UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Thalomid

Program	Prior Authorization
Medication	Thalomid® (thalidomide)
Issue Date	5/2016
Pharmacy and Therapeutics Approval Date	5/2017
Effective Date	7/2017

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 myelofibrosis-associated anemia, systemic light chain amyloidosis, Non-Hodgkin's Lymphoma - Castleman's disease and Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma.[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]

2. Coverage Criteria:

A. <u>Myeloma</u>

1. <u>Initial Authorization</u>

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. Waldenström's Macroglobulinemia (lymphoplasmacytic lymphoma) [off-label]

1. Initial Authorization

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

(1) Diagnosis of Waldenström's macroglobulinemia (lymphoplasmacytic lymphoma)

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.

D. Aphthous Stomatitis or Ulcer [off-label]

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.

E. Pyoderma Gangrenosum [off-label]

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.

F. Cutaneous Manifestations Systemic Lupus Erythematosus (SLE) [off-label]

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.

G. Systemic Light Chain Amyloidosis [off-label]

1. Initial Authorization

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

(1) Diagnosis of systemic light chain amyloidosis [off-label]

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.

H. Non-Hodgkin's Lymphomas (NHL)

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.

I. Myelofibrosis-Associated Anemia [off-label]

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 ≥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.

3. References:

1. Thalomid [package insert]. Summit, NJ: Celgene Corporation; January 2017.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed March 22, 2017.
3. Thalidomide. AHFS Drug Information® electronic version. American Society of Health-System Pharmacists, Inc. Bethesda, MD, USA. Accessed March 22, 2017.
4. Ehling A1, Karrer S, Klebl F, et al. Therapeutic management of pyoderma gangrenosum. Arthritis Rheum. 2004 Oct;50(10):3076-84.
5. Thalidomide. Drug Facts and Comparisons. Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health, Inc; March 16, 2017. Accessed March 22, 2017.
6. Thalidomide. *DRUGDEX*® System (electronic version) Truven Health Analytics, Greenwood Village, CO, USA: Available at: http://www.micromedexsolutions.com/ Accessed March 22, 2017.
7. 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.