

Specialty Guideline Management pomalidomide-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^{1,2}

- Pomalyst, in combination with dexamethasone, is indicated for adult patients with multiple myeloma (MM) 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.
- Pomalyst is indicated for the treatment of:
 - Adult patients with AIDS-related Kaposi sarcoma (KS) after failure of highly active antiretroviral therapy (HAART).
 - Kaposi sarcoma (KS) in adult patients who are HIV-negative.

Compendial Uses^{3,5}

- Multiple myeloma
- Systemic light chain amyloidosis

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- Kaposi sarcoma
- Primary central nervous system lymphoma
- POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome
- Plasma cell-related Monoclonal Immunoglobulin Deposition Disease (MIDD)
- Plasma cell-related Monoclonal Gammopathy of Renal Significance (MGRS)

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

Coverage Criteria

Multiple Myeloma¹⁻⁵

Authorization of 12 months may be granted for treatment of relapsed or progressive 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 if steroid intolerant
- 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
 - In combination with daratumumab/hyaluronidase and dexamethasone if immunomodulatory agent and proteasome inhibitor were previously given and the disease is bortezomib- or lenalidomide-refractory

Authorization of 12 months may be granted for treatment of multiple myeloma with CNS disease in

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combination with:

- Systemic chemotherapy if there are no other available alternatives; or
- Intrathecal chemotherapy and radiation therapy

Systemic Light Chain Amyloidosis³

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

Kaposi Sarcoma¹⁻³

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

- The requested medication will be used in combination with antiretroviral therapy for the treatment of HIV-related relapsed or refractory advanced Kaposi sarcoma
- Member is HIV-negative and the requested medication will be used as a single agent for relapsed or refractory advanced Kaposi sarcoma
- The requested medication will be used in combination with rituximab for the treatment of Kaposi-sarcoma associated herpesvirus (KSHV)-Associated Inflammatory Cytokine Syndrome (KICS)

Primary Central Nervous System Lymphoma³

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

POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) Syndrome, plasma cell-related Monoclonal Immunoglobulin Deposition Disease (MIDD), and plasma cell-related Monoclonal Gammopathy of Renal Significance (MGRS)^{3,5}

Authorization of 12 months may be granted for treatment of POEMS syndrome, plasma cell-related MIDD, and plasma cell-related MGRS.

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.

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References

1. Pomalyst [package insert]. Princeton, NJ: Bristol Myers Squibb Company; February 2025.
2. Pomalidomide [package insert]. Piscataway, NJ: Camber Pharmaceuticals, Inc.; November 2025.
3. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed October 1, 2025.
4. Darzalex Faspro [package insert]. Horsham, PA: Janssen Biotech, Inc.; July 2024.
5. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Multiple Myeloma. Version 2.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed September 25, 2025.