VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 02/02/2022; selected revision 06/22/2022

OVERVIEW

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

- **Ovarian, fallopian tube, or primary peritoneal cancer,** for the **maintenance treatment** of adult patients with recurrent epithelial disease who are in a complete or partial response to platinum-based chemotherapy.
- **Prostate cancer, metastatic castration-resistant (mCRPC)**, treatment of adult patients 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 1.2022 – January 18, 2022), therapy options for patients with recurrent disease are primarily dependent on whether the patient is considered platinum-resistant or platinum-sensitive (patients who relapse ≥ 6 months after initial chemotherapy).[3] NCCN guidelines recommends single-agent Rubraca 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 2A). 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 Zejula® (niraparib capsules), Lynparza® (olaparib tablets), or Rubraca can be considered as maintenance therapy options (category 1 for *BRCA* mutation; all others category 2A).
- **Prostate Cancer:** NCCN guidelines (version 3.2022 – January 10, 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 taxanes-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.
- **Uterine Neoplasms:** NCCN guidelines (version 1.2022 – November 4, 2021) state that Rubraca may be considered as a single-agent second-line therapy, useful in certain circumstances, for *BRCA2*-altered uterine leiomyosarcoma (category 2A).[6]

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 and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient is in complete or partial response after at least two platinum-based chemotherapy regimens.
     Note: Examples are carboplatin with gemcitabine, carboplatin with paclitaxel, cisplatin with gemcitabine.

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 disease; AND
   - **C)** Patient has *BRCA*-mutation positive (germline and/or somatic); 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 for 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 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; June 2022
2. The NCCN Ovarian Cancer Clinical Practice Guidelines in Oncology (version 1.2022 – January 18, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 21, 2022.
3. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 3.2022 – January 10, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 21, 2022.
4. The NCCN Drugs & Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 21, 2022. Search term: rucaparib.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**For all indications:** Added age requirement that patient ≥ 18 years.	03/10/2021
Early Annual Revision	**Ovarian, Fallopian Tube, or Primary Peritoneal Cancer – Treatment:** Criteria for patients currently receiving Rubraca was removed. The word "initial therapy" was also removed. **Prostate Cancer**: The words "castration resistant" were removed from the condition of approval and added to the criteria. **Uterine Leiomyosarcoma:** This condition of approval was added to the Other Uses with Supportive Evidence section based on NCCN guideline updates.	02/02/2022
Selected Revision	**Ovarian, Fallopian Tube, or Primary Peritoneal Cancer – Treatment:** The duration of approval was changed from 3 years to 1 year. **Ovarian, Fallopian Tube, or Primary Peritoneal Cancer –Maintenance Therapy:** The duration of approval was changed from 3 years to 1 year. **Prostate Cancer:** The duration of approval was changed from 3 years to 1 year. **Uterine Leiomyosarcoma:** The duration of approval was changed from 3 years to 1 year.	06/22/2022
Update	**06/30/22:** The following indication "Ovarian, fallopian tube, or primary peritoneal cancer, for the treatment of adult patients with deleterious *BReast CAncer (BRCA)* mutation (germline and/or somatic)-associated epithelial disease who have been treated with two or more chemotherapies" was removed from the overview section as per changes in FDA labeling. **Ovarian, Fallopian Tube, or Primary Peritoneal Cancer – Treatment:** Condition of approval and criteria were moved from the FDA-Approved Indications section to Other Uses with Supportive Evidence based on a change in FDA labeling.	--