



MEDICATION POLICY

Generic Name: Thalidomide

Therapeutic Class or Brand Name: Thalomid®

Applicable Drugs (if Therapeutic Class): N/A

Date of Origin: 2/1/13

Date Last Reviewed/Revised: 10/8/16

GPI Code: 9939207000

Prior Authorization Criteria (may be considered medically necessary when criteria I through V are met):

- I. Documented diagnosis of one of the following conditions A through B AND must meet criteria listed under applicable diagnosis:
 - A. Erythema Nodosum Leprosum (ENL).
 - B. Multiple myeloma AND criterion 1 is met:
 1. Must be used in combination with dexamethasone.
- II. Must be administered in compliance with the Thalomid REMS® program.
- III. Minimum age requirement: 12 years old.
- IV. Prescriber is an oncologist, hematologist, or dermatologist.
- V. Prescriber must be certified with the Thalomid REMS® Program.

Exclusion Criteria:

- Pregnancy.

Other Criteria:

- N/A

Quantity/Days Supply Restrictions:

- Quantities of up to 60 capsules per 30 days (the quantity is limited to a maximum of a 30 day supply per fill).

Approval Length:

- **Authorization:** 6 months.

Disclaimer: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgment in providing the most appropriate care for their patients.



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- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

Appendix:

N/A

References:

1. http://www.fchp.org/~media/Files/FCHP/Imported/Thalomid_thalidomide_M.pdf.ashx.
2. [Medi-Span](#).
3. <http://www.thalomid.com/wp-content/uploads/thalomid-prescribing-information.pdf>.

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Historical Tracking Of Changes Made To Policy	
10/8/2016	<ol style="list-style-type: none"> 1. Changed “REMS™” to “REMS®” throughout policy. 2. Updated “http://www.thalomid.com/pdf/Thalomid_PI.pdf” to “http://www.thalomid.com/wp-content/uploads/thalomid-prescribing-information.pdf” under References. 3. Removed “http://www.connecticare.com/provider/PDFs/Pharmacy/Thalomid.pdf” from References (link no longer valid).
7/10/2015	<ol style="list-style-type: none"> 1. Changed “I. Documented diagnosis of one of the following conditions A through B: A. Erythema nodosum leprosum (ENL); B. Multiple myeloma when used in combination with dexamethasone” to “I. Documented diagnosis of one of the following conditions A through B AND must meet criteria listed under applicable diagnosis: A. Erythema Nodosum Leprosum (ENL); B. Multiple myeloma AND criterion 1 is met: 1. Must be used in combination with dexamethasone” under Prior Authorization Criteria. 2. Removed “http://www.mvphealthcare.com/policies/medicare/thalidomide.pdf” from References (link no longer valid).
1/25/2014	<ol style="list-style-type: none"> 1. Adapted policy to new format. 2. Added GPI Code. 3. Changed Prior Authorization Criteria from: “Documented diagnosis of one of the Covered Uses listed below: *Erythema nodosum leprosum (ENL); *Multiple myeloma; Must be administered in compliance with the System for Thalidomide Education and Prescribing Safety (S.T.E.P.S.) program; Minimum age requirement: 12 years old; Prescriber is an oncologist, hematologist, or dermatologist; Prescribers must be registered with the S.T.E.P.S. Program” to: “I. Documented diagnosis of one of the following conditions A through B: A. Erythema nodosum leprosum (ENL); B. Multiple myeloma when used in combination with dexamethasone; II. Must be administered in compliance with the Thalomid REMS™ program; III. Minimum age requirement: 12 years old; IV. Prescriber is an oncologist, hematologist, or dermatologist; V. Prescriber must be certified with the Thalomid REMS™ Program”. 4. Added “Pregnancy” to Exclusion Criteria. 5. Changed Quantity/Days Supply Restrictions from “60 capsules per 30 days (quantity is limited to a maximum of a 30 day supply per fill)” to “Quantities of up to 60 capsules per 30 days (the quantity is limited to a maximum of a 30 day supply per fill)”. 6. Updated references to include Medi-Span.

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