

ISSUE DATE August 8, 2019	EFFECTIVE DATE January 1, 2020	NUMBER *See below
SUBJECT Prior Authorization of Thalidomide and Derivatives – 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: 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 Thalidomide and Derivatives 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 Thalidomide and Derivatives to the appropriate managed care organization.

BACKGROUND:

The Department of Human Services’ (Department) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed clinical literature and recommends the following:

*01-19-22	09-19-20	27-19-18	33-19-20
02-19-17	11-19-16	30-19-16	
03-19-16	14-19-16	31-19-22	
08-19-25	24-19-18	32-19-16	

<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 http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm</p>

- Preferred or non-preferred status for new drugs in therapeutic classes already included in the Preferred Drug List (PDL);
- Changes in the status of drugs on the PDL from preferred to non-preferred and non-preferred to preferred;
- New quantity limits;
- Classes of drugs to be added to or deleted from the PDL; and
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

DISCUSSION:

During the May 15, 2019, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of Thalidomide and Derivatives:

- Addition of a guideline that the requested Thalidomide and Derivative be prescribed by or in consultation with an appropriate specialist (i.e., hematologist/oncologist);
- Addition of a guideline that treatment of the beneficiary's diagnosis with the requested medication and the prescribed dose is consistent with U.S. Food and Drug Administration-approved labeling or medical literature; and
- Addition of a guideline that Thalidomide and Derivatives are subject to the guidelines in the Quantity Limits Chapter.

The revisions to the guidelines to determine medical necessity of Thalidomide and Derivatives, as recommended by the P&T Committee, 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 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

<http://www.dhs.pa.gov/provider/pharmacyservices/pharmacypriorauthorizationgeneralrequirements/index.htm>

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

<http://www.dhs.pa.gov/provider/pharmacyservices/drugsrequiringclinicalpriorauthorization/index.htm>

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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 by or in consultation with an appropriate specialist (i.e., hematologist/oncologist); **AND**
2. 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**
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. For a non-preferred Thalidomide and Derivative, **one** of the following:
 - a. Has a documented history of therapeutic failure, contraindication, or 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

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 in 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:
<http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm>.

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.

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

FOR RENEWALS OF PRESCRIPTIONS 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 from the prescriber of tolerability and a positive clinical response to the medication; **AND**
2. Is prescribed the Thalidomide and Derivative by or in consultation with an appropriate specialist (i.e., hematologist/oncologist); **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. If a prescription for a Thalidomide and Derivative is in 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:
<http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm>

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.