

PHARMACY COVERAGE GUIDELINE

POMALYST® (pomalidomide) oral Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):

- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively “Service”) is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider’s judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member’s benefit plan; and
- Is subject to change as new information becomes available.

Scope

- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance

- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The “Criteria” section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member’s benefit plan.
- The “Description” section describes the Service.
- The “Definition” section defines certain words, terms or items within the policy and may include tables and charts.
- The “Resources” section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the [request form](#) and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

- **Criteria for initial therapy:** Pomalyst (pomalidomide) and/or generic equivalent (if available) is considered **medically necessary** and will be approved when **ALL** the following criteria are met:
1. Prescriber is a physician specializing in the patient’s diagnosis or is in consultation with an Oncologist, Infectious Disease Specialist, or HIV Specialist
 2. Individual is 18 years of age or older
 3. Individual has a confirmed diagnosis of **ONE** of the following:
 - a. Used in combination with dexamethasone, for treatment of multiple myeloma in an individual who has received at least **two prior therapies** including lenalidomide and a proteasome inhibitor

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(such as bortezomib, carfilzomib or ixazomib) and have demonstrated disease progression on or within 60 days of completion of the last therapy

- b. AIDS-related Kaposi sarcoma (KS) after failure of highly active antiretroviral therapy (HAART) **or** KS in HIV-negative individuals
 - c. Other request for a specific oncologic direct treatment use that is found and listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A
4. Individual has completed **ALL** the following **baseline tests** before initiation of treatment and will have continued monitoring as clinically appropriate:
- a. Complete blood count
 - b. Liver function tests
 - c. Negative pregnancy test in a woman of child-bearing potential as required by the Risk Evaluation and Mitigation Strategy (REMS) [Note: This is waved if it is verified that Provider, Patient, and Pharmacy are enrolled in the REMS]
 - d. Verification that male individual on Pomalyst (pomalidomide) is enrolled in the REMS
 - e. Eastern Cooperative Oncology Group (ECOG) Performance Status is 0-2
5. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] ([see Definitions section](#))
6. There are **NO** FDA-label contraindications such as:
- a. Pregnancy
 - b. Severe hypersensitivity (e.g., angioedema, anaphylaxis) to pomalidomide or any of the excipients

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Pomalyst (pomalidomide) and/or generic equivalent (if available) is considered **medically necessary** and will be approved when **ALL** the following criteria are met (**samples are not considered for continuation of therapy**):
- 1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Oncologist, Infectious Disease Specialist, or HIV Specialist
 - 2. Individual has documentation of positive clinical response to therapy defined as there is no evidence of disease progression or unacceptable toxicity
 - 3. Individual has been adherent with the medication
 - 4. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use such as:
 - a. Contraindications as listed in the criteria for initial therapy section
 - b. Venous thromboembolism (DVT, PE)
 - c. Arterial thromboembolism (MI, CVA)

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- d. Grade 4 rash, exfoliative or bullous rash, or other serious cutaneous reactions such as Stevens-Johnson syndrome, toxic epidermal necrolysis, or drug reaction with eosinophilia and systemic symptoms
 - e. Liver failure
 - f. Tumor lysis syndrome
 - g. Neutropenia and other hematologic toxicity
 - h. Platelet count is less than 25,000/mcL
5. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] ([see Definitions section](#))
6. Individual's dose is at least 1 mg daily

Renewal duration: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of Non-Cancer Medications**
2. **Off-Label Use of Cancer Medications**

Description:

Pomalyst (pomalidomide) is a thalidomide analogue, **used in combination with dexamethasone, is indicated for the treatment of 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 the last therapy. Pomalyst (pomalidomide) is also indicated for **adult patients with AIDS-related Kaposi sarcoma (KS) after failure of highly active antiretroviral therapy (HAART) and for adults with KS who are HIV-negative**. This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Pomalidomide is an immunomodulatory agent with antineoplastic activity. In *in vitro* cellular assays, pomalidomide inhibited proliferation and induced apoptosis of hematopoietic tumor cells. Additionally, pomalidomide inhibited the proliferation of lenalidomide-resistant MM cell lines and synergized with dexamethasone in both lenalidomide-sensitive and lenalidomide-resistant cell lines to induce tumor cell apoptosis. Pomalidomide enhanced T-cell and natural killer (NK) cell-mediated immunity and inhibited production of pro-inflammatory cytokines (e.g., TNF- α and IL-6) by monocytes.

Use of Pomalyst (pomalidomide) is subject to a Risk Evaluation and Mitigation Strategies (REMS) program that requires provider, patient, and dispensing pharmacy be enrolled into the program. Only providers and Pharmacies enrolled into the REMS may prescribe and dispense the drug, respectively, to individuals who are also in the program. A REMS program attempts to manage known or potentially serious risks associated with a drug product

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and is required by the Food and Drug Administration (FDA) for some drugs to ensure that the benefits of a drug outweigh its risks.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
[MedWatch Forms for FDA Safety Reporting | FDA](#)

Pomalyst (pomalidomide) REMS items:

- Enrollment and agreement information
- Treatment initiation information
- Treatment maintenance information
- Pharmacy requirements and responsibilities
- Counseling on contraception and avoidance of pregnancy
- Pregnancy testing in females of childbearing potential
- Counseling on serious risks, warnings, and precautions and safe use

Proteasome inhibitors:

- Velcade (bortezomib)
- Kyprolis (carfilzomib)
- Ninlaro (ixazomib)

ECOG Performance status:

Eastern Co-operative Oncology Group (ECOG) Performance Status	
Grade	ECOG description
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours
3	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
4	Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
5	Dead
Oken, M.M., Creech, R.H., Tormey, D.C., Horton, J., Davis, T.E., McFadden, E.T., Carbone, P.P.: Toxicity And Response Criteria Of The Eastern Cooperative Oncology Group. Am J Clin Oncol 5:649-655, 1982	

NCCN recommendation definitions:

Category 1:

Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

Category 2A:

Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

Category 2B:

Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.

Category 3:

Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.



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Resources:

Pomalyst (pomalidomide) product information, revised by Celgene Corporation 02-2025. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed May 09, 2025.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Multiple Myeloma Version 2.2025. Updated April 11, 2025. Available at <https://www.nccn.org>. Accessed May 09, 2025.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Kaposi Sarcoma Version 2.2025. Updated January 14, 2025. Available at <https://www.nccn.org>. Accessed May 09, 2025.

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.

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