Clinical Policy: Rucaparib (Rubraca)

Reference Number: CP.PHAR.350
Effective Date: 09.01.17
Last Review Date: 02.18
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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 Centene Corporation® 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 and/or somatic BRCA mutation as detected by an FDA-approved test (e.g., FoundationFocus);
4. Failure or clinically significant adverse effects to two or more prior chemotherapy regimens;
5. Dose does not exceed 1200 mg/day.

Approval duration:
Medicaid/Health Insurance Marketplace – 6 months
Commercial – Length of Benefit

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Ovarian Cancer (must meet all)**:**
1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Rubraca and has received this medication for at least 30 days;
2. Member is responding positively to therapy (e.g., no disease progression, no significant toxicity, etc.);
3. If request is for a dose increase, new dose does not exceed 1200 mg/day.

Approval duration:
Medicaid/Health Insurance Marketplace – 12 months
Commercial – Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

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 policies – CP.CPA.09 for commercial and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
BRCA: Breast cancer susceptibility gene
PARP: Poly (ADP-ribose) polymerase

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
carboplatin (Paraplatin®) containing regimen	Varies	Varies
cisplatin (Platinol-AQ®) containing regimen	Varies	Varies
Docetaxel (Taxotere®)	Varies	Varies
Etoposide (Toposar®)	Varies	Varies
Gemcitabine (Gemzar®)	Varies	Varies
Doxorubicin (Doxil®, Lipodox® 50) ± Avastin® (bevacizumab)	Varies	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Paclitaxel ± Avastin (bevacizumab) or Votrient® (pazopanib)	Varies	Varies
Topotecan (Hycamtin®) ± Avastin (bevacizumab)	Varies	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: 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, and solid tumors.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Ovarian Cancer	600 mg PO BID	600 mg PO BID

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
New policy created. Clarified two prior chemo regimens; added examples of specific ovarian cancer types. Revised general formatting and updated therapeutic alternatives	1.5.17	02.17
Updated BRCA testing to allow for somatic mutations	3.10.17	05.17
Minor changes to verbiage and grammar. References updated.	06.17	11.17
1Q18 annual review: - No significant clinical changes - Added Age ≥18 years per PI - Updated Appendix B with additional acceptable prior treatment regimens based on NCCN Ovarian Cancer guidelines. - References reviewed and updated	11.13.17	02.18

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.