

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)
 - a. Acute treatment of the cutaneous manifestations of moderate to severe ENL
 - b. 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 Waldenström 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.