Reference number(s)
2234-A

SPECIALTY GUIDELINE MANAGEMENT

POMALYST (pomalidomide)

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. Treatment of multiple myeloma, in combination with dexamethasone, in adult patients who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of their last therapy
2. Treatment of adult patients with AIDS-related Kaposi sarcoma (KS) after failure of highly active antiretroviral therapy (HAART) or in adult patients with KS who are human immunodeficiency virus (HIV)-negative

B. Compendial Uses
1. Systemic light chain amyloidosis
2. Primary central nervous system lymphoma
3. POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome
4. Multiple myeloma

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 when any of the following criteria are met:
1. The member has previously received at least two prior therapies for multiple myeloma including an immunomodulatory agent and proteasome inhibitor and the requested medication will be used in one of the following regimens:
    i. In combination with elotuzumab and dexamethasone
    ii. In combination with ixazomib and dexamethasone
    iii. In combination with bortezomib and dexamethasone
    iv. In combination with cyclophosphamide and dexamethasone
    v. In combination with isatuximab-irfc and dexamethasone
    vi. In combination with dexamethasone
    vii. In combination with selinexor and dexamethasone
    viii. As a single agent
2. The member has previously received at least one prior therapy for multiple myeloma including an immunomodulatory agent and a proteasome inhibitor and the requested medication will be used in combination with daratumumab and dexamethasone

3. The member has previously received at least one prior therapy for multiple myeloma and the requested medication will be used in one of the following regimens:
    i. In combination with carfilzomib and dexamethasone
    ii. In combination with elotuzumab and dexamethasone if lenalidomide refractory
    iii. In combination with bortezomib and dexamethasone if lenalidomide refractory

B. Systemic light chain amyloidosis

Authorization of 12 months may be granted for treatment of relapsed or refractory systemic light chain amyloidosis in combination with dexamethasone.

C. Kaposi Sarcoma

Authorization of 12 months may be granted for the treatment of Kaposi sarcoma when either of the following criteria are met:

1. The requested medication will be used in combination with antiretroviral therapy for the treatment of HIV-related Kaposi sarcoma
2. Member is HIV-negative

D. Primary central nervous system lymphoma

Authorization of 12 months may be granted for treatment of primary central nervous system lymphoma as a single agent.

E. POEMS syndrome

Authorization of 12 months may be granted for treatment of POEMS syndrome in combination with dexamethasone.

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 when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

1. Pomalyst [package insert]. Princeton, NJ: Bristol Myers Squibb Company; March 2023.
2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed October 4, 2023.