BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

AKEEGA™ (niraparib & abiraterone) oral Generic Equivalent (if available)

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 prior authorization 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:** Akeega (niraparib & abiraterone) and/or generic equivalent (if available) 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. Deleterious or suspected deleterious BRCA-mutated (*BRCAm*) metastatic castration-resistant prostate cancer (mCRPC)

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. Akeega (niraparib and abiraterone) will be used with a corticosteroid (e.g., prednisone)

5. Individual should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy

6. Individual has completed **ALL** the following **baseline tests** before initiation of treatment and will have continued monitoring as clinically appropriate:
   a. *BRCA* gene alteration is present
   b. Blood pressure is controlled
   c. Potassium level is within normal limits or hypokalemia has been corrected
   d. Serum transaminases (ALT and AST) and bilirubin levels
   e. Eastern Cooperative Oncology Group (ECOG) status of 0 or 1

7. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

8. Individual is not currently taking any other drugs which may cause severe adverse reactions or a significant drug interaction requiring discontinuation such as use with strong CYP3A4 inducers (e.g., rifampin, rifabutin, phenobarbital, carbamazepine, others)

9. Individual does not have New York Heart Association (NYHA) Class II to IV heart failure

10. Individual does not have moderate or severe hepatic impairment

11. Individual does not have severe renal impairment (CrCl: 15–30 mL/min)

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Akeega (niraparib & abiraterone) and/or generic equivalent (if available) 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 has documentation of positive clinical response to therapy defined as there is no evidence of disease progression and there is no evidence of unacceptable toxicity

3. Individual has been adherent with the medication

4. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic

should be reported to the FDA] (see Definitions section)

5. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use such as:
    a. Hemoglobin remains less than 8 g/dL within 28 days of dose interruption or the individual has already undergone dose reduction to 100/1000 mg daily
    b. Platelet count remains less than 100,000/mcL within 28 days of dose interruption or the individual has already undergone dose reduction to 100/1000 mg daily
    c. Neutrophil count remains less than 1,000/mcL within 28 days of dose interruption or the individual has already undergone dose reduction to 100/1000 mg daily
    d. Hepatotoxicity is **ONE** of the following:
        i. ALT or AST ≥ 20 times the ULN
        ii. ALT > 3 × ULN and total bilirubin > 2 × ULN in the absence of biliary obstruction or other causes responsible for the concurrent elevation
        iii. Toxicity recurs at the reduced dose 100 mg/500 mg
    e. Non-hematological adverse reactions that persist despite medical management or has recurred after dose reduction
    f. Hypertensive crisis or other severe cardiovascular adverse reaction
    g. Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML)
    h. Posterior Reversible Encephalopathy Syndrome (PRES)

6. Individual is not currently taking any other drugs which may cause severe adverse reactions or a significant drug interaction requiring discontinuation such as use with strong CYP3A4 inducers (e.g., rifampin, rifabutin, phenobarbital, carbamazepine, others)

7. Individual does not have New York Heart Association (NYHA) Class II to IV heart failure

8. Individual does not have moderate or severe hepatic impairment

9. Individual does not have severe renal impairment (CrCl: 15–30 mL/min)

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:

Akeega (niraparib & abiraterone) a combination of niraparib, a poly (ADP-ribose) polymerase (PARP) inhibitor, and abiraterone acetate, a CYP17 inhibitor indicated with prednisone for the treatment of adult patients with

deleterious or suspected deleterious BRCA-mutated (*BRCAm*) metastatic castration-resistant prostate cancer (mCRPC). Select patients for therapy based on an FDA-approved test for Akeega.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

ECOG Performance status:

Eastern Co-operative Oncology Group (ECOG) Performance Status	
Grade	ECOG description
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours
3	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
4	Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
5	Dead
Oken, M.M., Creech, R.H., Tormey, D.C., Horton, J., Davis, T.E., McFadden, E.T., Carbone, P.P.: Toxicity And Response Criteria Of The Eastern Cooperative Oncology Group. Am J Clin Oncol 5:649-655, 1982	

NCCN recommendation definitions:

Category 1:
Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

Category 2A:
Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

Category 2B:
Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.

Category 3:
Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate

Resources:

Akeega (niraparib & abiraterone) product information, revised by Janssen Biotech, Inc. 08-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed July 24, 2025.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Prostate Cancer Version 2.2026 –Updated September 15, 2025. Available at https://www.nccn.org. Accessed October 06, 2025.

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.