Clinical Policy: Niraparib and Abiraterone Acetate (Akeega)

Reference Number: CP.PHAR.645
Effective Date: 12.01.23
Last Review Date: 11.23
Line of Business: Commercial, HIM, Medicaid

Revision Log

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

Description

Niraparib and 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 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 metastatic castration-resistant prostate cancer (mCRPC);
2. Prescribed by or in consultation with an oncologist or urologist;
3. Age ≥ 18 years;
4. Documentation of a deleterious or suspected deleterious germline or somatic BRCA 1/2 mutation as confirmed on a CLIA approved diagnostic test (e.g., Foundation One CDx, or BRAC Analysis CDx);
5. One of the following (a or b):
   a. Member has BRCA 1/2 mutation, and Akeega is prescribed in combination with prednisone;
   b. Documentation of disease progression despite bilateral orchiectomy or other androgen deprivation therapy (ADT) (*see Appendix D*);
6. For brand Akeega requests, member must use generic niraparib/abiraterone, 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., 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 – 6 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) 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, and CP.PMN.255 for Medicaid; or
    b. For drugs NOT on the formulary (commercial, health insurance marketplace) 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, 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, 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, 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. 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 – 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) 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, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) 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, 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, 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, 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
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
MDS: myelodysplastic syndrome
NCCN: National Comprehensive Cancer Network
PARP: poly (ADP-ribose) polymerase

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
olaparib (Lynparza®) + abiraterone (Zytiga®) + prednisone	olaparib 300 mg PO BID + abiraterone 1,000 mg PO QD + prednisone 5 mg PO BID	olaparib 600 mg/day + abiraterone 1,000 mg/day + prednisone 10 mg/day; 2,000 mg/day if taking a strong CYP3A4 inducer
talazoparib (Talzenna™) + enzalutamide (Xtandi®)	talazoparib 0.5 mg PO QD + enzalutamide 160 mg PO QD For talazoparib renally adjust as follows: • If moderate renal impairment (CrCl 30 – 59 mL/min): 0.35 mg PO QD • If severe renal impairment (CrCl 15 – 29 mL/min): 0.25 mg PO QD	talazoparib 0.5 mg/day + enzalutamide 160 mg/day; 240 mg/day if taking a strong CYP3A4 inducer

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

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, 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

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; August 2023. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216793s000lbl.pdf. Accessed August 24, 2023
2. National Comprehensive Cancer Network. Prostate Cancer Version 3.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed August 24, 2023.
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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	08.29.23	11.23

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.