

Clinical Pharmacy Program Guidelines for Thalomid

Program	Prior Authorization
Medication	Thalomid [®] (thalidomide)
Markets in Scope	Arizona, Hawaii, Nevada, Florida-CHIP, Maryland, New Jersey, New York, New York EPP, Ohio, Pennsylvania, Rhode Island, California
Issue Date	5/2016
Pharmacy and Therapeutics Approval Date	5/2019
Effective Date	7/2019

1. Background:

Thalomid[®] (thalidomide) is a synthetic glutamic acid derivative indicated for the acute treatment of cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL) and for treatment of newly diagnosed multiple myeloma in combination with dexamethasone. It is also indicated as maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence. It is not indicated as monotherapy for such ENL treatment in the presence of moderate to severe neuritis.¹

The National Cancer Comprehensive Network (NCCN) also recommends the use of Thalomid for treatment of AIDS-related Kaposi Sarcoma, myelofibrosis-associated anemia, B-Cell Lymphomas - Castleman’s disease.²

Evidence supports use of Thalomid for the following indications: recurrent aphthous stomatitis/ulcers in severely, terminally immunocompromised patients.^{6,8-18} Lastly, American Hospital Formulary Service Drug Information (AHFS DI) states there is evidence to support beneficial use of Thalomid in pyoderma gangrenosum and cutaneous manifestations of systemic lupus erythematosus.⁴

Because of the risk of serious malformations if given during pregnancy, the manufacturer has an extensive risk management program requiring registration by patients, prescribers and dispensing pharmacies. Additional information about the Thalomid Risk Evaluation and Mitigation Strategy (REMS) [Thalomid REMS[®]] program may be found at <http://www.thalomidrems.com/>.⁷

Thalomid contains a black boxed warning for embryo fetal toxicity and venous thromboembolism. Please see full prescribing information for additional details.

2. Coverage Criteria:

<p>A. Multiple Myeloma</p> <p>1. Initial Authorization</p>

a. Thalomid will be approved based on the following criterion:

- (1) Diagnosis of multiple myeloma
Authorization will be issued for 12 months.

2. Reauthorization

a. Thalomid will be approved based on the following criterion:

- (1) Patient does not show evidence of progressive disease while on Thalomid therapy

Authorization will be issued for 12 months.

B. Erythema Nodosum Leprosum (ENL)

1. Initial Authorization

a. Thalomid will be approved based on **both** of the following criteria:

- (1) Diagnosis of moderate to severe erythema nodosum leprosum (ENL)

-AND-

- (2) **One** of the following:

- (a) Used for acute treatment

-OR-

- (b) Used as maintenance therapy for prevention & suppression of cutaneous manifestations of ENL recurrence

Authorization will be issued for 12 months.

2. Reauthorization

a. Thalomid will be approved based on the following criterion:

- (1) Documentation of positive clinical response to Thalomid therapy

Authorization will be issued for 12 months.

C. Aphthous Stomatitis or Ulcer

1. Initial Authorization

- a. **Thalomid** will be approved based on the following criterion:

(1) Diagnosis of severe, recurrent aphthous stomatitis or ulcer

Authorization will be issued for 12 months.

2. Reauthorization

- a. **Thalomid** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Thalomid therapy

Authorization will be issued for 12 months.

D. Pyoderma Gangrenosum

1. Initial Authorization

- a. **Thalomid** will be approved based on **both** the following criteria:

(1) Diagnosis of pyoderma gangrenosum

-AND-

(2) Used as 3rd line treatment

Authorization will be issued for 12 months.

2. Reauthorization

- a. **Thalomid** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Thalomid therapy

Authorization will be issued for 12 months.

E. Cutaneous Manifestations Systemic Lupus Erythematosus (SLE)

1. Initial Authorization

- a. **Thalomid** will be approved based on the following criterion:

(1) Diagnosis of cutaneous manifestations of systemic lupus erythematosus (SLE)

Authorization will be issued for 12 months.

2. Reauthorization

a. Thalomid will be approved based on the following criterion:

- (1) Documentation of positive clinical response to Thalomid therapy

Authorization will be issued for 12 months.

F. B-Cell Lymphomas

1. Initial Authorization

a. Thalomid will be approved based on **both** of the following criteria:

- (1) Diagnosis of Castleman's Disease (CD)

-AND-

- (2) **Not** used as first line therapy

Authorization will be issued for 12 months.

2. Reauthorization

a. Thalomid will be approved based on the following criterion:

- (1) Patient does not show evidence of progressive disease while on Thalomid therapy

Authorization will be issued for 12 months.

G. Myelofibrosis-Associated Anemia

1. Initial Authorization

a. Thalomid will be approved based on **both** of the following criteria:

- (1) Diagnosis of primary myelofibrosis

-AND-

- (2) **One** of the following:

(a) **Both** of the following:

i. Serum erythropoietin levels <500 mU/mL

-AND-

ii. History of failure, contraindication, or intolerance to erythropoietins [e.g., Procrit (epoetin alfa)]

-OR-

(b) Serum erythropoietin levels \geq 500 mU/mL

Authorization will be issued for 12 months.

2. Reauthorization

a. Thalomid will be approved based on the following criterion:

(1) Documentation that member has evidence of symptom improvement or reduction in spleen/liver volume while on Thalomid

Authorization will be issued for 12 months.

H. AIDS-Related Kaposi Sarcoma

1. Initial Authorization

a. Thalomid will be approved based on **all** of the following criteria:

(1) Diagnosis of AIDS-related Kaposi Sarcoma

-AND-

(2) Patient is currently being treated with antiretroviral therapy (ART)

-AND-

(3) **Not** used as first line therapy

Authorization will be issued for 12 months.

2. Reauthorization

a. Thalomid will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Thalomid therapy

Authorization will be issued for 12 months.

I. NCCN Recommended Regimens

1. Initial Authorization

a. **Thalomid** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

a. **Thalomid** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Thalomid therapy

Authorization will be issued for 12 months.

3. References:

1. Thalomid [package insert]. Summit, NJ: Celgene Corporation; December 2017.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed April 10, 2019.
3. Thalidomide. AHFS Drug Information® electronic version. American Society of Health-System Pharmacists, Inc. Bethesda, MD, USA. Accessed April 2, 2018.
4. Ehling A1, Karrer S, Klebl F, et al. Therapeutic management of pyoderma gangrenosum. *Arthritis Rheum.* 2004 Oct;50(10):3076-84.
5. Thalidomide. *DRUGDEX*® System (electronic version) Truven Health Analytics, Greenwood Village, CO, USA: Available at: <http://www.micromedexsolutions.com/> Accessed April 2, 2018.
6. Thalomid REMS™. Available at <http://www.thalomidrems.com/>. Accessed March 22, 2017.

Program	Prior Authorization - Thalomid (thalidomide)
Change Control	
Date	Change
5/2016	New program.
5/2017	Removed progressive solitary plasmacytoma and smoldering myeloma. Added coverage criteria for MF-associated anemia per NCCN guidelines. Updated background and references.

5/2018	Added coverage for AIDS-related Kaposi Sarcoma. Removed systemic light chain amyloidosis and Waldenstrom macroglobinemia per NCCN guidelines. Added NCCN recommended regimen review criteria. Updated background and references.
5/2019	Minor changes to indication naming to align with NCCN guidelines. Updated background and references.