Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 09/01/2019**
Policy Number: PHW.PDL.014	**Effective Date: 01/01/2020** **Revision Date: 10/01/2019**
Policy Name: Growth Hormones	

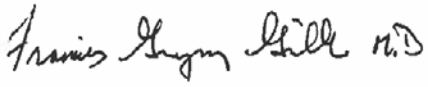
Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ✓ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

New Policy created.

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Growth Hormones

Reference Number: PHW.PDL.014
Effective Date: 01/01/2020
Last Review Date: 10/01/2019

Revision Log

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health and Wellness® that Growth Hormones is **medically necessary** when the following criteria are met:

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, or gastroenterologist); **AND**

5. Does not have a history of 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; **AND**

7. For a neonate beneficiary, both of the following:

a. Has a diagnosis of growth hormone deficiency confirmed according to the current consensus guidelines (e.g., Pediatric Endocrine Society)
b. Had appropriate imaging (magnetic resonance imaging [MRI] or computed tomography [CT]) of the brain with particular attention to the hypothalamic pituitary region to exclude the possibility of a tumor;

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. 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:
         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 **small for gestational age (SGA)**, **both** of the following:
         a. Was born SGA, defined as having a birth weight < 2500 g at a gestational age of 37 weeks and older or weight or length at birth > 2 SD below the mean for gestational age

b. Failed to manifest catch-up growth by 2 years of age, defined as height ≥ 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 **all** of the following:
   a. Is receiving treatment for Prader-Willi syndrome manifestations and comorbidities,
   b. Has growth failure defined as height > 2 SD below the age-related mean,
   c. **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

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:
         1. A body mass index (BMI) ≤ 18.5
         2. **Both** of the following:

a. A BMI ≤ 25
b. An unintentional or unexplained weight loss defined by **one** of the following:
    i. Weight loss of ≥ 10% from baseline premorbid weight
    ii. 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;

AND

11. If a prescription for a Growth Hormone is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.

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, or gastroenterologist); **AND**
4. Does not have a history of a contraindication to the prescribed medication; **AND**
5. For a **neonate beneficiary**, has an IGF-1 concentration in the normal range for age and gender; **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,
b. **One** of the following:
    i. Demonstrates a growth response ≥ 4.5 cm per year (pre-pubertal growth rate)
    ii. Demonstrates a growth response ≥ 2.5 cm per year (post-pubertal growth rate),
c. Has an IGF-1 concentration in the normal range for age and gender,
d. Has not reached expected final adult height (defined as mid-parental height),
e. 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, both** of the following:
    a. Experienced clinical benefit since starting the requested medication as evidenced by **one** of the following:
        i. Increase in total lean body mass,
        ii. Increase in exercise capacity,
        iii. Improved energy level
    b. Has a normal IGF-1;

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;

AND

10. If a prescription for a Growth Hormone is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.

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 6 months.
   b. Renewals of requests for prior authorization of a Growth Hormone will be approved for a total of 48 weeks of therapy.

2. For the treatment of **SBS**, approval of requests will be limited to 4 weeks consistent with the FDA-approved package labeling.

3. For neonates, pediatrics, and adults **all other indications:**
   a. Initial requests for prior authorization of a Growth Hormone will be approved for 6 months.
   b. Renewal of requests for prior authorization of a Growth Hormone will be approved for 12 months.

E. References

1. Grimberg A, et.al. Guidelines for Growth Hormone and Insulin-Like Growth Factor-I Treatment in Children and Adolescents: Growth Hormone Deficiency, Idiopathic Short Stature, and Primary Insulin-Like Growth Factor-I Deficiency. Hormone Research in Paediatrics. 2016;86:361–397.
2. Wilson TA, et al. Update of Guidelines for the Use of Growth Hormone in Children: The Lawson Wilkens Pediatric Endocrinology Society Drug and Therapeutics Committee, The Journal of Pediatrics; October 2003: 415-421.
3. American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for Growth Hormone Use in Adults and Children – 2003 Update, Endocrine Practice. January/February 2003; 9 (1).

4. American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for Growth Hormone Use in Growth Hormone-Deficient Adults and Transition Patients – 2009 Update, Endocrine Practice. 2009;15(Suppl 2).
5. Management of tissue wasting in patients with HIV infection – UpToDate.
6. 1993 Revised Classification System for HIV Infection and Expanded Surveillance Case Definition for AIDS Among Adolescents and Adults.
7. Abasi V. Growth and Normal Puberty, Pediatrics. 1998;102;507-511.

Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020