PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Oral – Poly [ADP-Ribose] Polymerase Inhibitor) – Akeega Prior Authorization Policy
- Akeega® (niraparib and abiraterone acetate tablets – Janssen Biotech)

REVIEW DATE: 12/17/2025

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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. 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 (*BRCA2*)-mutated (***BRCA2m***) **metastatic castration-sensitive prostate cancer** (mCSPC) in adults;
- Deleterious or suspected deleterious BReast CAncer (*BRCA*)-mutated (***BRCAm***) **metastatic castration-resistant prostate cancer** (mCRPC) in adults.

Guidelines

National Comprehensive Cancer Network (NCCN) guidelines for prostate cancer (version 4.2026 – December 4, 2025) recommend Akeega in combination with prednisone for patients with mCRPC with *BRCA1 or 2* mutation as "useful in certain circumstances" pre-androgen receptor pathway inhibitor (ARPI) therapy (category 1) or post-ARPI and pre-docetaxel therapy (category 2B). ARPI therapies include abiraterone, Xtandi® (enzalutamide capsules or tablet), Nubeqa® (darolutamide tablet), or Erleada® (apalutamide tablet).[2] The guidelines state to continue androgen deprivation therapy (ADT) to maintain castrate levels of serum testosterone (<50 ng/dL).

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 Indications

1. **Prostate Cancer, Metastatic, Castration-Resistant.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has a BReast CAncer (*BRCA)* mutation; AND
   - **C)** The medication is used in combination with prednisone; AND
   - **D)** 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.

2. **Prostate Cancer, Metastatic, Castration-Sensitive.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has BReast CAncer (*BRCA2)* mutation; AND
   - **C)** The medication is used in combination with prednisone; AND
   - **D)** 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 not medically necessary for ANY other use(s); criteria will be updated as new published data are available.

REFERENCES

1. Akeega® tablets [prescribing information]. Horsham, PA: Janssen; December 2025.
2. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 2.2025 – April 16, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 15, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	08/30/2023
Annual Revision	No criteria changes.	06/19/2024
Update	04/08/2025: The policy name was changed from "Oncology – Akeega PA Policy" to "Oncology (Oral – Poly [ADP-Ribose] Polymerase Inhibitor) – Akeega PA Policy".	N/A
Annual Revision	No criteria changes.	06/18/2025
Early Annual Revision	**Prostate Cancer, Metastatic, Castration-Resistant.** The criteria requirement of metastatic castration resistant was moved into the condition of approval. **Prostate Cancer, Metastatic, Castration-Sensitive:** New condition of approval was added under "FDA approved indication" section.	12/17/2025