PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 02/12/2025

INSTRUCTIONS FOR USE

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CIGNA NATIONAL FORMULARY COVERAGE:

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 BReast CAncer gene (*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 Including Fallopian Tube Cancer and Primary Peritoneal Cancer:** NCCN guidelines (version 3.2024 – July 15, 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).[2,6] 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 1.2025 – February 3, 2025) 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).[3,6]
- **Prostate Cancer:** NCCN guidelines (version 1.2025 – December 4, 2024) recommend Rubraca for *BRCA* mutation for patients who have progressed on prior novel hormone therapy and no prior docetaxel (category 1) as a "Preferred regimen" and for patients who have progressed on prior docetaxel and prior novel hormone therapy as "Useful in Certain Circumstances" (category 2A).[4,6]
- **Uterine Neoplasms:** NCCN guidelines (version 2.2025 – January 31, 2025) 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).[5,6]

POLICY STATEMENT

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

- **Rubraca® (rucaparib tablets – pharmaand GmbH)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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 of platinum-based chemotherapy regimen include 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, and E):
- **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 of GnRH analogs include 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
  Note: Examples of androgen receptor-directed therapy include abiraterone, Xtandi (enzalutamide capsules or tablets), Nubeqa (darolutamide tablets), or Erleada (apalutamide tablets).

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 COVERED

- **Rubraca® (rucaparib tablets – pharmaand GmbH)**

is(are) considered experimental, investigational or unproven for ANY other use(s); criteria will be updated as new published data are available.

REFERENCES

1. Rubraca® tablets [prescribing information]. Wein, Austria: pharmaand GmbH; December 2024
2. The NCCN Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer Clinical Practice Guidelines in Oncology (version 3.2024 – July 15, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed February 5, 2025.
3. The NCCN Pancreatic Adenocarcinoma Clinical Practice Guidelines in Oncology (version 2.2025 – February 3, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed February 5, 2025.
4. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 1.2025 – December 4, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed February 5, 2025.
5. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 2.2025 – January 31, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed February 5, 2025.
6. The NCCN Drugs & Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 5, 2025. Search term: rucaparib.

HISTORY

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	**Ovarian, Fallopian Tube, or Primary Peritoneal Cancer – Maintenance Therapy**: Criterion which previously stated that the patient is in complete or partial response after at least two platinum-based chemotherapy regimens was reworded to state, "Patient is in complete or partial response after a platinum-based chemotherapy regimen," due to changes in National Comprehensive Cancer Network (NCCN) guideline recommendations. Criteria were added for a patient with recurrent disease and a *BRCA* mutation or a patient who is in complete or partial response to first-line primary treatment due to updated NCCN guideline recommendations and FDA labeling changes.	01/11/2023
Annual Revision	**Pancreatic Adenocarcinoma**: Indication and criteria were added to Other Uses with Supportive Evidence based on NCCN guideline updates.	02/07/2024
Selected Revision	**Ovarian, Fallopian Tube, or Primary Peritoneal Cancer – Treatment:** Condition of approval and criteria were removed from "Other Uses with Supportive Evidence."	06/05/2024
Annual Revision	**Prostate Cancer:** The requirement that "the patient has been previously treated with at least one taxane-based chemotherapy; OR the patient is not a candidate or is intolerant to taxane-based chemotherapy, according to the prescriber" was removed.	02/12/2025