VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 12/15/2021; selected revision 06/22/2022

OVERVIEW

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

- 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 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 5.2022 – September 16, 2022) recommend Zejula for treatment of recurrent disease and for maintenance treatment.[2] For recurrent disease, 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).[2] Zejula is recommended following three or more lines of chemotherapy in patients whose cancer is associated with homologous recombination deficiency 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 2A) is also listed under other recommended targeted therapy regimen for platinum-sensitive disease. NCCN lists several other potentially active agents for recurrence therapy.[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. In patients with a germline or somatic *BRCA* mutation, both Lynparza and Zejula have a category 1 recommendation if no bevacizumab was used during primary therapy. If bevacizumab was used during primary therapy for patients with a germline or somatic *BRCA* mutation, Lynparza + bevacizumab is a category 1 recommendation for maintenance, whereas monotherapy with Lynparza or Zejula have category 2A recommendations. For patients with *BRCA* wild-type or unknown mutation status, Zejula (if no bevacizumab during primary therapy) and Lynparza with or without bevacizumab (if bevacizumab was used during primary therapy and patient has a homologous recombination deficiency) are among the recommendations for maintenance (category 2A for both). In patients with platinum-sensitive disease who have completed at least two lines of platinum-based therapy (preferred for those with a *BRCA* mutation) and have achieved a complete or partial response, Zejula, Rubraca, or Lynparza (all category 2A) can be considered for maintenance therapy.[2]
- **Uterine Neoplasms:** NCCN guidelines (version 1.2022 – November 4, 2021) recommend Zejula, Lynparza, and Rubraca as single-agent second-line therapies for *BRCA2*-altered uterine leiomyosarcoma, useful in certain circumstances (category 2A).[3]

POLICY STATEMENT

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

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Zejula is recommended in those who meet one of the following criteria:

FDA-Approved Indications

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

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, epirubicin, gemcitabine, ifosfamide, vinorelbine.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Zejula is not recommended in the following situations:

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; September 2022.
2. The NCCN Ovarian Cancer Clinical Practice Guidelines in Oncology (version 5.2022 – September 16, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed October 12, 2022.

3. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 1.2022 – November 4, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed December 13, 2021.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Ovarian, Fallopian Tube, or Primary Peritoneal Cancer**: Added age criteria for both indications (Maintenance and Treatment).	12/09/2020
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.	--