PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

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Off-Label Use Of A Cancer Medication For The Treatment Of Cancer Without A Specific Pharmacy Coverage Guideline

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.

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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.**

Off-Label Use Of A Cancer Medication For The Treatment Of Cancer Without A Specific Pharmacy Coverage Guideline (cont.)

Description:

For FDA-approved indications, also known as labeled indications, the FDA has reviewed and approved the medication for the specified indications for final marketing based on adequate, well-controlled clinical trials, which have documented safety and effectiveness. The use of a medication for conditions, indications or in circumstances other than those approved by the FDA is known as "off-label use".

Off-label use of medications that have received final FDA approval for marketing may be reviewed in any of the following ways: for medical necessity and/or investigational uses; during a review of a medication that requires prior authorization, during review of a medication due a non-formulary request for coverage, or during a review for any other prescription limitations. An approved NDA (New Drug Application), ANDA (Abbreviated New Drug Application), or BLA (Biologic License Application) is considered final FDA-marketing approval for the purposes of this policy.

Off-Label Use Of A Cancer Medication For The Treatment Of Cancer Without A Specific Pharmacy Coverage Guideline

Criteria:

- **Criteria for initial therapy:** An Off-label Use of a Cancer medication for the treatment of cancer without a specific Pharmacy Coverage Guideline is considered ***medically necessary*** and will be approved when **ONE** of the following criteria are met:

1. The off-label use is recognized as safe and effective for the requested type of cancer **and** that is listed **and** supported by in **ONE** of the nationally recognized compendia or guidelines:
   - American Hospital Formulary Service
   - National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium
   - Micromedex compendium
   - Elsevier Gold Standard's Clinical Pharmacology compendium
   - American Society of Clinical Oncologist (ASCO) treatment guidelines
   - Other authoritative reference as identified by the Secretary of the United States Department of Human Health Services

2. The off-label use is established from clinical trial(s) that have been published in peer reviewed professional medical journal(s) that has been submitted by the prescriber and **ALL** of the following apply:
   - At least two articles from major peer reviewed professional medical journals have recognized, based on scientific or medical criteria, the drug's safety and effectiveness for treatment of the indication for which the drug has been prescribed
   - No article from a major peer reviewed professional medical journal has concluded, based on scientific or medical criteria, that the drug is unsafe or ineffective or that the drug's safety and effectiveness cannot be determined for the treatment of the indication for which the drug has been prescribed

Off-Label Use Of A Cancer Medication For The Treatment Of Cancer Without A Specific Pharmacy Coverage Guideline (cont.)

- The literature meets the uniform requirements for manuscripts submitted to biomedical journals established by the international committee of medical journal editors or is published in a journal specified by the United States Department of Health and Human Services as acceptable peer reviewed medical literature pursuant to section 186(t)(2)(B) of the social security act (42 United States Code section 1395x(t)(2)(B))

3. Failure, contraindication or intolerance to established therapies per NCCN is verifiably documented

Initial approval duration: 6 months with initial fills of 14 days per fill for first 3 months

- **Criteria for continuation of coverage (renewal request):** for Off-label Use of a Cancer medication for the treatment of cancer without a specific Pharmacy Coverage Guideline is considered ***medically necessary*** and will be approved with documentation of **ALL** of the following:

1. Individual continues to be seen by an Oncologist
2. The condition has not progressed or worsened while on therapy
3. The individual is adherent with the medication
4. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude to its continued use
5. There are no significant interacting drugs

Renewal duration: 12 months

Resources:

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.

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.