



PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Zejula Prior Authorization Policy

- Zejula™ (niraparib capsules and tablets – GlaxoSmithKline)

REVIEW DATE: 01/11/2023; selected revision 05/10/2023

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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 adults with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy.
- Maintenance treatment of adults with deleterious or suspected deleterious germline BReast Cancer gene (BRCA)-mutated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer 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 1.2023 – December 22, 2022) 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). There is a footnote for Zejula that states in the absence of a *BRCA* mutation, HRD status may provide information on the magnitude of benefit of PARP inhibitor therapy. If bevacizumab was used during primary therapy, Zejula is only recommended for patients with a *BRCA* mutation (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.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 1.2023 – December 22, 2022) recommend Zejula, Lynparza, and Rubraca as single-agent second-line or subsequent therapies for *BRCA2*-altered uterine leiomyosarcoma, 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.

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 criteria (i or ii):

i. Patient meets both of the following criteria (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 criteria (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 criteria (A, B, and C):

A) Patient is ≥ 18 years of age; AND

B) Patient has a *BRCA2* mutation; 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, eirenicon, gemcitabine, ifosfamide, vinorelbine.

CONDITIONS NOT COVERED

Zejula™ (niraparib capsules and tablets – GlaxoSmithKline) is(are) considered experimental, investigational, or unproven for ANY other use(s).

REFERENCES

1. Zejula™ capsules [prescribing information]. Triangle Park, NC: GlaxoSmithKline; December 2022.
2. Zejula™ tablets [prescribing information]. Triangle Park, NC: GlaxoSmithKline; April 2023.
3. The NCCN Ovarian Cancer Clinical Practice Guidelines in Oncology (version 1.2023 – December 22, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed December 29, 2022
4. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 1.2023 – December 22, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed January 9, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Uterine Leiomyosarcoma: New indication with criteria was added based on NCCN guideline recommendations.	12/15/2021
Selected Revision	Ovarian, Fallopian Tube, or Primary Peritoneal Cancer – Maintenance Therapy: The duration of approval was changed from 3 years to 1 year. Ovarian, Fallopian Tube, or Primary Peritoneal Cancer – Treatment. The duration of approval was changed from 3 years to 1 year. Uterine Leiomyosarcoma: The duration of approval was changed from 3 years to 1 year.	06/22/2022
Update	10/12/2022: The following, “Treatment of adults with advanced disease 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 a genomic instability and who have progressed more than six months after response to the last platinum-based chemotherapy," was removed from the overview section as per changes in FDA labeling. Ovarian, Fallopian Tube, or Primary Peritoneal Cancer – Treatment: Condition of approval and criteria were moved from the FDA-approved Indications section to Other Uses with Supportive Evidence based on change in FDA labeling.	
Annual Revision	Ovarian, Fallopian Tube, or Primary Peritoneal Cancer – Maintenance Therapy: Criteria were added for patients with recurrent disease and a <i>BRCA</i> 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

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