



An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES  
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 8/15/2019  
LAST REVIEW DATE: 8/19/2021  
LAST CRITERIA REVISION DATE: 8/19/2021  
ARCHIVE DATE:

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## PIQRAY® (alpelisib) oral

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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](http://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](mailto:Pharmacyprecert@azblue.com). **Incomplete forms or forms without the chart notes will be returned.**



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### Criteria:

- **Criteria for initial therapy:** Piqray (alpelisib) 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. 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. **ALL** of the following baseline tests have been completed before initiation of treatment with continued monitoring 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
  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. There are no significant interacting drugs

**Initial approval duration:** 6 months

- **Criteria for continuation of coverage (renewal request):** Piqray (alpelisib) 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 responded while on therapy
    - a. Response is defined as:
      - i. No evidence of disease progression
      - ii. Documented evidence of efficacy, disease stability and/or improvement



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3. Individual has been adherent with the medication
4. Individual has not developed any significant adverse drug effects that may exclude continued use
  - a. Significant adverse effect such as:
    - i. Severe hypersensitivity
    - ii. Stevens-Johnson syndrome
    - iii. Erythema multiforme
    - iv. Toxic epidermal necrolysis
    - v. Drug reaction with eosinophilia and systemic symptoms (DRESS)
    - vi. Severe hyperglycemia, despite treatment
    - vii. Ketoacidosis
    - viii. Pneumonitis/Interstitial lung disease
    - ix. Severe diarrhea, despite anti-diarrheal agents
5. Dose is at least 200 mg daily
6. Individual does not have type 1 diabetes mellitus or uncontrolled type 2 diabetes mellitus
7. There are no significant interacting drugs

**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 a Non-cancer Medications**
  2. **Off-Label Use of a Cancer Medication for the Treatment of Cancer without a Specific Coverage Guideline**

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### **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 PI3K $\alpha$  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.



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### Resources:

Piqray (alpelisib) product information, revised by Novartis Pharmaceuticals Corporation 09-2020. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed on June 24, 2021.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Breast Cancer Version 4.2021 – Updated April 28, 2021. Available at <https://www.nccn.org>. Accessed on June 23, 2021.

National Comprehensive Cancer Network (NCCN) Compendium: Piqray. National Comprehensive Cancer Network (NCCN). NCCN Drugs & Biologics Compendium. Available at: <http://www.nccn.org>. Accessed on June 24, 2021.

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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