

# MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER	
October 18, 2019	January 1, 2020	*See below	
SUBJECT	rowth Factors – Pharmac	BY Sallyh. Kozel	
Services		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: http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S 001994.

## 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 Factors 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 Factors to the appropriate managed care organization.

## **BACKGROUND/DISCUSSION:**

The Department of Human Services (Department) is removing the Growth Factors class of drugs from the Preferred Drug List. The Department is updating the medical necessity guidelines for Growth Factors to reflect this change. All prescriptions for Growth Factors will

*01-19-78	09-19-74	27-19-72	33-19-74
02-19-72	11-19-71	30-19-70	
03-19-71	14-19-70	31-19-77	
08-19-80	24-19-72	32-19-70	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll-free number for your provider type

Visit the Office of Medical Assistance Programs Web site at <a href="http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm">http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm</a>

continue to require prior authorization based on package labeling, nationally recognized compendia, or peer-reviewed medical literature. There are no other changes to the medical necessity guidelines.

The revisions to the guidelines to determine medical necessity of Growth Factors 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 Factors 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 Factors) 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

## **RESOURCES:**

Prior Authorization of Pharmaceutical Services Handbook – SECTION I Pharmacy Prior Authorization General Requirements <u>http://www.dhs.pa.gov/provider/pharmacyservices/pharmacypriorauthorizationgeneralrequirem</u> <u>ents/index.htm</u>

Prior Authorization of Pharmaceutical Services Handbook – SECTION II Pharmacy Prior Authorization Guidelines <u>http://www.dhs.pa.gov/provider/pharmacyservices/drugsrequiringclinicalpriorauthorization/inde</u> <u>x.htm</u>

# MEDICAL ASSISTANCE HANDBOOK PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

# I. Requirements for Prior Authorization of Growth Factors

## A. Prescriptions That Require Prior Authorization

All prescriptions for Growth Factors must be prior authorized.

## B. Review of Documentation for Medical Necessity

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

- 1. Is being treated for 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 that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
- 4. Is prescribed the Growth Factor by or in consultation with an endocrinologist; AND
- 5. Does not have a history of a contraindication to the prescribed medication; **AND**
- 6. Has epiphyses that are confirmed as open for **any** of the following:
  - a. Males and females in Tanner stage greater than or equal to 3,
  - b. Females 12 years of age and older,
  - c. Males 14 years of age and older.

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 FACTORS: The determination of medical necessity of a request for renewal of a prior authorization for a Growth Factor that was previously approved will take into account whether the beneficiary:

- 1. Demonstrates a growth response equal to or greater than 4.5 cm/year (pre-pubertal growth rate) or equal to or greater than 2.5 cm/year (post-pubertal growth rate); **AND**
- 2. Has not reached the expected final adult height (defined as midparental height); AND
- 3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally

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recognized compendia, or peer-reviewed medical literature; AND

- 4. Does not have a history of a contraindication to the prescribed medication; AND
- 5. Has epiphyses that are confirmed as open for **any** of the following:
  - a. Males and females in Tanner stage greater than or equal to 3,
  - b. Females 12 years of age and older,
  - c. Males 14 years of age and older.

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 Factor. 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.