Clinical Policy: Rucaparib (Rubraca)
Reference Number: CP.PHAR.350
Effective Date: 09.01.17
Last Review Date: 02.20
Line of Business: Commercial, HIM, Medicaid

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 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® 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 cancer;
      2. Prescribed by or in consultation with an oncologist;
      3. Age ≥ 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 ≥ 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. Request meets one of the following (a or b):*
         a. Dose does not exceed 1,200 mg (4 tablets) per day;
         b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

*Prescribed regimen must be FDA-approved or recommended by NCCN
 Approval duration:
Medicaid/HIM – 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, HIM.PHAR.21 for health insurance marketplace, 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 a covered indication 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, request meets one of the following (a or b):
      a. New dose does not exceed 1,200 mg (4 tablets) per day;
      b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

   *Prescribed regimen must be FDA-approved or recommended by NCCN

 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.
   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, HIM.PHAR.21 for health insurance marketplace, 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, HIM.PHAR.21 for health insurance marketplace, 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.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ovarian Cancer</td>
<td>Various</td>
<td>Varies</td>
</tr>
<tr>
<td>Alimta® (pemetrexed)</td>
<td>Various</td>
<td>Varies</td>
</tr>
<tr>
<td>Alkeran® (melphalan)</td>
<td>Various</td>
<td>Varies</td>
</tr>
<tr>
<td>Avastin® (bevacizumab)</td>
<td>Various</td>
<td>Varies</td>
</tr>
<tr>
<td>carboplatin (Paraplatin®)</td>
<td>Various</td>
<td>Varies</td>
</tr>
<tr>
<td>cisplatin (Platinol-AQ®)</td>
<td>Various</td>
<td>Varies</td>
</tr>
<tr>
<td>cyclophosphamide (Cytoxan®)</td>
<td>Various</td>
<td>Varies</td>
</tr>
<tr>
<td>docetaxel (Taxotere®)</td>
<td>Various</td>
<td>Varies</td>
</tr>
<tr>
<td>doxorubicin (Doxil®, Adriamycin®)</td>
<td>Various</td>
<td>Varies</td>
</tr>
<tr>
<td>etoposide (Vepesid®)</td>
<td>Various</td>
<td>Varies</td>
</tr>
<tr>
<td>gemcitabine (Gemzar®)</td>
<td>Various</td>
<td>Varies</td>
</tr>
<tr>
<td>ifosfamide (Ifex®)</td>
<td>Various</td>
<td>Varies</td>
</tr>
<tr>
<td>irinotecan (Camptosar®)</td>
<td>Various</td>
<td>Varies</td>
</tr>
<tr>
<td>oxaliplatin (Eloxatin®)</td>
<td>Various</td>
<td>Varies</td>
</tr>
<tr>
<td>topotecan (Hycamtin®)</td>
<td>Various</td>
<td>Varies</td>
</tr>
<tr>
<td>Hexalen® (altretamine)</td>
<td>Various</td>
<td>Varies</td>
</tr>
<tr>
<td>paclitaxel</td>
<td>Various</td>
<td>Varies</td>
</tr>
</tbody>
</table>

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: Contraindications/Boxed Warnings

None reported

V. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ovarian cancer</td>
<td>600 mg PO BID</td>
<td>1,200 mg/day</td>
</tr>
</tbody>
</table>

VI. Product Availability

Tablets: 200 mg, 250 mg, 300 mg

VII. References

CLINICAL POLICY
Rucaparib

Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Description</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>New policy created. Clarified two prior chemo regimens; added examples of specific ovarian cancer types. Revised general formatting and updated therapeutic alternatives</td>
<td>1.5.17</td>
<td>02.17</td>
</tr>
<tr>
<td>Updated BRCA testing to allow for somatic mutations</td>
<td>3.10.17</td>
<td>05.17</td>
</tr>
<tr>
<td>Minor changes to verbiage and grammar. References updated.</td>
<td>06.17</td>
<td>11.17</td>
</tr>
<tr>
<td>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</td>
<td>11.13.17</td>
<td>02.18</td>
</tr>
<tr>
<td>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.</td>
<td>05.29.18</td>
<td>08.18</td>
</tr>
<tr>
<td>1Q 2019 annual review: no significant changes; references reviewed and updated.</td>
<td>11.20.18</td>
<td>02.19</td>
</tr>
<tr>
<td>1Q 2020 annual review: no significant changes; added HIM line of business; added quantity limit of 4 tablets for max dosing; references reviewed and updated.</td>
<td>10.29.19</td>
<td>02.20</td>
</tr>
</tbody>
</table>

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.

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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.

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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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