

# 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\*

**Drug strength requested:** \_\_\_\_\_

**Start date** (or date of next dose): \_\_\_\_\_

**Date of last dose** (if applicable): \_\_\_\_\_

**Dosing frequency:** \_\_\_\_\_

**ICD code(s):** \_\_\_\_\_

\*Norditropin FlexPro is the only covered product on the Michigan Medicaid Health Plan Common Formulary. Human growth hormone products currently available in the United States are exclusively produced from recombinant technology in the form of somatotropin. Although recombinant human growth hormone (rhGH) products are produced by different manufacturers, the molecular structure is the same for each brand name for somatotropin; hence, there are no expected differences in efficacy between products.

### Non-covered services

The following conditions are not covered:

- For children (age 17 or younger): constitutional growth delay; idiopathic short stature; familial short stature; growth promotion in patients with epiphyseal closure; or patients with acute or chronic catabolic illness.
- For adults (age 18 years or older): treated during childhood without documented evidence of persistent growth hormone deficiency; physiologic reductions in growth hormone related to aging; patients with acute or chronic catabolic illness; treatment of Turner's syndrome; or cystinosis.

## HUMAN GROWTH HORMONE (hGH) COVERAGE POLICY

Before Human Growth Hormone (hGH) is covered, the patient must meet all of the General Criteria for hGH and all of the Specific Criteria for the treatment diagnosis.

**INITIAL CRITERIA FOR CHILDREN ( $\leq 17$  years of age) for a 12-month authorization:**

**General Initiation Criteria for ALL Diagnoses:**

- Must be prescribed by a specialist in the condition being treated (e.g., pediatric endocrinologist, nephrologist)
- Other factors contributing to growth failure have been ruled out, or are being treated (e.g., inadequate caloric intake/malnutrition/eating disorder, untreated hypothyroidism)
- Recent height (within the last 3 months) is more than 2 SDS below the mean ( $< 3^{\text{rd}}$  percentile) for age and sex
- Recent weight (within the last 3 months) has been provided
- Pretreatment growth velocity is below the normal for age and sex

**Specific Initiation Criteria for Individual Diagnoses:**

**1. Growth hormone deficiency (GHD)**

- Growth plates must be open
- Documented GHD via 2 growth hormone stimulation tests with peak levels  $< 10$  mcg/L when the cause of GHD is unknown OR via 1 growth hormone stimulation test result  $< 10$  mcg/L when the cause of GHD is known:
  - Structural or developmental abnormalities: e.g. anencephaly, pituitary aplasia
  - Genetic disorders: e.g., PROP1 and PIT1 mutations, septo-optic dysplasia
  - Acquired causes: e.g., craniopharyngeomas, cranial irradiation, brain surgery, head trauma, CNS infections

**2. Turner's syndrome**

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

**3. Pre-transplant chronic renal insufficiency**

- Growth plates must be open
- Existing metabolic abnormalities (e.g., malnutrition, acidosis, secondary hyperparathyroidism and hyperphosphatemia) have been corrected

**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. SHOX deficiency**

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

**7. Small for Gestational Age (SGA)**

- Must be at least 2 years old and fail to manifest catch up growth by age 2
- Growth plates must be open
- Birth weight or length  $< 3^{\text{rd}}$  percentile for gestational age OR birth weight  $< 2500$  grams at a gestational age of  $> 37$  weeks

**Continuation criteria for children ( $< 17$  years of age) for a 12-month authorization:**

- Documentation to support final height has not been achieved
- No evidence of epiphyseal closure
- Growth velocity is  $> 5$  cm/year on current dose or  $< 5$  cm/year with intended dose increase
- For chronic renal insufficiency: there is insufficient evidence regarding benefit of treatment beyond 3 years

**INITIAL CRITERIA FOR ADULTS ( $\geq 18$  years or age) for a 12-month authorization (exceptions noted)**

**General Initiation Criteria for ALL Diagnoses:**

- Must be prescribed by a specialist in the condition being treated (e.g., pediatric endocrinologist, nephrologist)

**Specific Initiation Criteria for Individual Diagnoses:**

**1. Childhood-onset GHD**

- Documented GHD by:
  - Suboptimal response (less than 3 mcg/L) to a hypoglycemic challenge (unless contraindicated, then can use other accepted method); **OR**
  - GHD due to a known cause (structural lesions, genetic disorders, acquired causes)
- Baseline serum IGF-1 required

**2. Adult-Onset GHD**

- Baseline serum IGF-1 required
- Documented GHD by:
  - Suboptimal response (less than 3 mcg/L) to a hypoglycemic challenge (unless contraindicated, then can use other accepted method); **OR**
  - At least 2 other pituitary-related hormone deficiencies and an abnormally low IGF
- Documentation of one of the following:
  - 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
  - History of head trauma or subarachnoid hemorrhage

**3. HIV wasting/cachexia (initial authorization for 3 months)**

- Documented height, weight, and ideal body weight (IBW)
- Progressive weight loss below IBW over the last year not explained by a concurrent illness other than HIV infection
- Documented adequate caloric intake
- Failure of megestrol AND dronabinol
- Currently on antiretroviral therapy

**4. Short Bowel Syndrome (authorization for one 4-week course only)**

- Currently receiving specialized nutrition (e.g., TPN, PPN)

**5. Excess abdominal fat in HIV-infected patients with lipodystrophy (initial authorization for 3 months)**

- 18 – 65 years of age
- Men: waist circumference  $\geq 95$  cm (37.4”) and waist-to-hip ratio  $\geq 0.94$
- Women:  $\geq 94$  cm (37.0”) and waist-to-hip ratio  $\geq 0.88$
- Currently on antiretroviral therapy
- Patient is at risk for medical complications due to excess abdominal fat

**Continuation criteria for adults ( $> 18$  years of age) for 12 month authorization:**

**1. GHD (childhood- and adult-onset)**

- Low IGF-1, but dose is being increased OR IGF-1 is at a stable range

**2. HIV wasting/cachexia**

- Documentation to support response to therapy

**3. Excess abdominal fat in HIV-infected patients with lipodystrophy**

- Documentation to support response to therapy
- Decrease in baseline waist circumference
- Documentation that IGF-1 and A1C are being monitored

**CHILDREN**

**New request**

**Priority Health Precertification Documentation**

1. Is the provider a specialist in the condition being treated?  
 Yes       No. *Please list specialty:* \_\_\_\_\_
2. Have other factors contributing to growth failure been ruled out, or are being treated?  
 Yes       No. *Rationale for use:* \_\_\_\_\_
3. Is the patient's most recent height more than 2 SDS below the mean (<3<sup>rd</sup> percentile) for age and sex?  
 Yes.       No      Height: \_\_\_\_\_ Percentile: \_\_\_\_\_ Date: \_\_\_\_\_
4. What is the patient's most recent weight? Weight: \_\_\_\_\_ Date: \_\_\_\_\_
5. Is the patient's pretreatment growth velocity below the normal for age and sex?  
 Yes.       No      Growth velocity: \_\_\_\_\_ Date: \_\_\_\_\_

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

<input type="checkbox"/> <b>Growth hormone deficiency</b>  <i>(Documentation required)</i>	1. Are the patient's growth plates open? <input type="checkbox"/> Yes <input type="checkbox"/> No 2. Does patient have GHD with a known cause? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Structural or developmental abnormalities: _____ <input type="checkbox"/> Genetic disorder: _____ <input type="checkbox"/> Acquired cause: _____ 3. Has GHD been documented by 1 or 2 growth hormone stimulation test(s)? <input type="checkbox"/> Yes <input type="checkbox"/> No GH stimulation test result: _____ Date: _____ GH stimulation test result: _____ Date: _____
<input type="checkbox"/> <b>Turner's syndrome, Prader-Willi syndrome, Noonan Syndrome, SHOX deficiency</b>	1. Are the patient's growth plates open? <input type="checkbox"/> Yes <input type="checkbox"/> No 2. Has the diagnosis been confirmed by genetic testing? <input type="checkbox"/> Yes <input type="checkbox"/> No
<input type="checkbox"/> <b>Pre-transplant chronic renal insufficiency</b>	1. Are the patient's growth plates open? <input type="checkbox"/> Yes <input type="checkbox"/> No 2. Have any existing metabolic abnormalities been corrected? <input type="checkbox"/> Yes <input type="checkbox"/> No
<input type="checkbox"/> <b>Small for Gestational Age (SGA)</b>	1. Was the patient's birth weight or length < 3 <sup>rd</sup> percentile for age? <input type="checkbox"/> Yes <input type="checkbox"/> No 2. Was the patient born at > 37 weeks with birth weight < 2500 grams? <input type="checkbox"/> Yes <input type="checkbox"/> No 3. Did the child fail to manifest catch up growth by age 2 years? <input type="checkbox"/> Yes <input type="checkbox"/> No 4. Are the patient's growth plates open? <input type="checkbox"/> Yes <input type="checkbox"/> No

**CHILDREN-continuation request**

**Priority Health Precertification Documentation**

1. Has the patient's final height been reached?  Yes       No
2. Are the patient's growth plates open?       Yes       No
3. How long has the patient used human growth hormone? \_\_\_\_\_ years, \_\_\_\_\_ months
4. What is the patient's current growth velocity? \_\_\_\_\_ cm/year

**ADULTS**

**New request**

**Priority Health Precertification Documentation**

**Childhood-onset GHD**

1. Which of the following apply to the patient?

Patient had a suboptimal response (less than 3 mcg/L) to a hypoglycemic challenge  
If hypoglycemic challenge is contraindicated, describe other method: \_\_\_\_\_

GHD is due to a known cause. *Please list the cause:* \_\_\_\_\_

2. Baseline serum IGF-1: \_\_\_\_\_

**Adult-onset GHD**

1. Which of the following apply to the patient?

Patient had a suboptimal response (less than 3 mcg/L) to a hypoglycemic challenge  
If hypoglycemic challenge is contraindicated, describe other method: \_\_\_\_\_

At least 2 other pituitary-related hormone deficiencies

2. Baseline serum IGF-1: \_\_\_\_\_

3. 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
- History of head trauma or subarachnoid hemorrhage
- None, rationale for use: \_\_\_\_\_

**HIV wasting/cachexia**

1. List height, weight, and ideal body weight (IBW):

Height: \_\_\_\_\_ Weight: \_\_\_\_\_ IBW: \_\_\_\_\_

2. Has the patient experienced progressive weight loss in the past year not explained by another illness?

Yes  No

3. Has the patient had adequate calorie intake?

Yes  No

4. Has the patient tried and failed megestrol?

Yes. Dose: \_\_\_\_\_ Date: \_\_\_\_\_  
 No

5. Has the patient tried and failed dronabinol?

Yes. Dose: \_\_\_\_\_ Date: \_\_\_\_\_  
 No

6. Is the patient currently taking antiretroviral therapy?

Yes  No

**Short Bowel Syndrome**

1. Is the patient currently received specialized nutrition?

Yes  No

**Excessive abdominal fat in HIV-infected patients with lipdystrophy**

1. Patient's waist circumference: \_\_\_\_\_

2. Patient's waist-to-hip ratio: \_\_\_\_\_

3. Is the patient currently on antiretroviral therapy?

Yes  No

4. Is the patient at risk of medical complications due to the excessive abdominal fat?

Yes  No