BlueCross BlueShield of Arizona
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PHARMACY COVERAGE GUIDELINES	
SECTION: DRUGS	
ORIGINAL EFFECTIVE DATE:	**7/20/17**
LAST REVIEW DATE:	**5/16/19**
LAST CRITERIA REVISION DATE:	**5/16/19**
ARCHIVE DATE:	

ZEJULA™ (niraparib) oral capsule

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.**

ZEJULA™ (niraparib) oral capsule (cont.)

Criteria:

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

  1. Prescriber is a physician specializing in Cancer or is in consultation with an Oncologist

  2. Individual is 18 years of age or older

  3. A confirmed diagnosis of **ONE** of the following:
     - Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer, as single-agent maintenance therapy for patients with platinum-sensitive recurrent disease who have completed **two or more** lines of platinum-based therapy and are in a complete or partial response (Note: Avastin (bevacizumab) should be discontinued before initiating maintenance therapy with a PARP inhibitor)

     - 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. **ALL** of the following baseline tests have been completed before initiation of treatment with continued monitoring as clinically appropriate:
     - Pregnancy test in a woman of child bearing potential
     - Blood pressure and medically manage hypertension with antihypertensive medications
     - Complete blood count

  5. Will not be used in patients with severe renal impairment (creatinine clearance by Cockroft-Gault < 30 mL/min) or end-stage renal impairment undergoing hemodialysis

  6. Will not be used in patients with moderate to severe hepatic impairment (as defined by the National Cancer Institute – Organ Dysfunction Working Group (NCI-ODWG)) of **either**:
     - AST, ALT, ALP, GGT > 2.5 to 5 x ULN
     - Total bilirubin > 1.5 to 3 x ULN

  Initial approval duration: 6 months

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

  1. Individual continues to be seen by a physician specializing in Cancer or is in consultation with an Oncologist

  2. Individual's condition responded while on therapy
     - Response is defined as:
       - No evidence of disease progression
       - Dose is at least 100 mg once daily

ZEJULA™ (niraparib) oral capsule (cont.)

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:
     - Confirmed Myelodysplastic syndrome or acute myeloid leukemia (MDS/AML)
     - Adverse effect lasting more than 28 days while on 100 mg once daily
     - Adverse effect that did not return to acceptable levels or has recurred in a patient that underwent a dose interruption period or dose reduction of Zejula to 100 mg daily in **any** of the following: platelet count or neutrophil count or hemoglobin

5. There are no significant interacting drugs

Renewal duration: 12 months

Description:

Zejula (niraparib) is 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.

Niraparib is an inhibitor of poly (ADP-ribose) polymerase (PARP) enzymes, PARP-1 and PARP-2, which play a role in DNA repair. Studies have shown that niraparib-induced cytotoxicity may involve inhibition of PARP enzymatic activity and increased formation of PARP-DNA complexes resulting in DNA damage, apoptosis and cell death. Increased niraparib-induced cytotoxicity was observed in tumor cell lines with or without deficiencies in *BRCA1/2*. Niraparib decreased tumor growth in mouse xenograft models of human cancer cell lines with deficiencies in *BRCA1/2* and in human patient-derived xenograft tumor models with homologous recombination deficiency that had either mutated or wild type *BRCA1/2*.

Definitions:

National Cancer Institute – Organ Dysfunction Working Group (NCI-ODWG)

The NCI in the ‘‘Common Toxicity Criteria for Adverse Events’’ uses elevations of serum enzyme activities of alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), γ-glutamyltransferase (GGT), and total bilirubin to categorize the degree of liver toxicity.

	ALT, AST, ALP, GGT	Total bilirubin
Mild (grade 1)	If > ULN to 2.5 x ULN	If > ULN to 1.5 x ULN
Moderate (grade 2)	If > 2.5 to 5 x ULN	If > 1.5 to 3 x ULN
Severe (grade 3)	If > 5 to 20 x ULN	If > 3 to 8 x ULN
Life-threatening (grade 4)	If > 20 x ULN	If > 8 x ULN
Fatal (grade 5)	No definition	
ULN = upper limit of normal		

ZEJULA™ (niraparib) oral capsule (cont.)

Resources:

Zejula (niraparib). Package Insert. Revised by manufacturer 03-2017. Accessed 05-30-2017.

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.

Zejula (niraparib) product information accessed 07-17-18, 04-28-19 at DailyMed: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=0fe9d533-67a9-4981-978a-1e84755ae30b

NCCN Clinical Practice Guidelines in Oncology: Ovarian Cancer: Including Fallopian Tube Cancer and Primary Peritoneal Cancer. Version 2.2018, March 9, 2018. https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf

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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.