BlueCross BlueShield of Arizona
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PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 1/01/16**
SECTION: DRUGS	**LAST REVIEW DATE: 9/20/18**
	LAST CRITERIA REVISION DATE: 9/20/18
	ARCHIVE DATE:

POMALYST® (pomalidomide) oral capsule

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 capsule (cont.)

Criteria:

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

  1. Provider is an Oncologist
  2. Individual is 18 years of age or older
  3. A confirmed diagnosis of **ONE** of the following:
     - Multiple myeloma that has progressed on or within 60 days of completion of at least **two prior therapies** that included lenalidomide with a proteasome inhibitor such as Velcade (bortezomib), Kyprolis (carfilzomib) or Ninlaro (ixazomib)
     - 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, 2A, or 2B
  4. Pomalyst will be used in combination with dexamethasone
  5. **ALL** of the following baseline tests have been completed before initiation of treatment with continued monitoring as clinically appropriate:
     - Complete blood count
     - Liver function tests
  6. There are **NO** contraindications:
     - Contraindications include:
       - Pregnancy

  Initial approval duration: 6 months

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

  1. Continues to be seen by an Oncologist
  2. The multiple myeloma has not progressed while on therapy
  3. Individual has been adherent with the medication
  4. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use, such as:
     - Venous thromboembolism (DVT, PE)
     - Arterial thromboembolism (MI, CVA)
     - Allergic reaction (angioedema, skin exfoliation, bullae)

POMALYST® (pomalidomide) oral capsule (cont.)

- Liver failure
- Neuropathy
- Tumor lysis syndrome

5. There are no significant interacting drugs

Renewal duration: 12 months

Description:

Pomalyst (ponalidomide) 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.

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 (ponalidomide) 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 (ponalidomide) 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)

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Ninlaro (ixazomib)

Resources:

Pomalyst. Package Insert. Revised by manufacturer 04/2015. Accessed 08-04-2015.

Pomalyst. Package Insert. Revised by manufacturer 06/2016. Accessed 07-22-2016, 08-24-2017.

Pomalyst. Package Insert. Revised by manufacturer 05/2018. Accessed 07-19-2018.

NCCN Clinical Practice Guidelines in Oncology: Multiple myeloma. Version 3.2017, November 28, 2016. https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf

NCCN Clinical Practice Guidelines in Oncology: Multiple myeloma. Version 1.2019, July 20, 2018. https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf

UpToDate: Treatment of refractory multiple myeloma. Current through Aug 2017. https://www-uptodate-com.mwu.idm.oclc.org/contents/treatment-of-relapsed-or-refractory-multiple-myeloma?source=search_result&search=multiple%20myeloma&selectedTitle=4~150#H22

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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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:	Dosage Form:
Directions for Use:	Quantity: / Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

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Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.