| Reference number(s) |
| --- |
| 2234-A |

# Specialty Guideline Management
# Pomalyst

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Pomalyst | pomalidomide |

## 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.

### 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
- 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

### Compendial Uses[2]

- Systemic light chain amyloidosis
- Primary central nervous system lymphoma

- POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome
- Multiple myeloma

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

# Coverage Criteria

## Multiple Myeloma[1-2]

Authorization of 12 months may be granted for treatment of multiple myeloma when any of the following criteria are met:

- The member has previously received at least two prior regimens for multiple myeloma including an immunomodulatory agent and proteasome inhibitor and the requested medication will be used in one of the following regimens:
  - In combination with elotuzumab and dexamethasone
  - In combination with ixazomib and dexamethasone if lenalidomide- or anti-CD-38 refractory
  - In combination with cyclophosphamide and dexamethasone
  - In combination with isatuximab-irfc and dexamethasone if bortezomib- or lenalidomide-refractory
  - In combination with dexamethasone
  - In combination with selinexor and dexamethasone
  - As a single agent
- The member has previously received at least one prior regimen for multiple myeloma and the requested medication will be used in one of the following regimens:
  - In combination with carfilzomib and dexamethasone
  - In combination with bortezomib and dexamethasone if lenalidomide- or anti-CD-38 refractory
  - In combination with carfilzomib, daratumumab, and dexamethasone
  - In combination with daratumumab and dexamethasone if immunomodulatory agent and proteasome inhibitor were previously given and the disease is bortezomib- or lenalidomide-refractory

## Systemic Light Chain Amyloidosis[2]

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

### Kaposi Sarcoma[1,2]

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

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

### Primary Central Nervous System Lymphoma[2]

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

### POEMS Syndrome[2]

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

## Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

## References

1. Pomalyst [package insert]. Princeton, NJ: Bristol Myers Squibb Company; March 2023.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed October 1, 2024.