PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Rubraca Prior Authorization Policy
- Rubraca® (rucaparib tablets – Clovis Oncology)

REVIEW DATE: 01/11/2023

OVERVIEW

Rubraca, a poly (ADP-ribose) polymerase (PARP) inhibitor, is indicated for the following uses:[1]

- **Ovarian, fallopian tube, or primary peritoneal cancer, maintenance treatment** of adults with a deleterious *BRCA* mutation (germline and/or somatic)-associated recurrent epithelial disease who are in a complete or partial response to platinum-based chemotherapy.
- **Prostate cancer**, metastatic castration-resistant (mCRPC), treatment of adults with a deleterious *BRCA* mutation (germline and/or somatic)-associated disease who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy.

Guidelines

Rubraca is discussed in guidelines from the National Comprehensive Cancer Network (NCCN):

- **Ovarian Cancer:** NCCN guidelines (version 1.2023 – December 22, 2022) recommend single-agent Rubraca as maintenance therapy if the patient has had a complete or partial response to primary treatment in the following situations: no bevacizumab was used during primary therapy (category 2A) or bevacizumab was used during primary therapy and the patient has a germline or somatic *BRCA* mutation (category 2A).[2] In patients with platinum-sensitive disease who have completed two or more lines of platinum-based therapy and are in a partial or complete response, bevacizumab can be continued as maintenance therapy or Rubraca can be considered as maintenance therapy option if patient has a *BRCA* mutation and patient has not previously received a PARP inhibitor (category 1). Rubraca is also recommended as a preferred recurrence therapy for patients with platinum-sensitive or platinum-resistant ovarian cancer that has been treated with two or more lines of chemotherapy and have *BRCA* mutations (category 3).
- **Prostate Cancer:** NCCN guidelines (version 1.2023 – September 16, 2022) recommend Rubraca for *BRCA1* or *BRCA2* mutation (germline and/or somatic) for patients who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy in mCRPC, either as second-line or subsequent therapy (category 2A). It is listed under "useful in certain circumstances". The guidelines note that if the patient is not fit for chemotherapy, Rubraca can be considered even if taxane-based therapy has not been given.[3]
- **Uterine Neoplasms:** NCCN guidelines (version 1.2023 – December 22, 2022) state that Rubraca may be considered as a single-agent second-line therapy, useful in certain circumstances, for *BRCA2*-altered uterine leiomyosarcoma (category 2A).[4,5]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Rubraca. All approvals are provided for the duration note below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Rubraca is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Ovarian, Fallopian Tube, or Primary Peritoneal Cancer –Maintenance Therapy.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) Patient is in complete or partial response after a platinum-based chemotherapy regimen; AND
   Note: Examples are carboplatin with gemcitabine, carboplatin with paclitaxel, cisplatin with gemcitabine.
   C) Patient meets one of the following criteria (i or ii):
      i. Patient meets both of the following criteria (a and b):
         a) Patient has recurrent disease; AND
         b) Patient has a *BRCA* mutation; OR
      ii. Patient is in complete or partial response to first-line primary treatment.

2. **Prostate Cancer.** Approve for 1 year if the patient meets the following criteria (A, B, C, D, E, and F):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has metastatic castration resistant prostate cancer AND
   C) Patient has *BRCA* mutation-positive (germline and/or somatic) disease; AND
   D) Patient meets one of the following criteria (i or ii):
      i. The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog; OR
      Note: Examples are leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection),), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix subcutaneous injection), Orgovyx (relugolix tablets).
      ii. Patient has had a bilateral orchiectomy; AND
   E) Patient has been previously treated with at least one androgen receptor-directed therapy; AND
   Note: Androgen receptor-directed therapy includes abiraterone, Xtandi (enzalutamide tablets), Nubeqa (darulutamide tablets), or Erleada (apalutamide tablets).
   F) Patient meets one of the following criteria (i or ii):
      i. Patient has been previously treated with at least one taxane-based chemotherapy; OR
      Note: Examples are docetaxel, cabazitaxel.
      ii. Patient is not a candidate or is intolerant to taxane-based chemotherapy, according to the prescriber.

Other Uses with Supportive Evidence:

3. **Ovarian, Fallopian Tube, or Primary Peritoneal Cancer – Treatment.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has a *BRCA* mutation (germline or somatic) as confirmed by an approved test; AND
   C) Patient has progressed on two or more prior lines of chemotherapy.

4. **Uterine Leiomyosarcoma**. Approve for 1 year if the patient meets the following criteria (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has *BRCA2*-altered disease; AND
   C) Patient has tried one systemic regimen.
   Note: Examples of a systemic regimen include one or more of the following products: dacarbazine, docetaxel, doxorubicin, epirubicin, gemcitabine, ifosfamide, vinorelbine.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Rubraca is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Rubraca® tablets [prescribing information]. Boulder, CO: Clovis Oncology; December 2022
2. The NCCN Ovarian Cancer Clinical Practice Guidelines in Oncology (version 1.2023 – December 22, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 10, 2023.
3. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 1.2023 – September 16, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 10, 2023.
4. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 1.2023 – December 22, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 9, 2023.
5. The NCCN Drugs & Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 10, 2023. Search term: rucaparib.