BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 3/16/17**
SECTION: DRUGS	**LAST REVIEW DATE: 5/17/18**
	LAST CRITERIA REVISION DATE: 5/17/18
	ARCHIVE DATE:

RUBRACA™ (rucaparib camsylate) oral tablet

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

RUBRACA™ (rucaparib camsylate) oral tablet (cont.)

Criteria:

- **Criteria for initial therapy:** Rubraca (rucaparib camsylate) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is an Oncologist

  2. Individual is 18 years of age or older

  3. **ONE** of the following:
     - A confirmed diagnosis of advanced ovarian cancer with **ALL** of the following:
       - Documentation of previous treatment with 2 or more prior chemotherapies
       - Rubraca (rucaparib camsylate) will be used as monotherapy
     - A confirmed diagnosis of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer with the following:
       - Documentation of complete or partial response to platinum-based chemotherapy

  4. **ALL** of the following baseline tests have been completed before initiation of treatment:
     - Documentation of deleterious BRCA gene mutation, either inherited (germline) or acquired (somatic), confirmed by an FDA-approved test
     - Baseline complete blood count (CBC)
     - Comprehensive metabolic panel (CMP)
     - Negative pregnancy test in a woman of reproductive potential

  Initial approval duration: 1200 mg/day for 6 months

- **Criteria for continuation of coverage (renewal request):** Rubraca (rucaparib camsylate) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual continues to be in consultation with an Oncologist

  2. Individual's condition has not worsened while on therapy

  3. Individual has been adherent with the medication

  4. Individual has not developed any significant level 4 adverse drug effects that may exclude continued use
     - Significant adverse effect such as:
       - Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML)

  5. There are no significant interacting drugs

  Renewal duration: 1200 mg/day for 6 months

RUBRACA™ (rucaparib camsylate) oral tablet (cont.)

Description:

Rubraca (rucaparib camsylate) is indicated as monotherapy for the treatment of individuals with deleterious *BRCA* mutation (germline and/or somatic) associated advanced ovarian cancer who have been treated with two or more chemotherapies. Selection of individuals for therapy is based on an FDA-approved diagnostic test. Rubraca is also indicated 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.

Rucaparib is an inhibitor of the mammalian polyadenosine 5'-diphosphoribose polymerase (PARP) enzymes, including PARP-1, PARP-2, and PARP-3 that play a role in deoxyribonucleaic acid (DNA) transcription, cell cycle regulation, and DNA repair. Inhibition of PARP enzymatic activity results in increased formation of PARP-DNA complexes that cause DANA damage, apoptosis, and cell death, especially in tumor cell lines with deficiencies in *BRCA 1/2*.

Another PARP enzyme inhibitor, Lynparza (olaparib), is also indicated as monotherapy in individuals with deleterious or suspected deleterious germline *BRCA* mutated (as detected by an FDA-approved test) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy.

Resources:

Rubraca. Package Insert. Revised by manufacturer 12/2016, accessed 1/20/17; revised 2/2017, accessed 2/27/18; revised 4/2018, accessed 4/13/18.

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.

NCCN Clinical Practice Guidelines in Oncology: Ovarian cancer. Version 2.2018, Mar 9, 2018. https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf

UpToDate: First line chemotherapy for advanced (stage III or IV) epithelial ovarian, fallopian tubal, and peritoneal cancer. Current through Mar 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/first-line-chemotherapy-for-advanced-stage-iii-or-iv-epithelial-ovarian-fallopian-tubal-and-peritoneal-cancer?search=ovarian%20cancer&source=search_result&selectedTitle=4~150&usage_type=default&display_rank=4

UpToDate: Medical treatment for relapsed epithelial ovarian, fallopian tubal, and peritoneal cancer: Platinum-resistant disease. Current through Mar 2018. https://www-uptodate-com.mwu.idm.oclc.org/contents/medical-treatment-for-relapsed-epithelial-ovarian-fallopian-tubal-or-peritoneal-cancer-platinum-resistant-disease?search=ovarian%20cancer&source=search_result&selectedTitle=10~150&usage_type=default&display_rank=10

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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:	Dosage Form:
Directions for Use:	Quantity: / Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

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Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.