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Section:	Prescription Drugs	**Effective Date:**	January 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	January 1, 2017
Subject:	Rubraca	**Page:**	1 of 5

Last Review Date: December 8, 2023

Rubraca

Description

Rubraca (rucaparib)

Background
Rucaparib is an inhibitor of poly (ADP-ribose) polymerase (PARP) enzymes, including PARP-1, PARP-2, and PARP-3, which (when uninhibited) play a role in DNA repair. In vitro studies have shown that rucaparib-induced cytotoxicity may involve inhibition of PARP enzymatic activity and increased formation of PARP-DNA complexes resulting in DNA damage, apoptosis, and cell death. Increased rucaparib-induced cytotoxicity was observed in tumor cell lines with deficiencies in *BRCA* 1/2 (*BRCA* mutations) and other DNA repair genes (1).

Regulatory Status
FDA-approved indications: Rubraca is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated (1):

1. Ovarian cancer
    a. For the maintenance treatment of adult patients with a deleterious *BRCA* mutation (germline and/or somatic)-associated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.
2. Prostate cancer
    a. For the treatment of adult patients with a deleterious *BRCA* mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Rubraca.

Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML) can occur in patients exposed to Rubraca. Monitor patients for hematological toxicity at baseline and monthly thereafter (i.e., monitor complete blood count testing at baseline and monthly thereafter). Discontinue if MDS/AML is confirmed or until disease progression or unacceptable toxicity (1).

Rubraca can cause fetal harm when administered to a pregnant woman based on its mechanism of action and findings from animal studies. Advise females of reproductive potential to use effective contraception during treatment and for 6 months following the last dose of Rubraca. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with Rubraca and for 3 months following the last dose (1).

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

Related policies
Akeega, Lynparza, Zejula

Policy

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

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

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

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer
    a. Deleterious *BRCA* mutation
    b. Complete or partial response to platinum-based chemotherapy
    c. Used as maintenance treatment

2. Metastatic castration-resistant prostate cancer (mCRPC)
    a. Deleterious *BRCA* mutation as detected by an FDA-approved test
    b. Previous treatment with androgen receptor-directed therapy and a taxane-based chemotherapy
    c. Patient has had a bilateral orchiectomy **OR** patient will be receiving a gonadotropin-releasing hormone (GnRH) analog concurrently

AND ALL of the following for **ALL** indications:

1. Prescriber agrees to do a complete blood count (CBC) at baseline and then monthly thereafter
2. Females of reproductive potential **only**: patient will be advised to use effective contraception during therapy and for 6 months after the last dose
3. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment and for 3 months after the last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer
2. Metastatic castration-resistant prostate cancer (mCRPC)

AND ALL of the following for **ALL** indications:

1. Prescriber agrees to monitor complete blood counts (CBCs) monthly
2. **NO** disease progression or unacceptable toxicity
3. Females of reproductive potential **only**: patient will be advised to use effective contraception during therapy and for 6 months after the last dose
4. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment and for 3 months after the last dose

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

Quantity

Strength	Quantity
200 mg	360 tablets per 90 days
250 mg	
300 mg	

Duration 12 months

Prior – Approval *Renewal* Limits
Same as above

Rationale

Summary
Rubraca is an inhibitor of poly (ADP-ribose) polymerase (PARP) enzymes, including PARP-1, PARP-2, and PARP-3, which (when uninhibited) play a role in DNA repair. MDS/AML occurred in patients exposed to Rubraca, therefore monthly testing for hematological toxicity is required during treatment with Rubraca (1).

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

References
1. Rubraca [Package Insert]. Vienna, Austria: zr pharma& GmbH; June 2023.
2. NCCN Drugs & Biologics Compendium® Rucaparib 2023. National Comprehensive Cancer Network, Inc. Accessed on October 12, 2023.

Policy History

Date	Action
January 2017	Addition to PA
March 2017	Annual review

June 2017	Annual review
September 2017	Annual review Addition of quantity limits
May 2018	Addition of the diagnosis of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer to criteria
June 2018	Annual review
March 2019	Annual review
June 2020	Addition of indication: metastatic castration-resistant prostate cancer (mCRPC). Also revised ovarian cancer indications. Added contraception agreement requirement for male patients with female partners of reproductive potential
September 2020	Annual review
September 2021	Annual editorial review and reference update. Added requirement that the prostate cancer *BRCA* mutation must be confirmed by an approved FDA laboratory test
July 2022	Per PI update, removed indication of *BRCA*-positive epithelial ovarian, fallopian tube, or primary peritoneal cancer. Revised quantity limits chart so the strengths are set together for ease of patient dose adjustment
September 2022	Annual review and reference update
January 2023	Per PI update, added deleterious *BRCA* mutation to recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer indication
March 2023	Annual review and reference update
December 2023	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 8, 2023 and is effective on January 1, 2024.