UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 1421-4
Program	Prior Authorization/Notification
Medication	Akeega® (niraparib and abiraterone acetate)
P&T Approval Date	11/2023, 11/2024, 11/2025, 2/2026
Effective Date	5/1/2026

1. Background:

Akeega (niraparib and abiraterone acetate) is a combination of niraparib, a poly (ADP-ribose) polymerase (PARP) inhibitor, and abiraterone acetate, a CYP17 inhibitor indicated with prednisone for the treatment of adult patients with deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC) or metastatic castration-sensitive prostate cancer (mCSPC). Select patients for therapy based on an FDA-approved test for Akeega.

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. <u>Patients less than 19 years of age</u>

1. **Akeega** will be approved based on the following criterion:

   a. Member is less than 19 years of age

   Authorization will be issued for 12 months.

B. <u>Initial Authorization</u>

1. **Akeega** will be approved based on **<u>all</u>** of the following criteria:

   a. Diagnosis of one of the following:
      (1) Metastatic castration-resistant prostate cancer (mCRPC)
      (2) Metastatic castration-sensitive prostate cancer (mCSPC)

   -AND-

   b. Deleterious or suspected deleterious BRCA-mutated (BRCAm)

   -AND-

c. Used in combination with prednisone

Authorization will be issued for 12 months.

C. Reauthorization

1. **Akeega** will be approved based on the following criterion:

   a. Patient does not show evidence of progressive disease while on Akeega therapy

   Authorization will be issued for 12 months.

D. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Akeega [package insert]. Horsham, PA: Janssen Biotech, Inc.; December 2025.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed January 7, 2026.

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Change Control	
11/2023	New program
11/2024	Annual review. No changes to criteria. Updated references.
11/2025	Annual review. No changes to clinical criteria. Updated references.

2/2026	Added criteria for metastatic castration-sensitive prostate cancer (mCSPC). Updated background and references.