Gateway Health
It's Wholecare.

Gateway Health Plan
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

I. Requirements for Prior Authorization of Growth Hormones

A. Prescriptions That Require Prior Authorization

All prescriptions for Growth Hormones must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Growth Hormone, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Growth Hormone for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**
2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. Is prescribed the Growth Hormone by an appropriate specialist (e.g., neonatologist [in the neonatal period], endocrinologist, gastroenterologist, or nephrologist); **AND**
5. Does not have a contraindication to the prescribed medication; **AND**
6. For a non-preferred Growth Hormone, has a history of therapeutic failure of the preferred Growth Hormones approved or medically accepted for the beneficiary's diagnosis. See the Preferred Drug List (PDL) for the list of preferred Growth Hormones at: https://papdl.com/preferred-drug-list; **AND**
7. For a neonate beneficiary, has a diagnosis of growth hormone deficiency confirmed according to the current consensus guidelines (e.g., Pediatric Endocrine Society); **AND**
8. For a pediatric beneficiary, **all** of the following:
    a. For a beneficiary in Tanner stage ≥ 3, a female beneficiary 12 years of age or older, or a male beneficiary 14 years of age or older, has epiphyses that are confirmed as open,
    b. For a diagnosis other than Turner syndrome, Prader Willi syndrome, or short for gestational age (SGA), had appropriate imaging (MRI or CT) of the brain with particular attention to the hypothalamic and pituitary regions to exclude the possibility of a tumor,
    c. Has growth failure that is not due to idiopathic short stature, familial short stature, or constitutional growth delay,
    d. Had other causes of short stature excluded,
    e. **One** of the following:
        i. For a diagnosis of growth hormone deficiency**,** has a diagnosis of growth hormone deficiency confirmed according to the current consensus guidelines (e.g., Pediatric Endocrine Society),
        ii. For a diagnosis of insulin-like growth factor-1 (IGF-1) deficiency, **all** of the following:

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a) Has a height > 2.25 standard deviations (SD) below the mean for age or > 2 SD below the mid-parental height percentile,
b) Has a growth velocity < 25th percentile for bone age,
c) Had secondary causes of IGF-1 deficiency excluded (i.e., under-nutrition and hepatic disease),
d) Has a history of having passed growth hormone stimulation tests,

iii. For a diagnosis of chronic renal failure**, both** of the following:
a) Has a diagnosis of pediatric growth failure, defined as height > 2 SD below the age-related mean, due to chronic renal failure
b) Has not undergone a renal transplant,

iv. For a diagnosis of SGA**, both** of the following:
a) Was born SGA, defined as having weight or length at birth > 2 SD below the mean or weight below the 10th percentile for gestational age
b) Failed to manifest catch-up growth by 2 years of age, defined as height/length ≥ 2 SD below the mean for age and gender,

v. For a diagnosis of Turner syndrome, Noonan syndrome, or short stature homeobox (SHOX) syndrome, has growth failure defined as height > 2 SD below the age-related mean due to a documented diagnosis of Turner syndrome, Noonan syndrome, or SHOX syndrome,

vi. For a diagnosis of Prader-Willi syndrome, has a documented diagnosis of Prader-Willi syndrome and **both** of the following:
a) Has growth failure defined as height > 2 SD below the age-related mean
b) **One** of the following:
(i) Has no symptoms of sleep apnea
(ii) Has a history of sleep apnea or symptoms consistent with sleep apnea and has been fully evaluated and treated;

AND

9. For a beneficiary 18 years of age or older or a beneficiary at any age with closed epiphyses, **all** of the following:

a. Has a documented history of adult growth hormone deficiency as a result of **one** of the following:
i. Childhood-onset growth hormone deficiency,
ii. Pituitary or hypothalamic disease,
iii. Surgery or radiation therapy,
iv. Trauma,

b. Has a diagnosis of growth hormone deficiency confirmed according to the current consensus guidelines (e.g., American Association of Clinical Endocrinologists),

c. Is currently receiving replacement therapy for any other pituitary hormone deficiencies that is consistent with current medical standards of practice,

d. For a beneficiary with traumatic brain injury or subarachnoid hemorrhage, has documentation of results of stimulation testing obtained at least 12 months after the date of injury;

AND

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10. For the treatment of AIDS-related cachexia, **both** of the following:
    a. **Both** of the following:
        i. Has a diagnosis of wasting syndrome defined by **one** of the following:
            a) A body mass index (BMI) ≤ 18.5
            b) **Both** of the following:
                (i) A BMI ≤ 25
                (ii) An unintentional or unexplained weight loss defined by **one** of the following:
                    a. Weight loss of ≥ 10% from baseline premorbid weight
                    b. BMI < 20 in the absence of a concurrent illness or medical condition other than HIV infection that would explain these findings
        ii. Has wasting syndrome that is not attributable to other causes, such as depression, *Mycobacterium avium* complex infection, chronic infectious diarrhea, or malignancy (exception: Kaposi's sarcoma limited to the skin or mucous membranes)
    b. Despite a comprehensive AIDS treatment program that includes antiretrovirals, has a history of inadequate response or intolerance to **both** of the following:
        i. Nutritional supplements that increase caloric and protein intake
        ii. Steroid hormones such as megestrol;

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR GROWTH HORMONES: The determination of medical necessity of a request for renewal of a prior authorization for a Growth Hormone that was previously approved will take into account whether the beneficiary:

1. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
2. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed the Growth Hormone by an appropriate specialist (e.g., neonatologist [in the neonatal period], endocrinologist, gastroenterologist, or nephrologist); **AND**
4. Does not have a contraindication to the prescribed medication; **AND**
5. For a non-preferred Growth Hormone, has a history of therapeutic failure of the preferred Growth Hormones approved or medically accepted for the beneficiary's diagnosis. See the Preferred Drug List (PDL) for the list of preferred Growth Hormones at: https://papdl.com/preferred-drug-list; **AND**
6. For a pediatric beneficiary, **all** of the following:
    a. For a beneficiary in Tanner stage ≥ 3, a female beneficiary 12 years of age or older, or a male beneficiary 14 years of age or older, has epiphyses that are confirmed as open within the previous 6 months,
    b. Demonstrates a growth response ≥ 4 cm per year,
    c. Has not reached expected final adult height (defined as mid-parental height),

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d. For a diagnosis of Prader-Willi syndrome, demonstrates improvement in **one** of the following since starting the requested medication:
   i. Lean-to-fat body mass
   ii. Growth velocity;

AND

7. For a beneficiary 18 years of age or older or a beneficiary at any age with closed epiphyses, experienced clinical benefit since starting the requested medication as evidenced by **one** of the following:
   a. Increase in total lean body mass,
   b. Increase in exercise capacity,
   c. Improved energy level;

   AND

8. For the treatment of AIDS-related cachexia, demonstrates **one** of the following since starting the requested medication:
   a. Weight stabilization
   b. Weight increase;

   AND

9. If the request is for a dose increase, demonstrates compliance with the requested medication.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Growth Hormone. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Requests for prior authorization of Growth Hormones will be approved as follows:

1. For the treatment of AIDS-related cachexia:
   a. Initial requests for prior authorization of a Growth Hormone will be approved for up to 6 months.
   b. Renewals of requests for prior authorization of a Growth Hormone will be approved for up to a total of 48 weeks of therapy.
2. For the treatment of short bowel syndrome, approval of requests will be limited to 4 weeks consistent with the FDA-approved package labeling.
3. For all other indications:
   a. Initial requests for prior authorization of a Growth Hormone will be approved for up to 6 months.
   b. Renewal of requests for prior authorization of a Growth Hormone will be approved for up to 12 months.

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GROWTH HORMONES PRIOR AUTHORIZATION FORM *(form effective 01/03/2022)*

☐New request ☐Renewal request	# of pages: _____	Prescriber name:	
Name of office contact:		Specialty:	
Contact's phone number:		NPI:	State license #:
LTC facility contact/phone:		Street address:	
Beneficiary name:		Suite #:	City/state/zip:
Beneficiary ID#:	DOB:	Phone:	Fax:

CLINICAL INFORMATION

Drug requested:	Strength:	Beneficiary's weight:	
Directions:		Quantity:	Refills:
Diagnosis *(submit documentation)*:		Dx code (*required*):	
For a non-preferred Growth Hormone: Does the beneficiary have a history of trial and failure of or contraindication or intolerance to the preferred drugs in this class that are approved or medically accepted for treatment of the beneficiary's condition? *Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in this class.*		☐Yes ☐No *Submit documentation.*	

INITIAL requests

Complete the sections below that are applicable to the beneficiary and this request and SUBMIT DOCUMENTATION for each item.

☐Beneficiary is a NEONATE:
- ☐Has a diagnosis of growth hormone deficiency confirmed according to current consensus guidelines (eg, Pediatric Endocrine Society)

☐Beneficiary is LESS THAN 18 YEARS OF AGE with OPEN EPIPHYSES:
- ☐**For a beneficiary in Tanner stage ≥3, a female beneficiary 12 years of age or older, or a male bene**ficiary 14 years of age or older:
  - ☐Has epiphyses that are confirmed as open within the previous 6 months
- ☐Had appropriate imaging (MRI or CT) of the brain with particular attention to the hypothalamic and pituitary regions to exclude the possibility of a tumor (not applicable for the following diagnoses: Turner syndrome, Prader-Willi syndrome, or short for gestational age)
- ☐Has growth failure that is not due to idiopathic short stature, familial short stature, or constitutional growth delay
- ☐Had other causes of short stature excluded
- ☐Has a diagnosis of GROWTH HORMONE DEFICIENCY:
  - ☐Diagnosis is confirmed according to current consensus guidelines (eg, Pediatric Endocrine Society)
- ☐Has a diagnosis of INSULIN-LIKE GROWTH FACTOR-1 (IGF-1) DEFICIENCY:
  - ☐Has a height >2.25 standard deviations below the mean for age
  - ☐Has a height >2 standard deviations below the mid-parental height percentile
  - ☐Has a growth velocity below the 25th percentile for bone age
  - ☐Had secondary causes of IGT-1 deficiency excluded (ie, undernutrition and hepatic disease)
  - ☐Has a history of having passed growth hormone stimulation tests
- ☐Has a diagnosis of CHRONIC RENAL FAILURE:
  - ☐Has a diagnosis of pediatric growth failure defined as height >2 standard deviations below the age-related mean due to chronic renal failure
  - ☐Has not undergone a kidney transplant
- ☐Has a diagnosis of SHORT FOR GESTATIONAL AGE (SGA):
  - ☐Was born SGA defined as having weight or length at birth >2 standard deviations below the mean
  - ☐Was born SGA defined as having weight below the 10th percentile for gestational age
  - ☐Failed to manifest catch-up growth by 2 years of age defined as height/length ≥2 standard deviations below the mean for age and gender
- ☐Has a diagnosis of TURNER SYNDROME, NOONAN SYNDROME, OR SHORT STATURE HOMEOBOX (SHOX) SYNDROME:
  - ☐Has growth failure defined as height >2 standard deviations below the age-related mean due to a diagnosis of Turner syndrome, Noonan syndrome, or SHOX syndrome
- ☐Has a diagnosis of PRADER-WILLI SYNDROME:
  - ☐Has a documented diagnosis of Prader-Willi syndrome
  - ☐Has growth failure defined as height >2 standard deviations below the age-related mean
  - ☐Does not have symptoms of sleep apnea
  - ☐Has a history of sleep apnea or symptoms consistent with sleep apnea and has been fully evaluated and treated

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- ☐ Beneficiary is 18 YEARS OF AGE OR OLDER or has CLOSED EPIPHYSES:
  - ☐ Has a documented history of adult growth hormone deficiency as a result of:
    - ☐ Childhood-onset growth hormone deficiency
    - ☐ Pituitary or hypothalamic disease
    - ☐ Surgery or radiation therapy
    - ☐ Trauma
  - ☐ Diagnosis is confirmed according to current consensus guidelines (eg, American Association of Clinical Endocrinologists)
  - ☐ Is currently receiving replacement therapy for any other pituitary hormone deficiencies that is consistent with current medical standards of practice
  - ☐ Has a traumatic brain injury or subarachnoid hemorrhage
    - ☐ Has documentation of results of stimulation testing obtained at least 12 months after the date of injury

- ☐ For the treatment of AIDS-RELATED CACHEXIA:
  - ☐ Has a diagnosis of wasting syndrome defined by one of the following:
    - ☐ BMI ≤18.5
    - ☐ Both of the following:
      - ☐ BMI ≤25
      - ☐ Unintentional or unexplained weight loss defined by one of the following:
        - ☐ Weight loss of ≥10% from baseline premorbid weight
        - ☐ BMI <20 in the absence of a concurrent illness or medical condition (other than HIV) that would explain these findings
  - ☐ Has wasting syndrome that is not attributable to other causes such as depression, *Mycobacterium avium* complex infection, chronic infectious diarrhea, or malignancy (exception: Kaposi's sarcoma limited to the skin or mucous membranes)
  - ☐ Is receiving a comprehensive AIDS treatment that includes antiretrovirals
  - ☐ Had an inadequate response to or intolerance of nutritional supplements that increase caloric and protein intake
  - ☐ Had an inadequate response to or intolerance of steroid hormones such as megestrol

RENEWAL requests

Complete the sections below that are applicable to the beneficiary and this request and SUBMIT DOCUMENTATION for each item.

- ☐ Beneficiary is LESS THAN 18 YEARS OF AGE:
  - ☐ **For a beneficiary in Tanner stage ≥3, a female beneficiary 12 years of age or older, or a male beneficiary 14 years of age or** older:
    - ☐ Has epiphyses that are confirmed as open within the previous 6 months
  - ☐ Demonstrates a growth response ≥4 cm per year
  - ☐ Has not reached expected final adult height (defined as mid-parental height)
  - ☐ For a diagnosis of PRADER-WILLI SYNDROME:
    - ☐ Demonstrates improvement in lean-to-fat body mass since starting the requested medication
    - ☐ Demonstrates improvement in growth velocity since starting the requested medication

- ☐ Beneficiary is 18 YEARS OF AGE OR OLDER or has CLOSED EPIPHYSES:
  - ☐ Demonstrates an increase in total lean body mass since starting the requested medication
  - ☐ Demonstrates an increase in exercise capacity since starting the requested medication
  - ☐ Demonstrates an improved energy level since starting the requested medication

- ☐ For the treatment of AIDS-RELATED CACHEXIA:
  - ☐ Demonstrates weight stabilization since starting the requested medication
  - ☐ Demonstrates weight increase since starting the requested medication

- ☐ For a DOSE INCREASE:
  - ☐ Demonstrates compliance with the requested medication

PLEASE FAX COMPLETED FORM TO GATEWAY – PHARMACY DIVISION

Prescriber Signature:	Date:

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