



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3179-1
Program	Step Therapy
Medication	Akeega™ (niraparib and abiraterone acetate)
P&T Approval Date	3/2024
Effective Date	6/1/2024

1. Background:

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a patient trial of or contraindication to Lynparza® (olaparib) before providing coverage for Akeega (niraparib and abiraterone acetate).

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).¹

Lynparza® (olaparib) is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated in combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with deleterious or suspected deleterious BRCA-mutated (BRCAm) mCRPC.²

Members currently on Akeega therapy as documented in claims history will be allowed to continue on their current therapy. Members new to therapy will be required to meet the coverage criteria below.

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,b}:

A. Patients less than 19 years of age

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

a. Patient is less than 19 years of age

Authorization will be issued for 12 months.

B. Prostate Cancer

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

- a. Diagnosis of deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC).

-AND-

- b. Used in combination with prednisone

-AND-

c. **One** of the following:

- (1) History of failure, contraindication, or intolerance to Lynparza (olaparib) in combination with abiraterone and prednisone or methylprednisolone

-OR-

(2) **Both** of the following:

- (a) As continuation of therapy

-AND-

- (b) Patient has **not** received a manufacturer supplied sample at no cost in prescriber office, or any form of assistance from the Janssen sponsored Janssen CarePath program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Akeega*

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from Janssen sponsored Janssen CarePath program shall be required to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

C. Other Indications

1. **Akeega** will be approved

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.

^b Coverage of oncology medications may be approved based on state mandates.

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 and/or Notification may be in place.
- Coverage of oncology medications may be approved based on state mandates.

4. References:

1. Akeega [package insert]. Horsham, PA: Janssen Biotech, Inc.; August 2023.
2. Lynparza [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP, Inc.; November 2023.
3. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/professionals/drug_compendium/content/ Accessed February 5, 2024.

Program	Step Therapy – Akeega (niraparib and abiraterone acetate)
Change Control	
3/2024	New program.