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

PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 3/17/16**
SECTION: DRUGS	**LAST REVIEW DATE: 3/15/18**
	LAST CRITERIA REVISION DATE: 3/15/18
	ARCHIVE DATE:

LYNPARZA™ (olaparib) oral capsule and 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.**

LYNPARZA™ (olaparib) oral capsule and tablet (cont.)

Description:

Lynparza (olaparib) is indicated as monotherapy in patients 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. 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 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.

Lynparza (olaparib)

Medication class:
Antineoplastic - Poly (ADP-ribose) Polymerase (PARP) Inhibitor

FDA-approved indication(s):
- Breast cancer, metastatic (BRCA-mutated, HER2-negative) (**tablets**)
  Treatment of deleterious or suspected deleterious germline BRCA-mutated, HER2-negative metastatic breast cancer in patients who have been treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting; patients with hormone receptor-positive disease should have received a prior endocrine therapy (or be considered inappropriate for endocrine therapy).
- Ovarian cancer, advanced (BRCA-mutated) (**capsules or tablets**)
  Treatment of deleterious or suspected deleterious germline BRCA-mutated (as detected by an approved test) advanced ovarian cancer in patients who have been treated with 3 or more prior lines of chemotherapy.
- Ovarian cancer, recurrent (maintenance) (**tablets**)
  Maintenance treatment of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer in patients who are in a complete or partial response to platinum-based chemotherapy.

Recommended Dose:
- Breast cancer, metastatic, HER2-negative, BRCA-mutated:
  Tablets: 300 mg twice daily until disease progression or unacceptable toxicity.
- Ovarian cancer, advanced (BRCA-mutated):
  Capsules: 400 mg twice daily (every 12 hours) until disease progression or unacceptable toxicity.
  Tablets: 300 mg twice daily (every 12 hours) until disease progression or unacceptable toxicity.
- Ovarian cancer, recurrent (maintenance):

LYNPARZA™ (olaparib) oral capsule and tablet (cont.)

Tablets: 300 mg twice daily (every 12 hours) until disease progression or unacceptable toxicity.

Maximum dosage
- Not stated

Available Dosage Forms:
- Capsule: 50 mg
- Tablet: 100 mg, 150 mg
- Do not substitute the 50 mg capsules for the 100 mg or 150 mg tablets on a mg-per-mg basis due to differences in dosing and bioavailability, the bioavailability of the tablet is higher than the capsule

Warnings, Precautions, and other Clinical Information:
- Avoid use with moderate or strong CYP3A4 inhibitors, if unavoidable reduce Lynparza dosing
- Avoid use with moderate or strong CYP3A4 inducers
- Lynparza dose should be reduced in moderate renal impairment (Crcl 31-50 mL/min)
- The pharmacokinetics of Lynparza has not been evaluated in patients with severe renal impairment (Crcl < 30 mL/min)or end-stage renal disease
- There are no data on dose recommendations for patients with moderate or severe hepatic impairment (Child-Pugh Class B or C)
- Discontinue if Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML develops and is confirmed
- Discontinue if pneumonitis develops and is confirmed
- Pregnancy testing is recommended for woman of child bearing potential prior to starting Lynparza
- Woman of child bearing potential should use effective contraception
- Woman who is breast feeding an infant or child should stop breast feeding
- Males with female partners of reproductive potential should use effective contraception

Criteria:

- **Criteria for initial therapy**: Lynparza (olaparib) 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. A confirmed diagnosis of **ONE** of the following:
   - Maintenance treatment of an individual with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer **AND** individual is in a complete or partial response to platinum-based chemotherapy
   - Treatment of an individual with deleterious or suspected deleterious germline BRCA-mutated advanced ovarian cancer **AND** individual has been treated with three or more prior lines of chemotherapy
   - Treatment of an individual with deleterious or suspected deleterious germline BRCA-mutated, HER2-negative metastatic breast cancer **AND** individual has been treated with chemotherapy in

LYNPARZA™ (olaparib) oral capsule and tablet (cont.)

the neoadjuvant, adjuvant, or metastatic setting; patients with hormone receptor-positive disease should have received a prior endocrine therapy (or be considered inappropriate for endocrine therapy)

4. **ALL** of the following baseline tests have been completed before initiation of treatment:
   - FDA-approved test for the detection of *BRCA*-mutations
   - Complete blood count
   - Liver function tests
   - Creatinine clearance
   - Pregnancy test in a woman of childbearing potential, unless is using effective contraception

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Lynparza (olaparib) 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)
     - Pneumonitis
5. There are no significant interacting drugs

Renewal duration: 12 months

Resources:

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.

Lynparza capsule. Package Insert. Revised by manufacturer 10/2017. Accessed 02-27-2018.

Lynparza tablet. Package Insert. Revised by manufacturer 01/2018. Accessed 02-27-2018.

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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.

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