

<b>ISSUE DATE</b>  July 23, 2018	<b>EFFECTIVE DATE</b>  July 23, 2018	<b>NUMBER</b>  *See below
<b>SUBJECT</b>  Prior Authorization of Thalidomide and Derivatives - Pharmacy Services	<b>BY</b>  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](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 under 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' (DHS) Pharmacy and Therapeutics (P&T) Committee meets semi-annually to review published peer-reviewed clinical literature and make recommendations relating to the following:

*01-18-23	09-18-24	27-18-22	33-18-23
02-18-18	11-18-18	30-18-18	
03-18-18	14-18-19	31-18-24	
08-18-25	24-18-19	32-18-18	

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

- 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 the PDL; and
- Guidelines to determine medical necessity.

**DISCUSSION:**

During the May 16, 2018, meeting, the P&T Committee recommended the addition of a guideline in the Thalidomide and Derivatives class of drugs that will avoid an interruption in therapy, and ensure continuity of treatment, with a non-preferred drug that a beneficiary was prescribed within the past 90 days. DHS is also adding the standard guideline for therapeutic failure, intolerance, or contraindication to a preferred drug in the Thalidomide and Derivatives class of drugs to be consistent with the guidelines in other chapters. The proposed changes to the medical necessity guidelines were subject to public review and comment, and subsequently approved for implementation by DHS.

**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. DHS 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

SECTION II  
Thalidomide and Derivatives

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**I. Requirements for Prior Authorization of Thalidomide and Derivatives**

**A. Prescriptions That Require Prior Authorization**

Prescriptions that meet any of the following conditions must be prior authorized:

1. All prescriptions for preferred and non-preferred Thalidomide and Derivatives must be prior authorized. See the Preferred Drug List (PDL) for the list of preferred Thalidomide and Derivatives at: <https://papdl.com/preferred-drug-list>.

**B. Review of Documentation for Medical Necessity**

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

1. Has a diagnosis that is:
  - a. Indicated in the FDA-approved package insert,

**OR**

- b. Listed in nationally recognized compendia for the determination of medically-accepted indications for off-label uses for Thalidomide and Derivatives

**AND**

2. For a non-preferred Thalidomide and Derivative, the beneficiary has a documented history of therapeutic failure or intolerance of or contraindication to the preferred Thalidomide and Derivative approved for the beneficiary's indication.

**OR**

3. The beneficiary has a current history (within the past 90 days) of being prescribed the same non-preferred Thalidomide and Derivative.
4. In evaluating a request for prior authorization of a renewal of a prescription for a Thalidomide and Derivatives that was previously approved, the determination of whether the requested prescription is

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medically necessary will take into account documentation from the prescribing provider that the beneficiary had a positive clinical response to the therapy.

NOTE: As described in Section C, 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.

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.