BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES	
SECTION: DRUGS	
ORIGINAL EFFECTIVE DATE:	**7/20/2017**
LAST REVIEW DATE:	**5/20/2021**
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ZEJULA™ (niraparib)

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)

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 the patient's diagnosis 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:
    a. Advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy used as first-line maintenance treatment

    b. Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy used as maintenance treatment

    c. Treatment of advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with **three or more** prior chemotherapy regimens **and** whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by **either**:
        i. A deleterious or suspected deleterious *BRCA* mutation
        ii. Genomic instability and progression more than six months after response to last platinum-based chemotherapy

    d. 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:
    a. Negative pregnancy test in a woman of child bearing potential
    b. Blood pressure and medically manage hypertension with antihypertensive medications
    c. Eastern Cooperative Oncology Group (ECOG) Performance Status is 0-1

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 severe hepatic impairment (total bilirubin greater than 3-times the upper limit of normal and any aspartate aminotransferase (AST))

Initial approval duration: 6 months

ZEJULA™ (niraparib)

- **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 the patient's diagnosis or is in consultation with an Oncologist

  2. Individual's condition responded while on therapy
     a. Response is defined as:
        i. No evidence of disease progression
        ii. No evidence individual has developed any significant unacceptable adverse drug reactions that may exclude continued use

  3. Individual is using a dose of at least 100 mg once daily

  4. Individual has been adherent with the medication

  5. Individual has not developed any significant adverse drug effects that may exclude continued use
     a. Significant adverse effect such as:
        i. Confirmed Myelodysplastic syndrome or acute myeloid leukemia (MDS/AML)
        ii. Posterior Reversible Encephalopathy Syndrome (PRES)
        iii. Adverse effect lasting more than 28 days while on 100 mg once daily
        iv. 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

  6. 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

  7. Will not be used in patients with severe hepatic impairment (total bilirubin greater than 3-times the upper limit of normal and any aspartate aminotransferase (AST))

  8. There are no significant interacting drugs

  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 a Non-Cancer Medications**

  2. **Off-Label Use of a Cancer Medication for the Treatment of Cancer without a Specific Coverage Guideline**

ZEJULA™ (niraparib)

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 and for the treatment of adult patients with advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with three or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either: a deleterious or suspected deleterious *BRCA* mutation, or genomic instability and who have progressed more than six months after response to the last 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*.

Resources:

Zejula (niraparib) product information, revised by GlaxoSmithKline LLC 03-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed on March 20, 2021.

Moore KM, Markham MJ. Management of ovarian cancer associated with BRCA and other genetic mutations. In: UpToDate, Goff B, Dizon DS, Vora SR (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed on March 19, 2021.

Coleman RL, Sabbatini P. Medical treatment for relapsed epithelial ovarian, fallopian tube, or peritoneal cancer: Platinum sensitive disease. In: UpToDate, Goff B, Dizon DS, Vora SR (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed on March 19, 2021.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer Version 2.2021 – Updated February 26, 2021. Available at https://www.nccn.org. Accessed on March 19, 2021.

National Comprehensive Cancer Network (NCCN) Compendium: Zejula. National Comprehensive Cancer Network (NCCN). NCCN Drugs & Biologics Compendium. 2021(c); Available at: http://www.nccn.org. Accessed on March 19, 2021.

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.