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:** 1/4/18

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.

- **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://media.celgene.com/content/uploads/thalomid-pi.pdf.

MEDICATION POLICY

Historical Tracking Of Changes Made To Policy	
1/4/2018	1. **Updated** "http://www.thalomid.com/wp-content/uploads/thalomid-prescribing-information.pdf" **to** "http://media.celgene.com/content/uploads/thalomid-pi.pdf" **under References**.
10/8/2016	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 **Removed** "http://www.connecticare.com/provider/PDFs/Pharmacy/Thalomid.pdf" **from References** (link no longer valid).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	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	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.