Effective date: 9/1/2020
Review date: 7/2020, 7/2021, 5/2022, 5/2023 Scope: Medicaid

NON-ONCOLOGY POLICY
THALOMID (thalidomide)

For oncology indications, please refer to NHPRI Thalomid Oncology 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. 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. Multicentric Castleman's disease
   2. Recurrent aphthous stomatitis
   3. Recurrent HIV-associated aphthous ulcers
   4. Cachexia in patients with cancer or HIV-associated wasting syndrome
   5. Diarrhea in patients with HIV infection
   6. AIDS-Related Kaposi's sarcoma
   7. Behcet's syndrome
   8. Chronic graft-versus-host disease
   9. Crohn's disease

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

II. CRITERIA FOR INITIAL APPROVAL

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

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

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

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

E. 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.

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

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

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

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

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

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II who have not experienced unacceptable toxicity or disease progression while on the current regimen.

IV. QUANTITY LIMIT

- Thalomid 50mg & 100mg: 1 tablet per day or 28 tablets per 28 days
- Thalomid 150mg & 200mg: 2 tablets per day or 56 tablets per 28 days

V. REFERENCES

1. Thalomid [package insert]. Summit, NJ: Celgene Corporation; March 2023.
2. American Society of Health System Pharmacists. AHFS Drug Information. (Adult and Pediatric) Bethesda, MD. Electronic version, 2018. Available with subscription. URL: http://online.lexi.com/lco. Accessed March 25, 2019.
3. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: http://www.micromedexsolutions.com (cited: 10/4/2018).