PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 02/07/2024; selected revision 06/05/2024

OVERVIEW

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

- **Epithelial ovarian, fallopian tube, or primary peritoneal cancer, maintenance treatment** of deleterious *BRCA* mutation (germline and/or somatic)-associated recurrent disease in adults who are in a complete or partial response to platinum-based chemotherapy.
- **Prostate cancer**, metastatic castration-resistant (mCRPC), treatment of deleterious *BRCA* mutation (germline and/or somatic)-associated disease in adults who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy.
  This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Guidelines

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

- **Ovarian Cancer:** NCCN guidelines (version 2.2024 – May 13, 2024) 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 if patient has a *BRCA* mutation and patient has not previously received a PARP inhibitor (category 1) or if disease has not progressed during prior PARP inhibitor therapy (category 2A).
- **Pancreatic Adenocarcinoma:** NCCN guidelines (version 1.2024 – December 13, 2023) recommend Rubraca as maintenance therapy for metastatic disease with germline or somatic *BRCA1/2* or *PALB2* mutations. This recommendation is for patients who have received prior platinum based therapy and did not have progression following their most recent platinum-based chemotherapy and it is listed as "Useful in Certain Circumstances" (category 2A).
- **Prostate Cancer:** NCCN guidelines (version 4.2023 – September 7, 2023) 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 (category 2A). It is listed under "Useful in Certain Circumstances" for patients who have received prior novel hormone therapy and no prior docetaxel and for patients who have received prior docetaxel and prior novel hormone therapy. 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 1.2024 – September 20, 2023) state that Rubraca may be considered as a single-agent second-line therapy or subsequent therapy as "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 ALL of the following (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 (i or ii):
     - **i.** Patient meets both of the following (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 ALL of the following (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 (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 (darolutamide tablets), or Erleada (apalutamide tablets).
   - **F)** Patient meets one of the following (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. **Pancreatic Adenocarcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has a *BRCA* mutation or *PALB2* mutation; AND
   - **C)** Patient meets BOTH of the following (i and ii):
     - **i.** Patient has tried platinum-based chemotherapy; AND

ii. Patient has not had disease progression following the most recent platinum-based chemotherapy.

4. Uterine Leiomyosarcoma. Approve for 1 year if the patient meets ALL of the following (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, gemcitabine, ifosfamide, Yondelis (trabectedin intravenous infusion).

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 2.2024 – May 13, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 30, 2024.
3. The NCCN Pancreatic Adenocarcinoma Clinical Practice Guidelines in Oncology (version 1.2024 – December 13, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 30, 2024.
4. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 4.2023 – September 7, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 30, 2024.
5. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 1.2024 – September 20, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 30, 2024.
6. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 30, 2024. Search term: rucaparib.