BlueCross BlueShield Federal Employee Program

RUBRACA
(rucaparib)

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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 2024. National Comprehensive Cancer Network, Inc. Accessed on October 3, 2024.