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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	October 13, 2023
Subject:	Akeega	**Page:**	1 of 6

Last Review Date: March 8, 2024

Akeega

Description

Akeega (niraparib and abiraterone acetate)

Background
Akeega is a combination of niraparib, an inhibitor of poly (ADP-ribose) polymerase (PARP) enzymes, and abiraterone acetate, an androgen biosynthesis inhibitor. Niraparib inhibits PARP-1 and PARP-2 which play a role in DNA repair. In vitro studies have shown that niraparib-induced cytotoxicity may involve inhibition of PARP enzymatic activity and increased formation of PARP-DNA complexes resulting in DNA damage, apoptosis, and cell death. Abiraterone acetate is converted in vivo to abiraterone which inhibits 17 α-hydroxylase/C17,20-lyase (CYP17). This enzyme is expressed in testicular, adrenal, and prostatic tumor tissues and is required for androgen biosynthesis (1).

Regulatory Status
FDA-approved indication: Akeega 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 (*BRCA*m) metastatic castration-resistant prostate cancer (mCRPC). Select patients for therapy based on an FDA-approved test for Akeega (1).

Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML) can occur in patients treated with Akeega. Monitor patients for hematological toxicity and discontinue if MDS/AML is confirmed (1).

Akeega has been associated with myelosuppression. Complete blood counts should be tested weekly for the first month, every two weeks for the next two months, monthly for the remainder of the first year, then every other month, and as clinically indicated (1).

The patient should be monitored for hypokalemia, fluid retention and cardiovascular adverse reactions such as hypertension. Patients whose underlying medical conditions might be compromised by these adverse reactions should be closely monitored at least weekly for the first two months, then once a month. Hypertension and hypokalemia should be controlled and corrected prior and during Akeega treatment (1).

Hepatotoxicity, adrenocortical insufficiency, and hypoglycemia were reported with Akeega use. Liver function, signs and symptoms of adrenocortical insufficiency, and blood glucose should be monitored. Treatment should be modified, interrupted, or discontinued as needed (1).

The use of Akeega plus prednisone in combination with radium Ra 223 dichloride is not recommended. This has led to increased fractures and mortality (1).

Posterior reversible encephalopathy syndrome (PRES) has been observed in patients treated with Akeega. If PRES is suspected, promptly discontinue Akeega and administer appropriate treatment (1).

Akeega can cause fetal harm if exposed to pregnant females. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with Akeega and for 4 months following the last dose (1).

The safety and effectiveness of Akeega in pediatric patients have not been established (1).

Related policies
Lynparza, Rubraca, Zejula, Zytiga

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Akeega may be considered **medically necessary** if the conditions indicated below are met.

Akeega may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Metastatic castration-resistant prostate cancer (mCRPC)

AND ALL of the following:

1. Deleterious or suspected deleterious *BRCA* mutation
2. Used in combination with prednisone
3. Patient has had a bilateral orchiectomy **OR** patient will be receiving a gonadotropin-releasing hormone (GnRH) analog concurrently
4. Prescriber agrees to obtain a complete blood count (CBC) at baseline, weekly for the first month, and monthly thereafter
5. Prescriber agrees to monitor for cardiovascular effects
6. **NO** dual therapy with another androgen receptor inhibitor (see Appendix 1)
7. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment and for 4 months after the last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Metastatic castration-resistant prostate cancer (mCRPC)

AND ALL of the following:

1. Used in combination with prednisone
2. Prescriber agrees to obtain complete blood counts (CBCs) as clinically indicated
3. Prescriber agrees to monitor for cardiovascular effects

4. **NO** disease progression or unacceptable toxicity
5. **NO** dual therapy with an androgen receptor inhibitor (see Appendix 1)
6. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment and for 4 months after the last dose

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

Quantity 180 tablets per 90 days

Duration 12 months

Prior – Approval *Renewal* Limits
Same as above

Rationale

Summary
Akeega is a combination of niraparib, a PARP inhibitor and abiraterone, a CYP17 inhibitor. In combination with prednisone, Akeega is used for the treatment of adults with deleterious or suspected deleterious *BRCA* mutated metastatic castration-resistant prostate cancer. Akeega can cause MDS/AML, myelosuppression, hypokalemia, fluid retention, cardiovascular adverse reactions, hepatotoxicity, adrenocortical insufficiency, hypoglycemia, increased fractures and mortality with radium Ra 223 dichloride, PRES, and embryo-fetal toxicity. Appropriate monitoring parameters should be taken when administering Akeega and treatment should be modified, interrupted, or discontinued as recommended (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Akeega while maintaining optimal therapeutic outcomes.

References

1. Akeega [package insert]. Horsham, PA: Janssen Biotech, Inc.; August 2023.

2. NCCN Drugs & Biologics Compendium® Niraparib and abiraterone acetate 2024. National Comprehensive Cancer Network, Inc. Accessed on January 18, 2024.

Policy History

Date	Action
October 2023	Addition to PA
December 2023	Annual review
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.

Appendix 1 - List of Androgen Receptor Inhibitors

Generic Name	Brand Name
abiraterone	Yonsa
abiraterone	Zytiga
abiraterone/niraparib	Akeega
apalutamide	Erleada
darolutamide	Nubeqa
enzalutamide	Xtandi
nilutamide	Nilandron