# Clinical Policy: Niraparib/Abiraterone Acetate (Akeega)

Reference Number: CP.PHAR.645
Effective Date: 12.01.23
Last Review Date: 11.26
Line of Business: Commercial, HIM/ICHRA, Medicaid

Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

## Description

Niraparib/abiraterone acetate (Akeega™) is a combination of a poly (ADP-ribose) polymerase (PARP) inhibitor and a CYP17 inhibitor.

## FDA Approved Indication(s)

Akeega is indicated with prednisone for the treatment of adult patients with:

- Deleterious or suspected deleterious BRCA2-mutated (BRCA2m) metastatic castration-sensitive prostate cancer (mCSPC).
- 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.

## Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results, or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation® that Akeega is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Prostate Cancer** (must meet all)**:**

1. Diagnosis of mCRPC or mCSPC;
2. Prescribed by or in consultation with an oncologist or urologist;
3. Age ≥ 18 years;
4. Documentation of one of the following deleterious or suspected deleterious germline or somatic mutations as confirmed on a CLIA approved diagnostic test (e.g., Foundation One CDx, or BRAC Analysis CDx):
   a. For mCRPC: BRCA1 or BRCA2;
   b. For mCSPC: BRCA2;
5. Akeega is prescribed in combination with prednisone;
6. For brand Akeega requests, member must use generic niraparib/abiraterone acetate, if available, unless contraindicated or clinically significant adverse effects are experienced;
7. Prescribed concurrently with a gonadotropin-releasing hormone (GnRH) analog or member has had a bilateral orchiectomy;
8. Member has not previously received a PARP inhibitor (e.g., Lynparza®, Rubraca®, Talzenna®, Zejula®);

9. Request meets one of the following (a or b):*
    a. Dose does not exceed both of the following (i and ii):
        i. 200 mg niraparib/1,000 mg abiraterone acetate per day;
        ii. 2 tablets per day;
    b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration:**
**Medicaid/HIM/ICHRA** – 12 months
**Commercial –** 12 months or duration of request, whichever is less

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
    a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
    b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

## II. Continued Therapy

**A. Prostate Cancer** (must meet all)**:**

1. Currently receiving medication via Centene benefit or documentation supports that member is currently receiving Akeega for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. For brand Akeega requests, member must use generic niraparib/abiraterone acetate, if available, unless contraindicated or clinically significant adverse effects are experienced;
4. If request is for a dose increase, request meets one of the following (a or b):*
    a. New dose does not exceed both of the following (i and ii):
        i. 200 mg niraparib/1,000 mg abiraterone acetate per day;
        ii. 2 tablets per day;
    b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration:**
**Medicaid/HIM/ICHRA –** 12 months

**Commercial –** 12 months or duration of request, whichever is less

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

## III. Diagnoses/Indications for which coverage is NOT authorized:

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid or evidence of coverage documents.

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*

ADP: adenosine diphosphate
ADT: androgen deprivation therapy
AML: acute myeloid leukemia
BRCA: breast cancer gene
CLIA: Clinical Laboratory Improvement Amendments
FDA: Food and Drug Administration
gBRCAm: mutations in the germline BRCA genes
GnRH: gonadotropin-releasing hormone
HRR: homologous recombination repair
LHRH: luteinizing hormone-releasing hormone
mCRPC: metastatic castration-resistant prostate cancer
mCSPC: metastatic castration-sensitive prostate cancer
MDS: myelodysplastic syndrome
NCCN: National Comprehensive Cancer Network
PARP: poly (ADP-ribose) polymerase

*Appendix B: Therapeutic Alternatives*

Not applicable

*Appendix C: Contraindications/Boxed Warnings*

None reported

*Appendix D: General Information*

- The FDA approved Akeega with a genetic test called BRAC Analysis CDx, a companion diagnostic that will detect the presence of gBRCAm in blood samples from patients with ovarian and breast cancer. Additional information is available at http://www.fda.gov/companiondiagnostics.
- CRPC is prostate cancer that progresses clinically, radiographically, or biochemically despite castrate levels of serum testosterone (< 50 ng/dL). Per NCCN guidelines for the treatment of prostate cancer, androgen deprivation therapy (ADT) should be continued in the setting of CRPC while additional therapies are applied.
- Examples of ADT include:
  - Bilateral orchiectomy (surgical castration)
  - Luteinizing hormone-releasing hormone (LHRH) given with or without an antiandrogen:
    - LHRH (or GnRH) agonists: Zoladex® (goserelin), Vantas® (histrelin), leuprolide (Lupron Depot®, Eligard®), and Trelstar® (triptorelin)
    - Anti-androgens: bicalutamide (Casodex®), flutamide, nilutamide (Nilandron®), Xtandi (enzalutamide), Erleada® (apalutamide)
  - LHRH antagonist: Firmagon® (degarelix), Orgovyx® (relugolix)
- There is insufficient data regarding the use of consecutive PARP inhibitors. Most PARP inhibitor pivotal trials excluded prior PARP inhibitor use, the NCCN does not make any explicit recommendations (other than for ovarian cancer, where they state data is limited), and there are no randomized controlled trials evaluating such use.

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| mCRPC | 200 mg niraparib/1,000 mg abiraterone acetate PO QD in combination with 10 mg prednisone daily | 200 mg niraparib/1,000 mg abiraterone acetate per day |
| mCSPC | 200 mg niraparib/1,000 mg abiraterone acetate PO QD in combination with 5 mg prednisone daily | 200 mg niraparib/1,000 mg abiraterone acetate per day |

## VI. Product Availability

Tablets: 50 mg niraparib/500 mg abiraterone acetate, 100 mg niraparib/500 mg abiraterone acetate

## VII. References

1. Akeega Prescribing Information. Horsham, PA: Janssen Biotech, Inc; December 2025. Available at: www.akeega.com. Accessed July 9, 2026.
2. National Comprehensive Cancer Network. Prostate Cancer Version 5.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed July 16, 2026
3. Chi KN, Rathkopf D, Smith MR, et al. Niraparib and abiraterone acetate for metastatic castration-resistant prostate cancer. J Clin Oncol. 2023; 41:3339-3351.
4. Attard G, Agarwal N, Graff JN, et al. Niraparib and abiraterone acetate plus prednisone for HRR-deficient metastatic castration-sensitive prostate cancer: a randomized phase 3 trial. Nat Med. 2025 Dec; 31(12): 4109-4118. doi: 10.1038/s41591-025-03961-8.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Policy created | 08.29.23 | 11.23 |
| 4Q 2024 annual review: removed off-label use in those with "documentation of disease progression despite bilateral orchiectomy or other androgen deprivation therapy (ADT)" per NCCN; references reviewed and updated. | 07.11.24 | 11.24 |
| 4Q 2025 annual review: no significant changes; extended initial approval duration from 6 to 12 months for Medicaid/HIM; references reviewed and updated. | 07.10.25 | 11.25 |
| RT4: added new indication in BRCA2-mutated mCSPC. | 01.14.26 | |
| 4Q 2026 annual review: added ICHRA line of business; references reviewed and updated. | 07.09.26 | 11.26 |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**Note:**
**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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