SPECIALTY GUIDELINE MANAGEMENT

THALOMID (thalidomide)

POLICY

A. 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.

FDA-Approved Indications

Multiple Myeloma
- Thalomid in combination with dexamethasone is indicated for the treatment of patients with newly diagnosed multiple myeloma.

Erythema Nodosum Leprosum (ENL)
- Thalomid is indicated for the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum.
- Thalomid is indicated as maintenance therapy for prevention and suppression of the cutaneous manifestations of erythema nodosum leprosum recurrence.
- Limitations of Use: Thalomid is not indicated as monotherapy for erythema nodosum leprosum treatment in the presence of moderate to severe neuritis.

Compendial Uses
- Systemic light chain amyloidosis
- Waldenström’s macroglobulinemia/lymphoplasmacytic lymphoma
- Multicentric Castleman’s disease
- Recurrent aphthous stomatitis
- Recurrent HIV-associated aphthous ulcers
- Cachexia in patients with cancer or HIV-associated wasting syndrome
- Diarrhea in patients with HIV infection
- Kaposi’s sarcoma in HIV-infected patients
- Behcet’s syndrome
- Chronic graft-versus-host disease
- Crohn’s disease
- Myelofibrosis with myeloid metaplasia

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

B. CRITERIA FOR APPROVAL

For all diagnoses, monitoring for thromboembolism must be performed.

1. Multiple Myeloma
   Authorization of 12 months may be granted to members prescribed Thalomid for the treatment of multiple myeloma.

2. Myelofibrosis with Myeloid Metaplasia
   Authorization of 12 months may be granted to members prescribed Thalomid for the treatment of myelofibrosis with myeloid metaplasia.

3. Erythema Nodosum Leprosum
   Authorization of 12 months may be granted to members prescribed Thalomid for the treatment of erythema nodosum leprosum.
4. **Systemic Light Chain Amyloidosis**  
   Authorization of 12 months may be granted to members prescribed Thalomid for the treatment of systemic light chain amyloidosis.

5. **Waldenström’s Macroglobulinemia/Lymphoplasmacytic Leukemia**  
   Authorization of 12 months may be granted to members prescribed Thalomid for the treatment of Waldenström’s macroglobulinemia/lymphoplasmacytic leukemia.

6. **Multicentric Castleman’s Disease**  
   Authorization of 12 months may be granted to members prescribed Thalomid for the treatment of multicentric Castleman’s disease.

7. **Recurrent HIV-associated Aphthous Ulcers**  
   Authorization of 12 months may be granted to members prescribed Thalomid for the treatment of recurrent HIV-associated aphthous ulcers.

8. **Recurrent Aphthous Stomatitis**  
   Authorization of 12 months may be granted to members prescribed Thalomid for the treatment of recurrent aphthous stomatitis.

9. **Cachexia**  
   Authorization of 12 months may be granted to members prescribed Thalomid for the treatment of cachexia caused by cancer or HIV-infection.

10. **HIV-associated Diarrhea**  
    Authorization of 12 months may be granted to members prescribed Thalomid for the treatment of HIV-associated diarrhea.

11. **Kaposi’s Sarcoma**  
    Authorization of 12 months may be granted to members prescribed Thalomid for the treatment of Kaposi’s sarcoma in HIV-infected patients.

12. **Behcet’s Syndrome**  
    Authorization of 12 months may be granted to members prescribed Thalomid for the treatment of Behcet’s syndrome.

13. **Chronic Graft-versus-Host Disease**  
    Authorization of 12 months may be granted to members prescribed Thalomid for the treatment of chronic graft-versus-host disease.

14. **Crohn’s Disease**  
    Authorization of 12 months may be granted to members prescribed Thalomid for the treatment of Crohn’s disease.

C. **CONTINUATION OF THERAPY**  
   All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

D. **DOSEDAGE AND ADMINISTRATION**  
   Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

1. **Dosing Limits**  
   The following dosing limits apply:
• Multiple myeloma: 400 mg/day
• Myelofibrosis with myeloid metaplasia: 800 mg/day
• Erythema nodosum leprosum: 400 mg/day
• Systemic light chain amyloidosis: 800 mg/day
• Waldenström’s macroglobulinemia/lymphoplasmacytic leukemia: 400 mg/day
• Multicentric Castleman’s disease: 300 mg/day
• HIV-associated aphthous ulcers: 300 mg/day
• Recurrent aphthous stomatitis: 600 mg/day
• Cachexia: 400 mg/day
• HIV-associated diarrhea: 100 mg/day
• Kaposi’s sarcoma: 1000 mg/day
• Behcet’s syndrome: 400 mg/day
• Graft-versus-host disease: 1600 mg/day
• Crohn’s disease: 400 mg/day

REFERENCES