BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

RUBRACA™ (rucaparib camsylate) Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

➢ **Criteria for initial therapy:** Rubraca (rucaparib camsylate) and/or generic equivalent (if available) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met:

1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Oncologist

2. Individual is 18 years of age or older

3. Individual has a confirmed diagnosis of **ONE** of the following:
    a. Maintenance treatment of a deleterious *BRCA* mutation (germline and/or somatic)- associated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy

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b. Deleterious *BRCA* mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy

c. Other request for a specific oncologic direct treatment use that is found and listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A

4. Individual has received and completed **ALL** the following **baseline tests** before initiation of treatment and with continued monitoring of the individual as clinically appropriate:
   a. **ONE** of the following:
      i. **For the maintenance treatment of recurrent ovarian cancer:** presence of a deleterious *BRCA* mutation (germline and/or somatic)
      ii. **For the treatment of mCRPC:** presence of a deleterious *BRCA* mutation (germline and/or somatic) in plasma specimens
   b. Negative pregnancy test in a woman of reproductive potential
   c. Eastern Cooperative Oncology Group (ECOG) Performance Status of 0-1

5. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

6. For metastatic castration-resistant prostate cancer (mCRPC): Individual should also be receiving a gonadotropic-releasing hormone (GnRH) analog concurrently or have had a bilateral orchiectomy (see Definitions section)

7. Individual does not have severe hepatic impairment (total bilirubin greater than 3 times the upper limit of normal and any AST)

8. Individual does not have a creatinine clearance of less than 30 mL/min or on dialysis

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Rubraca (rucaparib camsylate) and/or generic equivalent (if available) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Oncologist

2. Individual's condition has responded while on therapy with response defined as there is no evidence of disease progression or unacceptable toxicity

3. Individual has been adherent with the medication

4. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

5. For metastatic castration-resistant prostate cancer (mCRPC): Individual should also be receiving a gonadotropic-releasing hormone (GnRH) analog concurrently or have had a bilateral orchiectomy (see Definitions section)

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

7. Individual does not have severe hepatic impairment (total bilirubin greater than 3 times the upper limit of normal and any AST)

8. Individual does not have a creatinine clearance of less than 30 mL/min or on dialysis

Renewal duration: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of Non-Cancer Medications**

2. **Off-Label Use of Cancer Medications**

Description:

Rubraca (rucaparib camsylate) is indicated for the maintenance treatment of adult patients with a deleterious *BRCA* mutation (germline and/or somatic) associated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. Rubraca is also indicated for the treatment of adult patients with a deleterious *BRCA* mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy. Selection of individuals for therapy is based on an FDA-approved diagnostic test. The prostate cancer indication was approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

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 or somatic BRCA-mutated (as detected by an FDA-approved test)

advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

Gonadotropin-releasing hormone (GnRH) analogs or agonists: (Also referred to as luteinizing hormone releasing hormone (LHRH) agonists or analogs)

Zoladex (goserelin acetate) subcutaneous implant
Vantas (histrelin acetate) subcutaneous implant
Eligard (leuprolide acetate) subcutaneous injection
Lupron Depot (leuprolide acetate) intramuscular injection
Trelstar (triptorelin pamoate) intramuscular injection

NCCN recommendation definitions:
Category 1:
Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2A:
Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2B:
Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
Category 3:
Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate

ECOG Performance status:

Eastern Co-operative Oncology Group (ECOG) Performance Status	
Grade	ECOG description
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours
3	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
4	Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
5	Dead
Oken, M.M., Creech, R.H., Tormey, D.C., Horton, J., Davis, T.E., McFadden, E.T., Carbone, P.P.: Toxicity And Response Criteria Of The Eastern Cooperative Oncology Group. Am J Clin Oncol 5:649-655, 1982	

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Resources:

Rubraca (rucaparib) product information, revised by Clovis Oncology, Inc. 2-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed May 06, 2024.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer Version 1.2024 – Updated January 17, 2024. Available at https://www.nccn.org. Accessed May 06, 2024.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Prostate Cancer Version 3.2024 – Updated March 08, 2024. Available at https://www.nccn.org. Accessed May 06, 2024.

Off Label Use of Cancer Medications: A.R.S. §§ 20-826® & (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.