BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

LYNPARZA™ (olaparib) oral
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 LYNPARZA (olaparib)

Criteria for Initial Therapy:

Prescriber Qualifications
- Prescribed by an Oncologist, Gynecologist, Gastroenterologist, or Urologist or is in consultation with an Oncologist, Gynecologist, Gastroenterologist, or Urologist depending on indication

Age Requirement
- 18 years or older

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Indication

- **Ovarian, Fallopian Tube, or Primary Peritoneal Cancer**
  - First line maintenance treatment for deleterious or suspected deleterious germline or somatic BRCA mutated advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer in complete or partial response to first line platinum based chemotherapy
  - In combination with bevacizumab for first line maintenance treatment of advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer in complete or partial response to first line platinum based chemotherapy that is associated with homologous recombination deficiency (HRD) positive status defined by either:
    1. Deleterious or suspected deleterious BRCA mutation
    2. Genomic instability
  - Maintenance treatment of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer in complete or partial response to platinum based chemotherapy
- **Breast Cancer**
  - Adjuvant treatment of deleterious or suspected deleterious germline BRCA mutated (gBRCAm), HER2 negative high risk early breast cancer treated with neoadjuvant or adjuvant chemotherapy
  - Treatment of deleterious or suspected deleterious gBRCAm, HER2 negative metastatic breast cancer treated with chemotherapy in neoadjuvant, adjuvant, or metastatic setting
  - Hormone receptor (HR) positive breast cancer must have prior endocrine therapy or be considered inappropriate for endocrine therapy
- **Pancreatic Adenocarcinoma**
  - First line maintenance treatment of deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma with no disease progression on at least 16 weeks of first line platinum
  - based chemotherapy
- **Prostate Cancer (Metastatic Castration Resistant Prostate Cancer)**
  - Treatment of deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene mutated metastatic castration resistant prostate cancer who has progressed following prior treatment with enzalutamide or abiraterone
  - In combination with abiraterone and prednisone or prednisolone for treatment of deleterious or suspected deleterious BRCA mutated metastatic castration resistant prostate cancer
  - Individual should also receive a gonadotropin releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy
- **Other Oncologic Uses**
  - Other direct oncologic treatment uses listed in National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A

Baseline Clinical Evaluation

- FDA approved test for detection of mutations
- Complete blood count Bilirubin and transaminases
- Negative pregnancy test in a woman of childbearing potential
- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 to1

Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if 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)

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Safety
- There is **NONE** of the following:
  - Severe renal impairment or end stage renal disease (creatinine clearance less than or equal to 30 mL/min)
  - Severe hepatic impairment (Child Pugh Class C)
  - Use with strong or moderate CYP3A inducers (e.g., rifampin, rifabutin, phenobarbital, carbamazepine, dexamethasone, nafcillin)

Documentation Requirements
- A completed request form must be submitted including:
  - Chart notes
  - Lab results (mutation test, pregnancy test, ECOG status)
  - 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 Qualification
- Continues to be seen by an Oncologist, Gynecologist, Gastroenterologist, or Urologist or is in consultation with an Oncologist, Gynecologist, Gastroenterologist, or Urologist depending on indication

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 (if 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
- There is **NONE** of the following:
  - Severe renal impairment or end stage renal disease (creatinine clearance less than or equal to 30 mL/min)
  - Severe hepatic impairment (Child Pugh Class C) including drug induced liver injury (DILI)
  - Use with strong or moderate CYP3A inducers (e.g., rifampin, rifabutin, phenobarbital, carbamazepine, dexamethasone, nafcillin)
  - Myelodysplastic Syndrome/Acute Myeloid Leukemia
  - Pneumonitis

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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:

Lynparza (olaparib) is indicated for the maintenance treatment in adult patients with deleterious or suspected deleterious germline or somatic *BRCA* mutated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy; it is indicated in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either: a deleterious or suspected deleterious *BRCA* mutation, and/or genomic instability; it is indicated for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy; it is indicated for the treatment of adult patients with deleterious or suspected deleterious germline *BRCA*-mutated (g*BRCA*m) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy; it is indicated for the treatment of adult patients with deleterious or suspected deleterious *gBRCA*m, HER2-negative metastatic breast cancer, who have been treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy; it is indicated for the maintenance treatment of adult patients with deleterious or suspected deleterious *gBRCA*m metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen; it is indicated for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone; and it is indicated in combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC).

Olaparib is an inhibitor of poly-adenosine 5'-diphosphoribose (ADP-ribose) polymerase (PARP) enzymes, including PARP1, PARP2, and PARP3. PARP enzymes are involved in normal cellular homeostasis, such as DNA transcription, cell cycle regulation, and DNA repair. Olaparib has been shown to inhibit growth of select

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tumor cell lines *in vitro* and decrease tumor growth in mouse xenograft models of human cancer both as monotherapy or following platinum-based chemotherapy. *In vitro* studies have shown that olaparib-induced cytotoxicity may involve inhibition of PARP enzymatic activity and increased formation of PARP-DNA complex, resulting in disruption of cellular homeostasis and cell death.

BRACAnalysis CDx™ is an in vitro diagnostic device intended for the qualitative detection and classification of variants in the protein coding regions and intron/exon boundaries of the BRCA1 and BRCA2 genes using genomic DNA obtained from whole blood specimens collected in EDTA. Results of the test are used as an aid in identifying ovarian cancer patients with deleterious or suspected deleterious germline BRCA variants eligible for treatment with Lynparza™ (olaparib). This assay is for professional use only and is to be performed only at Myriad Genetic Laboratories, a single laboratory site located at 320 Wakara Way, Salt Lake City, UT 84108.

Definitions:

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

Eastern Co-operative Oncology Group (ECGO) Performance Status:

Grade	ECOG description
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physical 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 self-care but unable to carry out any work activities, up and about more than 50% of waking hours
3	Capable of only limited self-care, 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, MM, Creech, RH, Tormey, DC, et al.: Toxicity and Response Criteria Of The Eastern Cooperative Oncology Group. Am J Clin Oncol 5:649-655, 1982	

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

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

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Eligard (leuprolide acetate) subcutaneous injection
Lupron Depot (leuprolide acetate) intramuscular injection
Trelstar (triptorelin pamoate) intramuscular injection

Resources:

Lynparza (olaparib) tablet product information, revised by AstraZeneca Pharmaceuticals, LP. 07-2025. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed November 10, 2025.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Breast Cancer Version 1.2026 – Updated January 16, 2026. Available at https://www.nccn.org. Accessed January 24, 2026.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer Version 3.2025 – Updated July 16, 2025. Available at https://www.nccn.org. Accessed January 24, 2026.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Pancreatic Adenocarcinoma Version 2.2025 – Updated February 03, 2025. Available at https://www.nccn.org. Accessed January 24, 2026.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Prostate Cancer Version 5.2026 – Updated January 23, 2026. Available at https://www.nccn.org. Accessed January 24, 2026.

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.

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