

Positive Quality Intervention: Use of Rucaparib (Rubraca®) In the Treatment of Ovarian, Fallopian Tube, Primary Peritoneal or Prostate Cancer

Description: The purpose of this PQI is to discuss the various indications for rucaparib (Rubraca).

Background: Rucaparib is an oral tricyclic indole and inhibitor of poly(ADP-ribose) polymerases (PARPs) PARP 1, PARP 2 and PARP 3, with antineoplastic activity.¹ PARPs are a group of enzymes activated by single-strand DNA breaks. PARP inhibitors block the ability of PARP to repair DNA that has been damaged including the recruitment of other DNA repair proteins.² Rucaparib selectively binds to PARP 1, 2 and 3 and inhibits PARP mediated DNA repair. The enhanced accumulation of DNA strand breaks ultimately promotes genomic instability and leads to cell arrest and apoptosis. This activity may also increase the cytotoxicity of DNA-damaging agents possibly reversing resistance to chemotherapy and radiation therapy.

Rucaparib is indicated as maintenance treatment in adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. Rucaparib is also indicated in adult patients with a deleterious BRCA mutation- associated metastatic castration resistant prostate cancer who have been previously treated with androgen receptor-directed therapy and taxane-based chemotherapy. Along with rucaparib approval, the FDA has approved next-generation sequencing (NGS)-based companion diagnostic to identify patients with advanced ovarian cancer eligible for treatment with rucaparib. The test detects alterations in BRCA1 and BRCA2 genes in the tumor tissue of ovarian cancer patients.

PQI Process:

- Rucaparib initial dose for any indication is 600 mg (2 x 300 mg tabs) taken twice daily
- No initial dose adjustment required for renal or hepatic impairment
- May be taken with or without food
- Treatment should be continued until disease progression or toxicity
- If the patient is receiving rucaparib for metastatic castration-resistant prostate cancer (mCRPC) they should also be receiving a gonadotropin-releasing hormone (GnRH) analog
- If the mCRPC patient is not receiving a GnRH they should have had a bilateral orchiectomy
- Most common ADR's requiring dose adjustment in ovarian cancer based on ARIEL 3 study^{3,4}
 - Thrombocytopenia
 - Anemia
 - Nausea
 - Fatigue/asthenia
- Most common ADR's requiring dose adjustment in mCRPC based on Triton2 study^{3,4}
 - Anemia
 - Asthenia/fatigue
 - Thrombocytopenia
 - Nausea

Important notice: NCODA has developed this Positive Quality Intervention platform. This platform represents a brief summary of medication uses and therapy options derived from information provided by the drug manufacturer and other resources. This platform is intended as an educational aid and does not provide individual medical advice and does not substitute for the advice of a qualified healthcare professional. This platform does not cover all existing information related to the possible uses, directions, doses, precautions, warning, interactions, adverse effects, or risks associated with the medication discussed in the platform and is not intended as a substitute for the advice of a qualified healthcare professional. The materials contained in this platform are for informational purposes only and do not constitute or imply endorsement, recommendation, or favoring of this medication by NCODA, which assumes no liability for and does not ensure the accuracy of the information presented. NCODA does not make any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.

PQI Process Continued:

Table 1. Recommended Dose Modification Schedule for Adverse Reactions³

Dose Reduction	Dose
Starting Dose	600 mg twice daily (2 x 300 mg tablets)
First Dose Reduction	500 mg twice daily (2 x 250 mg tablets)
Second Dose Reduction	400 mg twice daily (2 x 200 mg tablets)
Third Dose Reduction	300 mg twice daily (1 x 300 mg tablet)

Available Tablet Strengths:

- 200 mg tablet – blue, round, film coated, “C2” imprint
- 250 mg tablet – white, diamond, film coated “C25” imprint
- 300 mg tablet – yellow, oval, immediate release, film coated “C3” imprint

Patient Centered Activities:

- Patient Education
 - Provide [Oral Chemotherapy Education \(OCE\)](#) Sheet
 - Patients may have their dose adjusted several times during their course of treatment
 - If the patient misses a dose they should skip the missed dose and resume their regular dosing schedule⁵
 - Rucaparib should be stored at room temperature, away from heat, moisture and light
- Monitoring
 - Myelodysplastic syndrome/ acute myeloid leukemia have occurred, Grades 3 or 4 (8%) in patients taking rucaparib³
 - Monitor for hematologic toxicity at baseline and monthly
 - Monitor for symptoms of fatigue, anemia and AST/ALT elevation

Supplemental Information:

[Rubraca® Connections Co-Pay program⁶](#)

- \$0 Co-pay program for patients with commercial insurance
- Patients may receive support up to \$30,000 per calendar year

[Rubraca® Connections Patient Assistance Program⁷](#)

- For patients with no health insurance or insurance that does not cover Rubraca®
- Based on household income and diagnosis

[Clovis4YOU™⁸](#) Daily patient support via text messaging

- Medication and refill reminders
- Nutrition tips and more

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3. Rubraca (rucaparib) Package Insert Revised: 10/2020
4. Rubraca (rucaparib) dosing, indications, interactions, adverse effects, and more. (2020, October 9). <https://reference.medscape.com/drug/rubraca-rucaparib-1000121>.
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6. "Rubraca Connections" Co-Pay Program <https://www.rubraca.com/ovarian-cancer/patient-support-resources/patient-savings-support-programs>
7. "Rubraca Connections." Patient assistance Program <https://www.rubracaconnections.com/>.
8. Clovis4You™ Patient Support Program <https://www.rubraca.com/ovarian-cancer/clovis4you-support-program>.

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