < 75 mL/min? | ☐ Yes | ☐ No |
| | 5. Is there evidence of active malignancy? | ☐ Yes | ☐ No |
| ☐ **Prader-Willi syndrome** | 1. Are the patient's growth plates open? | ☐ Yes | ☐ No |
| | 2. Is the diagnosis confirmed by appropriate genetic testing? | ☐ Yes | ☐ No |
| ☐ **Noonan Syndrome** | 1. Are the patient's growth plates open? | ☐ Yes | ☐ No |
| | 2. Is the diagnosis of Noonan Syndrome confirmed by genetic testing? | ☐ Yes | ☐ No |
| ☐ **Small for Gestational Age (SGA)** | 1. Child's birth weight or length is less than the 10th percentile of birth weight for gestational age | ☐ Yes | ☐ No |
| | 2. Are the patient's growth plates open? | ☐ Yes | ☐ No |
| | 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 | ☐ Yes | ☐ No |

## 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



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Last reviewed 01/2021

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**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 <u>one</u> 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: _____**


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