Clinical Policy: Rucaparib (Rubraca)

Revision Log

Reference Number: PA.CP.PHAR.350
Effective Date: 01/18
Last Review Date: 07/18

Description
Rucaparib (Rubraca®) is a poly (ADP-ribose) polymerase (PARP) inhibitor

FDA Approved Indication(s)
Rubraca is indicated for the treatment of patients with deleterious BRCA (breast cancer susceptibility gene) mutation (germline and/or somatic) associated advanced ovarian cancer who have been treated with two or more chemotherapies. Select patients for therapy based on an FDA-approved companion diagnostic for Rubraca.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Pennsylvania Health and Wellness® that Rubraca is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Ovarian Cancer (must meet all)**:**

1. Diagnosis of ovarian cancer including endometrioid ovarian, fallopian tube, or primary peritoneal carcinoma;
2. Age ≥18 years;
3. Deleterious or suspected deleterious germline or somatic BRCA mutated as detected by an FDA-approved test (e.g. Foundation Focus);
4. Failure or clinically significant adverse effects to two or more prior chemotherapy regimens;
5. Dose does not exceed 1200 mg/day (4 tablets).

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to PA.CP.PMN.53

II. Continued Therapy

A. Ovarian Cancer (must meet all)**:**

1. Currently receiving medication via health plan benefit or member has previously met initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy (e.g.: no disease progression, no significant toxicity, etc.);
3. Dose does not exceed 1200 mg/day (4 tablets).

Approval duration: 12 months

B. Other diagnoses/indications (1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.

Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
BRCA: Breast cancer susceptibility gene
LOH: Loss of heterozygosity
PARP: Poly (ADP-ribose) polymerase

Appendix B: General Information

- Information on the FDA approved test for the detection of a tumor BRCA mutation in patients with ovarian cancer is available at: http://www.fda.gov/CompanionDiagnostics.
- Rubraca is being evaluated in clinical trials for pancreatic cancer, breast cancer, solid tumors

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Ovarian Cancer	600 mg by mouth twice daily	600 mg by mouth twice daily

VI. Product Availability

Tablets: 200 mg, 300 mg

VII. References

1. Rubraca Prescribing Information. Boulder, CO: Clovis Oncology, Inc.; February 2017. Available at: http://clovisoncology.com/files/rubraca-prescribing-info.pdf. Accessed November 13, 2017.
2. NCCN Clinical Practice Guideline: Ovarian Cancer Version 4.2017. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed November 13, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Added Age ≥18 years per PI. References reviewed and updated	02/18	