

Policy Type: PA/SP

Pharmacy Coverage Policy: EOCCO152

Description

Rucaparib (Rubraca) is an orally administered poly (ADP-ribose) polymerase (PARP) inhibitor indicated for the treatment, or maintenance therapy, of ovarian, fallopian tube, or primary peritoneal cancer.

Length of Authorization

- Initial: Six months
- Renewal: 12 months

Quantity limits

| Product Name | Dosage Form | Indication | Quantity Limit |
|---------------------|----------------|---|--------------------|
| rucaparib (Rubraca) | 200 mg tablets | <u>Maintenance for:</u> recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer; | 60 tablets/30 days |
| | 250 mg tablets | | |
| | 300 mg tablets | | |

Initial Evaluation

- I. Rucaparib (Rubraca) may be considered medically necessary when the following criteria below are met:
 - A. Member is 18 years of age or older; **AND**
 - B. Medication is prescribed by, or in consultation with, an oncologist; **AND**
 - C. Rucaparib (Rubraca) will be used as monotherapy; **AND**
 - D. Member has not progressed on a prior PARP inhibitor (e.g., olaparib [Lynparza], niraparib [Zejula]) therapy; **AND**
 - E. A diagnosis of one of the following:
 1. **Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer; AND**
 - i. Provider is requesting for maintenance therapy; **AND**
 - ii. Member has experienced disease progression on or after at least two or more prior platinum-based chemotherapy regimens (e.g., cisplatin, carboplatin, oxaliplatin); **AND**
 - iii. Member is in complete or partial response to their last platinum-based chemotherapy regimen (i.e., platinum sensitive); **AND**
 - iv. Rucaparib (Rubraca) will be started within eight weeks of completion of the most the most recent platinum-based chemotherapy regimen; **OR**

- v. Provider attests with supporting documentation that member's recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer has not progressed since the most recent platinum-based chemotherapy regimen; **OR**
 - 2. **Advanced ovarian, fallopian tube, or primary peritoneal cancer; AND**
 - i. Provider is requesting for treatment therapy, and not maintenance therapy; **AND**
 - ii. Member has been treated with two or more prior lines of chemotherapy; **AND**
 - iii. Member has deleterious *BRCA* mutation (germline and/or somatic) confirmed by a FDA-approved compendia diagnostic for rucaparib (Rubraca).
- II. Rucaparib (Rubraca) is considered investigational when used for all other conditions, including but not limited to:
- A. Used in combination with other chemotherapy or targeted therapy regimen.
 - B. Breast Cancer
 - C. Prostate Cancer
 - D. Advance Solid Tumors
 - E. Melanoma
 - F. Pancreatic cancer
 - G. Gastroesophageal cancer

Renewal Evaluation

- I. Member has received a previous prior authorization approval for this agent through this health plan; **AND**
- II. Member is not continuing therapy based off being established on therapy through samples, manufacturer coupons, or otherwise. Initial policy criteria must be met for the member to qualify for renewal evaluation through this health plan; **AND**
- III. Medication is prescribed by, or in consultation with, an oncologist; **AND**
- IV. Member does not have evidence of disease progression.

Supporting Evidence

- I. The safety and efficacy of rucaparib (Rubraca) in the setting of maintenance therapy for recurrent ovarian cancer was studied in a double-blind, multicenter trial (ARIEL3) where 564 adult patients with platinum-sensitive recurrent epithelial ovarian fallopian tube, or primary peritoneal cancer. The patients were randomized 2:1 rucaparib (Rubraca) 600 mg orally daily or matched placebo within 8 weeks of their last dose of platinum-based therapy. The major efficacy outcome was progression-free survival (PFS) assessed by investigator, which ARIEL 3 demonstrated a statistically significant improvement in PFS in the rucaparib (Rubraca) arm as compared to the placebo arm. In the rucaparib (Rubraca) arm, the median PFS was 10.8 months

compared to 5.4 months in the placebo arm with a hazard ratio (HR) of 0.36 and 95% CI (0.3, 0.45).

- II. Therapy in the maintenance setting was initiated within eight weeks after completion of the last dose of platinum-based chemotherapy. The intent is that treatment is started within a reasonable timeframe consistent with a maintenance treatment plan (i.e. as close to 8 weeks as possible), but recognize that scheduling or other factors may impact the ability of a patient to start exactly within these first eight weeks.
- III. The safety and efficacy of rucaparib (Rubraca) for the treatment of advanced ovarian cancer after two or more chemotherapies was studied in two multicenter, single-arm, and open-label trials with 106 adult patients that have advanced *BRCA*-mutant ovarian cancer who had progressed after two or more prior chemotherapies. The efficacy outcomes were objective response rate (ORR) and duration of response (DOR) assessed by the investigator and independent radiology review; the average ORR was 54% and the average DOR was 9.2 months.
- IV. There is a lack of strong scientific evidence from randomized controlled trials supporting safety and efficacy to support the use of a subsequent PARP inhibitor following progression of disease on another PARP inhibitor.

Investigational or Not Medically Necessary Uses

- I. There is a lack of strong scientific evidence from randomized controlled trials supporting safety and efficacy for the use of rucaparib (Rubraca) in the following settings listed below:
 - A. Used in combination with other chemotherapy or targeted therapy regimen.
 - B. Breast Cancer
 - C. Prostate Cancer
 - D. Solid Tumors

References

1. Rubraca [Prescribing Information]. Boulder, CO: Clovis Oncology, Inc. April 2018.
2. Coleman RL, Oza AM, Lorusso D, et al. Rucaparib Maintenance Treatment for Recurrent Ovarian Carcinoma After Response to Platinum Therapy (ARIEL3): A Randomized, Double-blind, Placebo-controlled, Phase 3 Trial. *Lancet*. 2017 Oct 390(10106): 1949–1961. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5901715/pdf/nihms956813.pdf>

Policy Implementation/Update:

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|----------------|---------------------------|
| Date Created | December 2016 |
| Date Effective | February 2017 |
| Last Updated | December 2019 |
| Last Reviewed | 12/2016, 05/2018, 12/2019 |

| Action and Summary of Changes | Date |
|---|----------------|
| <p>Criteria transition into policy with the following updates made: addition of supporting evidence and investigation section, broke out the different indications (treatment versus maintenance therapy), included mutation status for the treatment of recurrent ovarian cancer, included criterion around prior PARP inhibitor use, increase initial approval duration from three months to six months to be consistent with other payers, included age criterion per label, and removed the 8 weeks criterion around most recent platinum-based therapy in the setting of maintenance therapy in recurrent ovarian cancer; in place of the 8 weeks criterion, provider attestation and documentation is required instead.</p> | <p>12/2019</p> |