

ISSUE DATE December 6, 2019	EFFECTIVE DATE January 1, 2020	NUMBER *See below
SUBJECT Prior Authorization of Growth Hormones – Pharmacy Services		BY  Sally A. Kozak, Deputy Secretary Office of Medical Assistance Programs

IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: <https://www.dhs.pa.gov/providers/Providers/Pages/PROMISe-Enrollment.aspx>.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Growth Hormones submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program and providing services in the fee-for-service delivery system. Providers rendering services in the MA managed care delivery system should address any questions related to Growth Hormones to the appropriate managed care organization.

BACKGROUND:

The Department of Human Services’ (Department) Drug Utilization Review (DUR) Board meets semi-annually to review provider prescribing and dispensing practices for efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists

*01-19-109	09-19-105	27-19-104	33-19-106
02-19-103	11-19-102	30-19-101	
03-19-102	14-19-101	31-19-109	
08-19-112	24-19-104	32-19-101	

<p>COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:</p> <p>The appropriate toll-free number for your provider type</p> <p>Visit the Office of Medical Assistance Programs Web site at https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx.</p>

through the Department's Prospective Drug Use Review and Retrospective Drug Use Review programs.

DISCUSSION:

During the September 13, 2019, meeting, the DUR Board recommended that prescriptions for Growth Hormones that exceed the quantity limits established by the Department require prior authorization. The board also recommended the following revisions to the guidelines to determine medical necessity of Growth Hormones:

- Addition of guidelines that the beneficiary's diagnosis, age, and prescribed dose are consistent with FDA-approved labeling or medical literature;
- Revision of the guideline for non-preferred Growth Hormones to take into account the beneficiary's diagnosis;
- Revision of the guidelines to confirm a diagnosis of pediatric growth hormone deficiency to align with national guidelines established by the Pediatric Endocrine Society and the American Association of Clinical Endocrinologists; and
- Addition of guidelines to address the treatment of short stature homeobox syndrome and short bowel syndrome.

The revisions to the guidelines to determine medical necessity of Growth Hormones, as recommended by the DUR Board, were subject to public review and comment and subsequently approved for implementation by the Department.

PROCEDURE:

The procedures for prescribers to request prior authorization of Growth Hormones are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Growth Hormones) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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. 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, **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:

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- 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 < 25 th 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,

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- 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 co-morbidities,
 - 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:

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- a) A body mass index (BMI) \leq 18.5
- b) **Both** of the following:
 - (i) A BMI \leq 25
 - (ii) An unintentional or unexplained weight loss defined by **one** of the following:
 - a. Weight loss of \geq 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;

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 the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at:
<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

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**

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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 the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at:
<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

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. Revisions to 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.

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

2. For the treatment of SBS, 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.

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).
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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.