

SPECIALTY GUIDELINE MANAGEMENT

THALOMID (thalidomide)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

1. Thalomid in combination with dexamethasone is indicated for the treatment of patients with newly diagnosed multiple myeloma.
2. Erythema Nodosum Leprosum (ENL)
 1. Acute treatment of the cutaneous manifestations of moderate to severe ENL
 2. Maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence

Limitations of Use: not indicated as monotherapy for ENL treatment in the presence of moderate to severe neuritis

B. Compendial Uses

1. Myelofibrosis-related anemia
2. Systemic light chain amyloidosis
3. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma
4. Multicentric Castleman's disease
5. Recurrent aphthous stomatitis
6. Recurrent HIV-associated aphthous ulcers
7. Cachexia in patients with cancer or HIV-associated wasting syndrome
8. Diarrhea in patients with HIV infection
9. Kaposi's sarcoma in HIV-infected patients
10. Behcet's syndrome
11. Chronic graft-versus-host disease
12. Crohn's disease

All other indications are considered experimental/investigational and are not covered benefits.

II. CRITERIA FOR INITIAL APPROVAL

A. **Multiple Myeloma**

Authorization of 12 months may be granted for treatment of multiple myeloma.

B. **Recurrent HIV-associated Aphthous Ulcers**

Authorization of 12 months may be granted for treatment of recurrent HIV-associated aphthous ulcers.

C. **Behcet's Syndrome**

Authorization of 12 months may be granted for treatment of Behcet's syndrome.

D. **Myelofibrosis-related anemia**

Authorization of 12 months may be granted for treatment of myelofibrosis-related anemia.

E. Systemic Light Chain Amyloidosis

Authorization of 12 months may be granted for treatment of systemic light chain amyloidosis.

F. Erythema Nodosum Leprosum

Authorization of 12 months may be granted for treatment of erythema nodosum leprosum.

G. Crohn's Disease

Authorization of 12 months may be granted for treatment of Crohn's disease.

H. Kaposi's Sarcoma

Authorization of 12 months may be granted for treatment of Kaposi's sarcoma in HIV-infected patients.

I. Chronic Graft-versus-Host Disease

Authorization of 12 months may be granted for treatment of chronic graft-versus-host disease.

J. Waldenström's Macroglobulinemia/Lymphoplasmacytic Leukemia

Authorization of 12 months may be granted for treatment of Waldenström's macroglobulinemia/lymphoplasmacytic leukemia.

K. Multicentric Castleman's Disease

Authorization of 12 months may be granted for treatment of multicentric Castleman's disease.

L. Recurrent Aphthous Stomatitis

Authorization of 12 months may be granted for treatment of recurrent aphthous stomatitis.

M. Cachexia

Authorization of 12 months may be granted for treatment of cachexia caused by cancer or HIV-infection.

N. HIV-associated Diarrhea

Authorization of 12 months may be granted for treatment of HIV-associated diarrhea.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

IV. REFERENCES

1. Thalomid [package insert]. Summit, NJ: Celgene Corporation; August 2015.
2. American Society of Health System Pharmacists. AHFS Drug Information. (Adult and Pediatric) Bethesda, MD. Electronic version, 2016. Available with subscription. URL: <http://online.lexi.com/lco>. Accessed October 19, 2016.
3. **The NCCN Drugs & Biologics Compendium® © 2016 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed October 19, 2016.**
4. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: <http://www.micromedexsolutions.com> (cited: 10/19/2016).
5. Treon SP, Soumerai JD, Branagan AR, et al. Thalidomide and rituximab in Waldenstrom macroglobulinemia. *Blood*. 2008; 112(12): 4452-7.
6. The NCCN Clinical Practice Guidelines in Oncology® Multiple Myeloma (Version 1.2017). © 2016 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed **October 20, 2016**.
7. The NCCN Clinical Practice Guidelines in Oncology® Systemic Light Chain Amyloidosis (Version 1.2016). © 2016 National Comprehensive Cancer Network, Inc. Available at: www.nccn.org. Accessed September 28, 2016.

8. The NCCN Clinical Practice Guidelines in Oncology® Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma (Version 2.2016) © 2016 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed September 28, 2016.
9. The NCCN Clinical Practice Guidelines in Oncology® Non-Hodgkin's Lymphomas (Version 3.2016) © 2016 National Comprehensive Cancer Network, Inc. Available at: www.nccn.org. Accessed September 8, 2016.