BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 1/01/2016**
SECTION: DRUGS	**LAST REVIEW DATE: 8/19/2021**
	LAST CRITERIA REVISION DATE: 8/19/2021
	ARCHIVE DATE:

POMALYST® (pomalidomide) oral

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

POMALYST® (pomalidomide) oral

Criteria:

- **Criteria for initial therapy:** Pomalyst (pomalidomide) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation an Oncologist, Infectious Disease Specialist, or HIV Specialist

  2. Individual is 18 years of age or older

  3. 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. **ALL** of the following baseline tests have been completed before initiation of treatment with 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

  5. There are **NO** FDA-label contraindications, such as:
     a. Pregnancy

  6. There are no significant interacting drugs

  Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Pomalyst (pomalidomide) is considered ***medically necessary*** and will be approved with documentation of **ALL** of the following:

  1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation an Oncologist, Infectious Disease Specialist, or HIV Specialist

2. Individual's condition responded while on therapy
    a. Response is defined as:
        i. No evidence of disease progression
        ii. 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
    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. Platelet count is less than 25,000/mcL

5. Dose is at least 1 mg daily

6. There are no significant interacting drugs

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 a Non-cancer Medications**

    2. **Off-Label Use of a Cancer Medication for the Treatment of Cancer without a Specific Coverage Guideline**

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).

POMALYST® (pomalidomide) oral

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

Proteasome inhibitors:
- Velcade (bortezomib)
- Kyprolis (carfilzomib)
- Ninlaro (ixazomib)

Resources:

Pomalyst (pomalidomide) product information, revised by Celgene Corporation 12-2020. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed on June 24, 2021.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Multiple Myeloma Version 7.2021 – Updated April 26, 2021. Available at https://www.nccn.org. Accessed on June 24, 2021.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Kaposi Sarcoma Version 2.2021 – Updated June 07, 2021. Available at https://www.nccn.org. Accessed on June 24, 2021.

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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.