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/or 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.

Medical Necessity Requirements for RUBRACA (rucaparib camsylate)

Criteria for Initial Therapy:

Prescriber Qualifications
- Prescribed by an Oncologist or in consultation with an Oncologist

Indication
- Maintenance treatment of deleterious *BRCA* mutation (germline and/or somatic)-associated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer in complete or partial response to platinum-based chemotherapy

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- Deleterious *BRCA* mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) previously treated with androgen receptor-directed therapy and taxane-based chemotherapy
- Other oncologic direct treatment uses listed in National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A

Age Requirement
- 18 years or older

Baseline Clinical Evaluation
- **For maintenance treatment of recurrent ovarian cancer:** presence of deleterious BRCA mutation (germline and/or somatic)
- **For mCRPC:** presence of deleterious BRCA mutation (germline and/or somatic) in plasma specimens
- **For mCRPC**: must be receiving gonadotropin-releasing hormone (GnRH) analog concurrently or have had bilateral orchiectomy
- Negative pregnancy test for women of reproductive potential
- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0–1

Brand Specific Criteria
- Have failure, contraindication or intolerance with **THREE** generic equivalents (when available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the United States Food and Drug Administration (FDA) (see Definitions section)

Safety
- No severe hepatic impairment (total bilirubin greater than 3 times the upper limit of normal and any AST)
- No creatinine clearance less than 30 mL/min or dialysis

Documentation Requirements
- A completed request form must be submitted, including:
  - Chart notes
  - Lab results (BRCA mutation status, pregnancy test)
  - Supporting clinical documentation

Initial Therapy Criteria Approval Duration
- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy)
Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy

Prescriber Qualifications
- Continues to be seen by a physician specializing in or is in consultation with an Oncologist

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Clinical Response
- No evidence of disease progression or unacceptable toxicity

Adherence
- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria
- Have failure, contraindication or intolerance with **THREE** generic equivalents (when available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety
- No significant adverse drug effects such as Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML)
- No severe hepatic impairment (total bilirubin greater than 3 times the upper limit of normal and any AST)
- No creatinine clearance less than 30 mL/min or dialysis

Additional Requirements:
- For mCRPC: must be receiving gonadotropin-releasing hormone (GnRH) analog concurrently or have had bilateral orchiectomy

Documentation Requirements
- Chart notes
- Supporting clinical documentation with evidence of improvement in given indication
- Lab values that confirm safe use from above criteria

Continuation Therapy Criteria Approval Duration
- 12 months OR end of plan year

Criteria for Off-Label Use Requests:

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

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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	

Resources:

Rubraca (rucaparib) product information, revised by Clovis Oncology, Inc. 12-2022. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed February 21, 2025.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer Version 1.2025 – Updated March 05, 2025. Available at https://www.nccn.org. Accessed April 18, 2025.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Prostate Cancer Version 2.2025 – Updated April 16, 2025. Available at https://www.nccn.org. Accessed April 01, 2025.

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.