

## **Clinical Policy: Rucaparib (Rubraca)**

Reference Number: CP.PHAR.350

Effective Date: 09.01.17

Last Review Date: 08.18

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<sup>®</sup>) is a poly (ADP-ribose) polymerase (PARP) inhibitor.

### **FDA Approved Indication(s)**

Rubraca is indicated:

- For the treatment of adult patients with deleterious BRCA mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies. Select patients for therapy based on an FDA-approved companion diagnostic for Rubraca
- For the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy

### **Policy/Criteria**

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that Rubraca is **medically necessary** when the following criteria are met:

#### **I. Initial Approval Criteria**

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

1. Diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal carcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age  $\geq$  18 years;
4. One of the following (a or b):
  - a. Both i and ii:
    - i. Deleterious or suspected deleterious germline and/or somatic BRCA mutation;
    - ii. Failure of  $\geq$  2 lines of chemotherapy unless contraindicated or clinically significant adverse effects are experienced;
  - b. Completed 2 platinum-based chemotherapy regimens and is in a complete or partial response;
5. Dose does not exceed 1200 mg/day.

##### **Approval duration:**

**Medicaid** – 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 for ovarian cancer and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 1200 mg/day.

**Approval duration:**

**Medicaid** – 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

FDA: Food and Drug Administration

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.*

<b>Drug Name</b>	<b>Dosing Regimen</b>	<b>Dose Limit/ Maximum Dose</b>
carboplatin-containing regimen	Varies	Varies
cisplatin-containing regimen	Varies	Varies
docetaxel (Taxotere <sup>®</sup> )	Varies	Varies
etoposide (Toposar <sup>®</sup> )	Varies	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
gemcitabine (Gemzar <sup>®</sup> )	Varies	Varies
doxorubicin (Adriamycin <sup>®</sup> ) ± Avastin <sup>®</sup> (bevacizumab)	Varies	Varies
paclitaxel ± Avastin (bevacizumab) or Votrient <sup>®</sup> (pazopanib)	Varies	Varies
topotecan (Hycamtin <sup>®</sup> ) ± Avastin (bevacizumab)	Varies	Varies

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

*Appendix C: Contraindications*

Not applicable

*Appendix D: General Information*

- 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 BID

**VI. Product Availability**

Tablets: 200 mg, 250 mg, 300 mg

**VII. References**

1. Rubraca Prescribing Information. Boulder, CO: Clovis Oncology, Inc.; April 2018. Available at: <http://clovisoncology.com/files/rubraca-prescribing-info.pdf>. Accessed April 18, 2018.
2. NCCN Clinical Practice Guideline: Ovarian Cancer Version 2.2018. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/ovarian.pdf](https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf). Accessed April 10, 2018.

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; uUpdated Appendix B with additional acceptable prior treatment regimens based on NCCN Ovarian Cancer guidelines; references reviewed and updated	11.13.17	02.18

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Criteria added for new FDA indication: maintenance treatment of ovarian cancer which is in complete/partial response to platinum-based chemotherapy; references reviewed and updated.	05.29.18	08.18

**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.

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**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.

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