

## PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology – Akeega Prior Authorization Policy

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

**REVIEW DATE:** 08/30/2023

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### 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.<sup>1</sup>

### GUIDELINES

National Comprehensive Cancer Network (NCCN) guidelines for prostate cancer (version 3.2023 – August 7, 2023) do not include Akeega yet.<sup>2</sup> 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.

**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 the following (A, B, C, D, and E):
  - A) Patient is  $\geq 18$  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

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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 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