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| ISSUE DATE June 30, 2023 | EFFECTIVE DATE July 10, 2023 | NUMBER *See below |
| SUBJECT Clinical Prior Authorization of Non-PDL Drugs – 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:

1. Inform providers that the Department of Human Services (Department) will require prior authorization of prescriptions for the following drugs that are not included on the Statewide Preferred Drug List (non-PDL drugs): gene therapy drugs, chimeric antigen receptor T-cell (CAR-T) drugs, drugs approved by the U.S. Food & Drug Administration (FDA) through the Accelerated Approval, Priority Review, Breakthrough Therapy, or Fast Track programs, drugs classified as orphan drugs by the FDA, and drugs specified in the Pennsylvania Bulletin.
2. Issue new handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for the following non-PDL drugs that are submitted for prior authorization: gene therapy drugs, CAR-T drugs, drugs approved by the FDA through the Accelerated Approval, Priority Review, Breakthrough Therapy, or Fast Track programs, drugs classified as orphan drugs by the FDA, and drugs specified in the Pennsylvania Bulletin.

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| *01-23-14 | 09-23-14 | 27-23-08 | 33-23-14 |
| 02-23-07 | 11-23-07 | 30-23-11 | |
| 03-23-07 | 14-23-07 | 31-23-15 | |
| 08-23-18 | 24-23-13 | 32-23-07 | |

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 website at <https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx>.

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 the following non-PDL drugs to the appropriate managed care organization: gene therapy drugs, CAR-T drugs, drugs approved by the FDA through the Accelerated Approval, Priority Review, Breakthrough Therapy, or Fast Track programs, drugs classified as orphan drugs by the FDA, and drugs specified in the Pennsylvania Bulletin.

BACKGROUND:

The Department's Drug Utilization Review (DUR) Board meets to review provider prescribing and dispensing practices for efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists through the Department's Prospective DUR and Retrospective DUR programs.

DISCUSSION:

During the April 26, 2023, meeting, the DUR Board recommended that the Department require prior authorization of prescriptions for the following non-PDL drugs to ensure appropriate utilization: gene therapy drugs, CAR-T drugs, drugs approved by the FDA through the Accelerated Approval, Priority Review, Breakthrough Therapy, or Fast Track programs, drugs classified as orphan drugs by the FDA, and drugs specified in the Pennsylvania Bulletin. The DUR Board recommended guidelines to determine medical necessity of prescriptions for non-PDL gene therapy drugs, CAR-T drugs, drugs approved by the FDA through the Accelerated Approval, Priority Review, Breakthrough Therapy, or Fast Track programs, drugs classified as orphan drugs by the FDA, and drugs specified in the Pennsylvania Bulletin that 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 non-PDL gene therapy drugs, CAR-T drugs, drugs approved by the FDA through the Accelerated Approval, Priority Review, Breakthrough Therapy, or Fast Track programs, drugs classified as orphan drugs by the FDA, and drugs specified in the Pennsylvania Bulletin 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 Clinical Prior Authorization of Non-PDL Drugs) 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 and products 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

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Pharmacy-Prior-Authorization-General-Requirements.aspx>

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Clinical-Guidelines.aspx>

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

I. Requirements for Clinical Prior Authorization of Non-PDL Drugs That Do Not Have a Drug- or Class-Specific Medical Assistance Prior Authorization Guideline

A. Prescriptions That Require Prior Authorization

Prescriptions for drugs that are non-PDL drugs and are not otherwise addressed by a drug- or class-specific Medical Assistance Prior Authorization Guideline that meet any of the following conditions must be prior authorized:

1. Gene therapy drugs.
2. Chimeric antigen receptor T-cell (CAR-T) drugs.
3. Drugs approved by the U.S. Food & Drug Administration (FDA) through the Accelerated Approval, Priority Review, Breakthrough Therapy, or Fast Track programs.
4. Drugs classified as orphan drugs by the FDA.
5. Drugs specified in the Pennsylvania Bulletin.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a drug defined in Section A., the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the requested drug for the treatment of a diagnosis that is indicated in the 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 are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. Is prescribed the requested drug by or in consultation with an appropriate specialist; **AND**
5. Does not have a contraindication to the prescribed drug; **AND**
6. Has documentation of baseline lab results as recommended in the FDA-approved package labeling; **AND**
7. Has a history of therapeutic failure of or a contraindication or an intolerance to first-line therapy(ies) if applicable according to consensus treatment guidelines; **AND**
8. Has not failed a previous course or trial of the requested drug; **AND**

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

9. Is not currently enrolled in a clinical trial for the requested drug; **AND**
10. If a prescription for a drug defined in Section A. 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 A DRUG DEFINED IN SECTION A:
The determination of medical necessity of a request for renewal of a prior authorization for a drug defined in Section A. that was previously approved will take into account whether the beneficiary:

1. Has documentation of a positive clinical response to the drug; **AND**
2. Is prescribed a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed the requested drug by or in consultation with an appropriate specialist; **AND**
4. Does not have a contraindication to the prescribed drug; **AND**
5. Has documentation of results of recent lab monitoring as recommended in the FDA-approved package labeling; **AND**
6. If applicable, is continuing treatment with the requested drug based on recent lab results as recommended in the FDA-approved package labeling; **AND**
7. If a prescription for a drug defined in Section A. 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.

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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 drug defined in Section A. 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 drug defined in Section A. will be approved as follows:

1. **One** of the following:
 - a. For drugs with a specified limited duration of therapy, requests for prior authorization will be approved for the duration specified in FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.
 - b. For drugs without a specified limited duration of therapy in FDA-approved package labeling, requests for prior authorization will be approved for up to 6 months.