

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>;

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 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

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.

THALIDOMIDE AND DERIVATIVES PRIOR AUTHORIZATION FORM

<input type="checkbox"/> FOR ONCOLOGY USE			
<input type="checkbox"/> New request <input type="checkbox"/> Renewal request		Total # of pages: _____	Prescriber name:
Name of office contact:		Specialty:	Office NPI:
Contact's phone number:		NPI:	State license #:
Facility contact/phone:		Street address:	
Beneficiary name:		Suite #:	City/state/zip:
Beneficiary ID#:	DOB:	Phone:	Fax:
Medication will be billed via: <input type="checkbox"/> Pharmacy <input type="checkbox"/> Medical (Jcode: _____)		Place of Service: <input type="checkbox"/> Hospital <input type="checkbox"/> Provider's Office <input type="checkbox"/> Home <input type="checkbox"/> Other	

CLINICAL INFORMATION

Drug requested:	Dosage form:	Strength:
Directions:	Quantity:	Refills:
Diagnosis:	Submit documentation confirming diagnosis, such as chart notes, lab results, biopsy results, etc.	
Diagnosis code:		

INITIAL requests

Has the beneficiary been taking the requested medication in the past 90 days?	<input type="checkbox"/> Yes – Submit documentation. <input type="checkbox"/> No
<u>For requests for a non-preferred medication:</u> Does the beneficiary have a history of trial and failure of or contraindication or intolerance to the preferred medications in this class that are FDA-approved or medically accepted for the treatment of the beneficiary's diagnosis? Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred medications in this class.	<input type="checkbox"/> Yes – Submit all supporting documentation of drug regimen tried and treatment outcomes. <input type="checkbox"/> No

RENEWAL requests

Since the requested medication was started, has the beneficiary experienced a positive clinical response to therapy?	<input type="checkbox"/> Yes – Submit documentation of beneficiary's response to therapy. <input type="checkbox"/> No
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PLEASE FAX COMPLETED FORM TO GATEWAY – PHARMACY DIVISION

Prescriber Signature:	Date:
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