



PRIOR AUTHORIZATION POLICY

- POLICY:** Oncology – Akeega Prior Authorization Policy
- Akeega™ (niraparib and abiraterone acetate tablets – Janssen Biotech)

REVIEW DATE: 08/30/2023

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Akeega is a combination of niraparib, a poly (ADP-ribose) polymerase (PARP) inhibitor, and abiraterone acetate, a cytochrome P450 (CYP)17 inhibitor, indicated with prednisone for the treatment of deleterious or suspected deleterious BReast CAncer (BRCA)-mutated (**BRCAm**) **metastatic castration-resistant prostate cancer** (mCRPC) in adults.¹

GUIDELINES

National Comprehensive Cancer Network (NCCN) guidelines for prostate cancer (version 3.2023 – August 7, 2023) do not include Akeega yet.² In the first-line setting for mCRPC, the “preferred” regimens are abiraterone, docetaxel, or Xtandi® (enzalutamide tablets and capsules) [all category 1]; the following regimens are listed as “useful in certain circumstances”: Lynparza® (olaparib tablets) + abiraterone for patients with *BRCAm* (category 1) and Talzenna® (talazoparib capsules) + Xtandi for patients with *HRRm* (category 1).

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Akeega. All approvals are provided for the duration noted below.

- **Akeega™ (niraparib and abiraterone acetate tablets – Janssen Biotech)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. Prostate Cancer. Approve for 1 year if the patient meets the following (A, B, C, D, and E):

- A)** Patient is ≥ 18 years of age; AND
- B)** Patient has metastatic castration-resistant prostate cancer; AND
- C)** Patient has a BReast Cancer (*BRCA*) mutation; AND
- D)** The medication is used in combination with prednisone; AND
- E)** Patient meets one of the following (i or ii):
 - i.** The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog; OR
Note: Examples are leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix acetate subcutaneous injection), and Orgovyx (relugolix tablets).
 - ii.** Patient has had a bilateral orchiectomy.

CONDITIONS NOT COVERED

- **Akeega™ (niraparib and abiraterone acetate tablets – Janssen Biotech)**

is(are) considered experimental, investigational or unproven for ANY other use(s).

REFERENCES

1. Akeega™ tablets [prescribing information]. Horsham, PA: Janssen; August 2023.
2. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 3.2023 – August 7, 2023). © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on August 17, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	08/30/2023

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