Pennsylvania
Department of Human Services

Medical Assistance BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
November 13, 2024	January 6, 2025	*See below

SUBJECT

Prior Authorization of Thalidomide and Derivatives – Pharmacy Services

BY

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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.pa.gov/en/agencies/dhs/resources/for-providers/provider-enrollment-information/provider-enrollment-documents.html.

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 Thalidomide and Derivatives submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program. The guidelines to determine the medical necessity of Thalidomide and Derivatives will be utilized in the fee-for-service and managed care delivery systems. Providers rendering services to MA beneficiaries in the managed care delivery system should address any questions related to the prior authorization of Thalidomide and Derivatives to the appropriate managed care organization.

BACKGROUND/DISCUSSION:

The Department of Human Services (Department) is updating the medical necessity guidelines for Thalidomide and Derivatives to consider therapeutically equivalent brands and generics when evaluating a request for a non-preferred Thalidomide and Derivative and to delete the guideline related to tolerability from the requests for renewal of prior authorization section. There are no other changes to the medical necessity guidelines.

*01-25-30	09-25-30	27-25-30	33-25-30
02-25-30	11-25-30	30-25-30	
03-25-30	14-25-30	31-25-30	
08-25-31	24-25-30	32-25-30	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

Fee-for-Service Provider Service Center: 1-800-537-8862

Visit the Office of Medical Assistance Programs website at:
https://www.pa.gov/en/agencies/dhs/departments-offices/omap-info.html

The revisions to the guidelines to determine medical necessity of prescriptions for Thalidomide and Derivatives 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 Thalidomide and Derivatives 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 Thalidomide and Derivatives) 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.pa.gov/en/agencies/dhs/resources/pharmacy-services/pharmacy-prior-authorization-general-requirements.html

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines
https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/clinical-guidelines.html

I. Requirements for Prior Authorization of Thalidomide and Derivatives

A. Prescriptions That Require Prior Authorization

All prescriptions for Thalidomide and Derivatives must be prior authorized.

B. Review of Documentation for Medical Necessity

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

1. Is prescribed the Thalidomide and Derivative 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 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 Thalidomide and Derivative by or in consultation with an appropriate specialist (i.e., hematologist/oncologist); **AND**

4. For a non-preferred Thalidomide and Derivative**, one** of the following:

   a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Thalidomide and Derivatives approved or medically accepted for the beneficiary's diagnosis
   b. Has a current history (within the past 90 days) of being prescribed the same non-preferred Thalidomide and Derivative (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred).

   See the Preferred Drug List (PDL) for the list of preferred Thalidomide and Derivatives at: https://papdl.com/preferred-drug-list;

   AND

5. If a prescription for a Thalidomide and Derivative 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.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement 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 PRESCRIPITONS FOR THALIDOMIDE AND DERIVATIVES: The determination of medical necessity of a request for prior authorization for a Thalidomide and Derivative that was previously approved will take into account whether the beneficiary:

1. Has documentation of a positive clinical response to the prescribed 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 Thalidomide and Derivative by or in consultation with an appropriate specialist (i.e., hematologist/oncologist); **AND**

4. For a non-preferred Thalidomide and Derivative with a therapeutically equivalent brand or generic that is preferred on the PDL, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred therapeutically equivalent brand or generic that would not be expected to occur with the requested drug.

   See the PDL for the list of preferred Thalidomide and Derivatives at: https://papdl.com/preferred-drug-list;

   AND

5. If a prescription for a Thalidomide and Derivative 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.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html.

   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 Thalidomide and Derivative. 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.