UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1108-11
Program	Prior Authorization/Notification
Medication	Thalomid® (thalidomide)
P&T Approval Date	12/8/2009, 9/2010, 12/2010, 9/2011, 8/2012, 7/2013, 5/2014, 5/2015, 5/2016, 5/2017, 5/2018, 5/2019, 5/2020, 5/2021, 5/2022, 5/2023
Effective Date	8/1/2023; Oxford only: 8/1/2023

1. Background:

Thalomid® (thalidomide) is a synthetic glutamic acid derivative indicated for the treatment of patients with newly diagnosed multiple myeloma (MM) in combination with dexamethasone. It is also indicated for the acute treatment of cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL) and 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 histiocytic neoplasms – Langerhans cell histiocytosis and Rosai-Dorman disease, myelofibrosis-associated anemia, B-Cell Lymphomas – Castleman's disease, and Kaposi Sarcoma.[2]

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/.[3]

Coverage Information:

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. Patients less than 19 years of age

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

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. Multiple Myeloma

1. **Initial Authorization**

   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.

C. 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 and 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.

D. 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) **One** of the following:

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

-OR-

(b) **All** of the following:

i. Therapy is for active idiopathic multicentric CD with no evidence of organ failure
ii. Used in combination with cyclophosphamide and prednisone
iii. Patient is human immunodeficiency virus (HIV)-negative
iv. Patient is human herpesvirus-8 (HHV8)-negative

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.

E. Kaposi Sarcoma

1. **Initial Authorization**

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

(1) **One** of the following:

(a) Diagnosis of HIV-negative Kaposi Sarcoma

-OR-

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

i. Diagnosis of AIDS-related Kaposi Sarcoma

-AND-

ii. Patient is currently being treated with antiretroviral therapy (ART)

-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.

F. 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 ≥ 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.

G. Histiocytic Neoplasms

1. **Initial Authorization**

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

(1) Diagnosis of Langerhans cell histiocytosis

-OR-

(2) Diagnosis of Rosai-Dorfman Disease

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. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Thalomid [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; December 2022.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed March 22, 2023.
3. Thalomid REMS®. Available at http://www.thalomidrems.com/. Accessed March 22, 2023.

Program	Prior Authorization/Notification – Thalomid (thalidomide)
Change Control	
5/2014	Annual review with no change to clinical coverage.
5/2015	Added smoldering myeloma and expanded ENL. Removed mantle cell lymphoma, AIDS- related Karposi sarcoma; AIDS-related wasting, GVHD, Crohn's disease, glioblastoma multiforme, erosive lichen planus, MDS, Behçet's disease, and ulcers in HIV-infected patients. Updated background and references.
5/2016	Annual review. Broke out systemic light chain amyloidosis. Added criteria for Castleman's disease. Updated background and references.
5/2017	Annual review. Changed member to patient. Removed progressive solitary plasmacytoma and smoldering myeloma. Added coverage criteria for MF-associated anemia per NCCN guidelines. Updated background and references.
5/2018	Annual review. Added coverage criteria for AIDS related Kaposi Sarcoma, removed systemic light chain amyloidosis and Waldenstrom macroglobulinemia per NCCN guidelines. Updated background and references.
5/2019	Annual review. Minor changes to indication naming to align with NCCN guidelines, with no changes to clinical intent. Updated background and references.
5/2020	Annual review. No changes to coverage criteria. Updated references.
5/2021	Annual review. Added non-HIV Kaposi Sarcoma and histiocytic neoplasms criteria according to NCCN guidelines. Updated references.
5/2022	Annual review. Removed off-label criteria, aphthous stomatitis or ulcer, pyoderma gangrenosum, and cutaneous manifestations systemic lupus

	erythematosus. Updated B-cell lymphoma and Kaposi sarcoma criteria per NCCN guidance. Updated background and references.
5/2023	Annual review with no changes to coverage criteria. Updated background and references. Added state mandate footnote.