PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Zejula Prior Authorization Policy
- Zejula™ (niraparib capsules and tablets – GlaxoSmithKline)

REVIEW DATE: 02/07/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Zejula, a poly (ADP-ribose) polymerase (PARP) inhibitor, is indicated for **ovarian, fallopian tube, or primary peritoneal cancer** for the following uses:[1,2]

- Maintenance treatment of advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer in adults who are in a complete or partial response to first-line platinum-based chemotherapy.
- Maintenance treatment of deleterious or suspected deleterious germline BReast CAncer gene (*BRCA)*-mutated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer in adults who are in a complete or partial response to platinum-based chemotherapy.

Guidelines

Zejula is discussed in the National Comprehensive Cancer Network (NCCN) guidelines:

- **Ovarian Cancer:** NCCN guidelines (version 1.2024 – January 17, 2024) recommend Zejula for treatment of recurrent disease and for maintenance treatment.[2] For treatment of recurrent disease, monotherapy with Lynparza® (olaparib capsules), Rubraca® (rucaparib tablets), and Zejula are listed under "Other Recommended Regimens" for both platinum-sensitive and platinum-resistant disease (all category 3).[3] Zejula is recommended following three or

more lines of prior chemotherapy in patients whose cancer is associated with homologous recombination deficiency (HRD) defined by either a deleterious or suspected deleterious *BRCA* mutation or genomic instability and progression > 6 months after response to the last platinum-based chemotherapy. Zejula + bevacizumab (category 2B) is also listed under other recommended targeted therapy regimen for platinum-sensitive disease.[2] Maintenance recommendations following primary treatment apply to Stage II, III, or IV ovarian cancer after primary treatment if the patient is in complete or partial response. If bevacizumab was not used during primary therapy, Zejula is recommended (category 1 for *BRCA* mutation; category 2A for *BRCA* wild-type of unknown). If bevacizumab was used during primary therapy, Zejula is recommended for patients with a *BRCA* mutation as single agent and in combination with bevacizumab (if patient is unable to tolerate Lynparza) [category 2A] and Zejula is recommended for patients with HRD disease in combination with bevacizumab (if unable to tolerate Lynparza) [category 2A]. In patients with platinum-sensitive disease who have completed at least two lines of platinum-based therapy and have achieved a complete or partial response, Zejula, Rubraca, or Lynparza can be considered for maintenance therapy if PARP therapy has not previously been used (category1) and if disease has not progressed during prior PARP inhibitor treatment (category 2A).[2] There is a footnote that states Zejula is limited to those with a deleterious or suspected deleterious germline *BRCA* mutation (category 1).

- **Uterine Neoplasms:** NCCN guidelines (version 1.2024 – September 20, 2023) recommend Zejula, Lynparza, and Rubraca as single-agent second-line or subsequent therapies for *BRCA2*-altered uterine leiomyosarcoma as "Useful in Certain Circumstances" (category 2A).[4]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Zejula. All approvals are provided for the duration noted below.

- **Zejula™ (niraparib capsules and tablets – GlaxoSmithKline)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Ovarian, Fallopian Tube, or Primary Peritoneal Cancer – Maintenance Therapy.** Approve for 1 year if the patient meets the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient is in complete or partial response after a platinum-based chemotherapy regimen; AND
     Note: Examples of chemotherapy regimens are carboplatin with gemcitabine, carboplatin with paclitaxel, cisplatin with gemcitabine.
   - **C)** Patient meets one of the following (i or ii):
     - **i.** Patient meets both of the following (a and b):

a) Patient has recurrent disease; AND
b) Patient has a *BRCA* mutation; OR

ii. Patient is in complete or partial response to first-line primary treatment.

Other Uses with Supportive Evidence

2. Ovarian, Fallopian Tube, or Primary Peritoneal Cancer – Treatment. Approve for 1 year if the patient meets the following (A, B, and C):

A) Patient is ≥ 18 years of age; AND

B) Patient has tried at least three prior chemotherapy regimens; AND
Note: Examples of chemotherapy regimens are carboplatin/gemcitabine, carboplatin/liposomal doxorubicin, carboplatin/paclitaxel, cisplatin/gemcitabine, capecitabine, irinotecan.

C) Patient has homologous recombination deficiency (HRD)-positive disease as confirmed by an approved test.
Note: HRD-positive disease includes patients with *BRCA* mutation-positive disease.

3. Uterine Leiomyosarcoma. Approve for 1 year if the patient meets the following (A, B, and C):

A) Patient is ≥ 18 years of age; AND

B) Patient has a *BRCA2*-altered disease; AND

C) Patient has tried one systemic regimen.
Note: Examples of a systemic regimen include one or more of the following products: dacarbazine, docetaxel, doxorubicin, gemcitabine, ifosfamide, Yondelis (trabectedin intravenous infusion).

CONDITIONS NOT COVERED

- **Zejula™ (niraparib capsules and tablets – GlaxoSmithKline)**

is(are) considered experimental, investigational, or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Zejula™ capsules [prescribing information]. Triangle Park, NC: GlaxoSmithKline; April 2023.
2. Zejula™ tablets [prescribing information]. Triangle Park, NC: GlaxoSmithKline; April 2023.
3. The NCCN Ovarian Cancer Clinical Practice Guidelines in Oncology (version 1.2024 – January 17, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed February 2, 2024.
4. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 1.2024 – September 20, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed February 2, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Ovarian, Fallopian Tube, or Primary Peritoneal Cancer – Maintenance Therapy:** Criteria were added for patients with recurrent disease and a *BRCA* mutation or for patients who are in complete or partial response to first-line primary treatment due to updated NCCN guideline recommendations and updated FDA labeled indication.	01/11/2023
Selected Revision	The tablet formulation was added to the policy.	05/10/2023
Annual Revision	**Uterine Leiomyosarcoma:** Criterion which states "patient has *BRCA2*-mutation" was reworded to state "patient has *BRCA2*-altered disease."	02/07/2024