

Specialty Guideline Management

Akeega

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Akeega	niraparib and abiraterone acetate

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications¹

Akeega is indicated with prednisone for the treatment of adult patients with deleterious or suspected deleterious breast cancer gene [BRCA-mutated (BRCAm)] metastatic castration-resistant prostate cancer (mCRPC). Select patients for therapy based on an FDA-approved test for Akeega.

Compendial Use²

Prostate Cancer

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Documentation of laboratory report confirming BRCA mutation status.

Coverage Criteria

Prostate Cancer^{1,2}

Authorization of 12 months may be granted for treatment of metastatic castration-resistant prostate cancer when all of the following criteria are met:

- The disease has deleterious or suspected deleterious BRCA mutation
- The member has had a bilateral orchiectomy or will be using the requested medication in combination with a luteinizing hormone-releasing hormone (LHRH) agonist (e.g., goserelin, leuprolide) or antagonist (e.g., degarelix, relugolix).
- The requested medication will be used in combination with prednisone

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Akeega [package insert]. Horsham, PA: Janssen Biotech, Inc.; August 2023.
2. The NCCN Drugs & Biologics Compendium™ © 2024 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed December 17, 2024.