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 a covered benefit 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 (MM).
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: Thalomid is not indicated as monotherapy for ENL treatment in the presence of moderate to severe neuritis.

B. Compendial Uses
1. Multiple Myeloma
2. Myelofibrosis-associated anemia
3. Multicentric Castleman disease
4. Aphthous stomatitis
5. Kaposi sarcoma
6. Chronic graft-versus-host disease
7. Crohn's disease
8. Histiocytic neoplasms
   i. Langerhans cell histiocytosis
   ii. Rosai-Dorfman 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. Myelofibrosis-associated Anemia
Authorization of 12 months may be granted for treatment of myelofibrosis-associated anemia when all of the following criteria are met:
1. The requested medication will be given in combination with prednisone
2. The member has serum erythropoietin (EPO) 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 erythropoiesis-stimulating agents

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

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

E. Kaposi Sarcoma
Authorization of 12 months may be granted for treatment of Kaposi sarcoma as subsequent therapy.

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

G. Multicentric Castleman Disease
Authorization of 12 months may be granted for treatment of multicentric Castleman disease.

H. Aphthous Stomatitis
Authorization of 12 months may be granted for treatment of AIDS-related aphthous stomatitis and recurrent aphthous stomatitis in immunocompromised members.

I. Histiocytic Neoplasms
Authorization of 12 months may be granted for treatment of histiocytic neoplasms, including Langerhans cell histiocytosis and Rosai-Dorfman disease, as a single agent.

III. CONTINUATION OF THERAPY

A. Multiple Myeloma, Multicentric Castleman Disease, Histiocytic Neoplasms, and Kaposi sarcoma
Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for multiple myeloma, multicentric Castleman Disease, histiocytic neoplasms, or Kaposi sarcoma 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, multicentric Castleman disease, histiocytic neoplasms, or Kaposi sarcoma, who have improvement in symptoms and no unacceptable toxicity.

IV. REFERENCES

1. Thalomid [package insert]. Summit, NJ: Celgene Corporation; February 2021.
2. AHFS Drug Information. (Adult and Pediatric) Bethesda, MD. American Society of Health System Pharmacists, Inc. Electronic version. Updated March 28, 2022. Available with subscription. URL: http://online.lexi.com/lco. Accessed October 4, 2022.
3. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed October 4, 2022.
4. DRUGDEX® System (electronic version). Micromedex Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: http://www.micromedexsolutions.com. Accessed October 4, 2022.
5. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; Updated September 21, 2022. https://online.lexi.com. Accessed October 4, 2022.