PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 02/07/2024; selected revision 06/05/2024

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 2.2024 – May 13, 2024) recommend Zejula for for maintenance treatment.[2] 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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

1. **Ovarian, Fallopian Tube, or Primary Peritoneal Cancer – Maintenance Therapy.** Approve for 1 year if the patient meets ALL of 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. **Uterine Leiomyosarcoma.** Approve for 1 year if the patient meets ALL of 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 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; April 2023.
2. Zejula™ tablets [prescribing information]. Triangle Park, NC: GlaxoSmithKline; April 2023.
3. The NCCN Ovarian Cancer Clinical Practice Guidelines in Oncology (version 2.2024 – May 13, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 30, 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.