

PA DEPARTMENT OF HUMAN SERVICES  
MAAC BRIEFING DOCUMENT  
THALIDOMIDE AND DERIVATIVES

**Proposed Effective Date:** January 1, 2020

Revisions are noted with a ~~strike through~~ for deletions and **bold and underline** for additions.

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

A. Revisions to Prescriptions That Require Prior Authorization

All prescriptions for Thalidomide and Derivatives must be prior authorized.

1. See the Preferred Drug List (PDL) for the list of preferred Thalidomide and Derivatives at: <https://papdl.com/preferred-drug-list>.
2. **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>.

B. Revisions to 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. **Is prescribed the Thalidomide and Derivative by or in consultation with an appropriate specialist (ie, hematologist/oncologist); AND**
3. **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**
4. **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**
5. For a non-preferred Thalidomide and Derivative, **one of the following:**

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- a. ~~The beneficiary~~ Has a documented history of therapeutic failure, ~~or~~ contraindication, or intolerance ~~of or contraindication~~ to the preferred Thalidomide and Derivatives approved **or medically accepted** for the beneficiary's indication **diagnosis** ~~OR~~
- b. ~~The beneficiary~~ Has a current history (within the past 90 days) of being prescribed the same non-preferred Thalidomide and Derivative;

**AND**

6. **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.**

NOTE: ~~As described in Section G,~~ 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. ~~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 medically necessary will take into account~~ **Has** documentation from the prescriber that the beneficiary had a positive clinical response to the therapy **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 (ie, 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.**

**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.**

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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.