BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 5/20/2021
LAST REVIEW DATE: 5/19/2022
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UKONIQ™ (umbralisib) 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.**

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Criteria:

- **Criteria for initial therapy:** Ukoniq (umbralisib) 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 with an Oncologist

  2. Individual is 18 years of age or older

  3. A confirmed diagnosis of **ONE** of the following:
     a. Relapsed or refractory marginal zone lymphoma (MZL) who have received at least **one** prior anti-CD20-based regimen

     b. Relapsed or refractory follicular lymphoma (FL) who have received at least **three** prior lines of systemic therapy

     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. Documentation of a negative pregnancy test in a woman of childbearing potential
     b. Eastern Cooperative Oncology Group (ECOG) Performance Status of 0-1

  5. There is documentation of prophylaxis for *pneumocystis jirovecii* pneumonia during treatment with Ukoniq (umbralisib)

  6. There is documentation of prophylactic antivirals during treatment with UKONIQ to prevent cytomegalovirus (CMV) infection, including CMV reactivation in patients with a history of CMV infection

  7. Individual does not have moderate (total bilirubin greater than1.5-3 times the upper limit of normal (ULN) and any aspartate aminotransaminase (AST)) or severe hepatic impairment (total bilirubin greater than 3 times ULN and any AST

  Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Ukoniq (umbralisib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Oncologist

  2. Individual's condition has responded while on therapy
     a. Response is defined as:

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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. Requested dose is at least 400 mg daily

5. Individual has not developed any significant adverse drug effects that may exclude continued use
   a. Significant adverse effect such as:
      i. Severe and persistent neutropenia
      ii. Recurrent or severe or life-threatening diarrhea or non-infectious colitis
      iii. Hepatotoxicity
      iv. Severe or life-threatening cutaneous reactions that do not improve, worsen, or recur
      v. Any grade Stevens-Johnson syndrome or toxic epidermal necrolysis or drug reaction with eosinophilia and systemic symptoms
      vi. Any other adverse reaction that is life-threatening
      vii. Confirmed *pneumocystis jirovecii* pneumonia

6. There are no significant interacting drugs

7. Individual does not have moderate (total bilirubin greater than1.5-3 times the upper limit of normal (ULN) and any aspartate transaminase (AST)) or severe hepatic impairment (total bilirubin greater than 3 times ULN and any AST

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:

Ukoniq (umbralisib) inhibits multiple kinases and is indicated for the treatment of adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based regimen and it is also indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) who have received at least three prior lines of systemic therapy.

These indications are approved under accelerated approval based on overall response rate. Continued approval for these indications may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

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Resources:

Ukoniq (umbralisib) product information, revised by TG Therapeutics, Inc. 02-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed May 13, 2022.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): B-Cell Lymphomas Version 3.2022 – Updated April 25, 2022. Available at https://www.nccn.org. Accessed May 13, 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.