PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 06/19/2024

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 4.2024 – May 17, 2024) recommend Akeega for patients with mCRPC with *BRCA* mutation as "useful in certain circumstances" in the following situations: no prior docetaxel and no prior novel hormone therapy (category 1); progression on prior docetaxel and no prior hormone therapy (category 2A); progression on prior novel hormone therapy and no prior docetaxel (category 2B).[2] There is a footnote which states: Akeega is a treatment option for patients with mCRPC and a pathogenic *BRCA1* or *BRCA2* mutation (germline and/or somatic) who have not yet had treatment in the setting of mCRPC, depending on prior treatment in other disease settings. Use of Akeega for those who have received prior novel hormone therapy is controversial because a benefit of this combination over use of a PARP inhibitor alone has not been shown in this setting, but responses are likely. The fine-particle formulation of abiraterone can be given with single-agent niraparib as a substitute for the combination Akeega tablet (category 2B; other recommended option).

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

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Akeega is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Prostate Cancer.** Approve for 1 year if the patient meets ALL of 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 RECOMMENDED FOR APPROVAL

Coverage of Akeega is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Akeega™ tablets [prescribing information]. Horsham, PA: Janssen; August 2023.
2. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 4.2024 – May 17, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 17, 2024.