



PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 9/15/16
LAST REVIEW DATE: 9/20/18
LAST CRITERIA REVISION DATE: 9/21/17
ARCHIVE DATE:

Off-Label Use of Non-Cancer Medications

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.

An exception request for **Off-Label Use of a non-cancer medication** 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.**



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Off-Label Use of Non-Cancer Medications (cont.)

Criteria: An exception request for **Off-Label Use of a non-cancer medication** may be considered *medically necessary* and will be approved with **ALL** of the following criteria met:

1. The drug has been approved by the FDA for at least **ONE** other indication
2. Provider submits a diagnosis and treatment plan that includes the rationale for the exception for off-label use
3. Failure, contraindication, or intolerance to **ALL** other FDA-approved medications that are on the formulary
4. Evidence that supports the off-label use is recognized as safe and effective and is supported by **ONE** of the nationally recognized compendia, guidelines, or literature:
 - American hospital Formulary Service
 - Micromedex compendium that meet ALL of the following:
 - Strength of Recommendation of Class I or IIa
 - Strength of Evidence Category A or B
 - Strength of Efficacy Class I or IIa (evidence favors efficacy)
 - Elsevier Gold standard's Clinical Pharmacology compendium
 - Other authoritative reference as identified by the Secretary of the United States Department of Human Health Services
 - At least **TWO** articles from major peer reviewed professional medical journals that have recognized, based on scientific or medical criteria, the safety and effectiveness for the exception
5. There are no contraindications for use of the requested drug
6. There are no benefit or contract exclusions that apply

Description:

For FDA-approved indication(s), also known as labeled indication(s), the FDA has reviewed and approved the medication for the specified use(s) for 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 previously received FDA approval for marketing may be reviewed 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.



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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	
<input type="checkbox"/> Standard <input type="checkbox"/> Urgent. Sign here: _____	<input type="checkbox"/> Exigent (requires prescriber to include a written statement)

Clinical Information	
1. What is the diagnosis? Please specify below. ICD-10 Code: _____ Diagnosis Description: _____	
2. <input type="checkbox"/> Yes <input type="checkbox"/> No Was this medication started on a recent hospital discharge or emergency room visit?	
3. <input type="checkbox"/> Yes <input type="checkbox"/> 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

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

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