BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

POMALYST® (pomalidomide) oral

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 precertification 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) 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. Use in combination with dexamethasone, for treatment of multiple myeloma who have received at least **two prior therapies** including lenalidomide and a proteasome inhibitor such as Velcade (bortezomib), Kyprolis (carfilzomib) or Ninlaro (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. The individual has received and completed **ALL** the following **baseline tests** before initiation of treatment and with continued monitoring of the individual 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. There are **NO** FDA-label contraindications, such as pregnancy.

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Pomalyst (pomalidomide) 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's condition has responded while on therapy with response defined as **ALL** of the following:
   a. No evidence of disease progression
   b. Documented evidence of efficacy, disease stability and/or improvement

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. Significant adverse effect such as:
      i. Venous thromboembolism (DVT, PE)
      ii. Arterial thromboembolism (MI, CVA)
      iii. Allergic reaction (angioedema, skin exfoliation, bullae, anaphylaxis
      iv. Liver failure
      v. Tumor lysis syndrome
      vi. Severe cutaneous reactions such as Stevens-Johnson syndrome, toxic epidermal necrolysis, or drug reaction with eosinophilia and systemic symptoms
      vii. Neutropenia
      viii. Platelet count is less than 25,000/mcL

5. Individual's dose is at least 1 mg daily

PHARMACY COVERAGE GUIDELINE

POMALYST® (pomalidomide) oral

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 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:

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

PHARMACY COVERAGE GUIDELINE

POMALYST® (pomalidomide) oral

Proteasome inhibitors:

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

Resources:

Pomalyst (pomalidomide) product information, revised by Celgene Corporation 10-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed August 04, 2022.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Multiple Myeloma Version 5.2022 – Updated March 09, 2022. Available at https://www.nccn.org. Accessed August 04, 2022.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Kaposi Sarcoma Version 1.2022 – Updated February 03, 2022. Available at https://www.nccn.org. Accessed August 04, 2022.

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.