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