BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

PIQRAY® (alpelisib) oral

This Pharmacy Coverage Guideline (PCG):

- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope

- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance

- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require precertification is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

- **Criteria for initial therapy:** Piqray (alpelisib) is considered ***medically necessary*** and will be approved when **ALL** 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. Individual has a confirmed diagnosis of **ONE** of the following:
     a. In combination with fulvestrant (brand Faslodex or generic) for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer following progression on or after an endocrine-based regimen

b. 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. The individual has received and completed **ALL** the following **baseline tests** before initiation of treatment and with continued monitoring of the individual as clinically appropriate:
    a. Fasting plasma glucose
    b. Hemoglobin A1c
    c. Negative pregnancy test in a woman of child-bearing potential
    d. Eastern Cooperative Oncology Group (ECOG) performance status is 0 or 1
    e. Presence of one or more PIK3CA mutations in tumor tissue or plasma specimens (if no mutation is detected in plasma specimens, test tumor tissue)

5. Individual does not have a history of Stevens-Johnson syndrome, erythema multiforme, or toxic epidermal necrolysis

6. Individual does not have type 1 diabetes mellitus or uncontrolled type 2 diabetes mellitus

7. Individual does not have severe renal impairment (creatinine clearance of less than 30 mL/min)

8. Individual is not using strong CYP3A4 inducer drugs (ex., carbamazepine, phenobarbital, phenytoin, rifampin, others)

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Piqray (alpelisib) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met **(samples are not considered for continuation of therapy**):

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 with response defined as **ALL** of the following:
    a. No evidence of disease progression
    b. Documented evidence of efficacy, disease stability and/or improvement

3. Individual has been adherent with the medication

4. Individual has not developed any significant adverse drug effects that may exclude continued use such as:
    a. Severe hypersensitivity
    b. Stevens-Johnson syndrome
    c. Erythema multiforme
    d. Toxic epidermal necrolysis
    e. Drug reaction with eosinophilia and systemic symptoms (DRESS)
    f. Severe hyperglycemia, despite treatment
    g. Ketoacidosis
    h. Pneumonitis/Interstitial lung disease

i. Severe diarrhea, despite anti-diarrheal agents
j. Severe colitis with abdominal pain, mucous or blood in stool

5. Individual's dose is at least 200 mg daily

6. Individual does not have type 1 diabetes mellitus or uncontrolled type 2 diabetes mellitus

7. Individual does not have severe renal impairment (creatinine clearance of less than 30 mL/min)

8. Individual is not using strong CYP3A4 inducer drugs (ex., carbamazepine, phenobarbital, phenytoin, rifampin, others)

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:

Piqray (alpelisib) is indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test, following progression on or after an endocrine-based regimen.

In breast cancer cell lines, alpelisib inhibited phosphorylation of phosphatidylinositol-3-kinase (PI3K). It has inhibitory activity predominantly against PI3Kα and showed activity in cell lines harboring a PIK3CA mutation. PI3K inhibition by alpelisib treatment has been shown to induce an increase in estrogen receptor (ER) transcription in breast cancer cells.

Resources:

Piqray (alpelisib) product information, revised by Novartis Pharmaceuticals Corporation 05-2022. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed August 04, 2022.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Breast Cancer Version 4.2022 – Updated June 21, 2022. Available at https://www.nccn.org. Accessed August 04, 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.