Reference number(s)
2368-A

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. Multicentric Castleman's disease
3. Recurrent aphthous stomatitis
4. Recurrent HIV-associated aphthous ulcers
5. Cachexia in patients with cancer or HIV-associated wasting syndrome
6. Diarrhea in patients with HIV infection
7. AIDS-Related Kaposi's sarcoma
8. Behcet's syndrome
9. Chronic graft-versus-host disease
10. Crohn's disease

All other indications are considered experimental/investigational and not medically necessary.

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 when all of the following criteria are met:

1. The requested medication will be given as a single agent or in combination with prednisone
2. The member has serum erythropoietin levels of either of the following:
   a. 500 mU/mL or greater
   b. Less than 500 mU/mL and no response or loss of response to erythropoietic stimulating agents

E. Erythema Nodosum Leprosum
Authorization of 12 months may be granted for treatment of erythema nodosum leprosum.

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

G. AIDS-Related Kaposi's Sarcoma
Authorization of 12 months may be granted for treatment of AIDS-related Kaposi's sarcoma in combination with antiretroviral therapy.

H. Chronic Graft-versus-Host Disease
Authorization of 12 months may be granted for treatment of chronic graft-versus-host disease.

I. Multicentric Castleman's Disease
Authorization of 12 months may be granted for treatment of relapsed, refractory or progressive multicentric Castleman's disease.

J. Recurrent Aphthous Stomatitis
Authorization of 12 months may be granted for treatment of recurrent aphthous stomatitis.

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

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

III. CONTINUATION OF THERAPY

A. Multiple Myeloma and Multicentric Castleman's Disease
Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for multiple myeloma or multicentric Castleman's disease when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

B. All Other Indications
Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II, other than multiple myeloma or multicentric Castleman's disease, who have improvement in symptoms and no unacceptable toxicity.

IV. REFERENCES

1. Thalomid [package insert]. Summit, NJ: Celgene Corporation; October 2019.
2. American Society of Health System Pharmacists. AHFS Drug Information. (Adult and Pediatric) Bethesda, MD. Electronic version, 2019. Available with subscription. URL: http://online.lexi.com/lco. Accessed October 01, 2019.
3. The NCCN Drugs & Biologics Compendium® © 2019 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed October 01, 2019.

4. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: http://www.micromedexsolutions.com. Accessed October 4, 2019.
5. The NCCN Clinical Practice Guidelines in Oncology® Multiple Myeloma (Version 2.2020). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org.
6. The NCCN Clinical Practice Guidelines in Oncology® B-cell Lymphomas (Version 5.2019) © 2019 National Comprehensive Cancer Network, Inc. Available at: www.nccn.org. Accessed October 4, 2019.