VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Zejula™ (niraparib capsules – Tesaro, Inc.)

DATE REVIEWED: 11/20/2019; selected revision 05/13/2020

OVERVIEW

Zejula, a poly (ADP-ribose) polymerase (PARP) inhibitor, is indicated[1]:

1) For the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy;

2) 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;

3) Zejula 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) a deleterious or suspected deleterious *BRCA* mutation OR b) genomic instability and who have progressed more than six months after response to the last platinum-based chemotherapy.

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for ovarian cancer (version 1.2020 – March 11, 2020) has the following recommendations[2]:

Recurrent Disease – Treatment

Therapy options for patients with recurrent disease are primarily dependent on whether the patient is considered platinum-resistant or platinum-sensitive (patients who relapse ≥ 6 months after initial chemotherapy). For recurrent disease, Lynparza™ (olaparib capsules), Rubraca™ (rucaparib tablets), and Zejula are among the preferred targeted therapy agents for both platinum-sensitive and platinum-resistant disease (all category 2A). All are recommended following two or more lines of chemotherapy (Lynparza and Rubraca) or three or more lines of chemotherapy (Zejula) are are otherwise recommended as per their FDA-approved use in the treatment of patients with advanced ovarian cancer. Zejula + bevacizumab (category 2A) is also an Other Recommended targeted therapy regimen for platinum-sensitive disease. NCCN lists several other potentially active agents for recurrence therapy.

First-Line Maintenance

Maintenance recommendations following primary treatment (first-line maintenance) apply to stage II, III, or IV ovarian cancer after primary treatment if the patient is in complete or partial remission. 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 + bevacizumab (if bevacizumab was used during primary therapy) are among the recommendations for maintenance (category 2A for both).

Recurrent Disease – Maintenance

In patients with platinum-sensitive disease who have completed at least two lines of platinum-based therapy for persistent disease or recurrence and have achieved a complete or partial response, Zejula, Rubraca, or Lynparza (all category 2A) can be considered for maintenance therapy.

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Zejula. All approvals are provided for 3 years in duration unless otherwise noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Ovarian, Fallopian Tube, or Primary Peritoneal Cancer –Maintenance Therapy.** Approve for 3 years if the patient is in complete or partial response after platinum-based chemotherapy regimen.
   Note: Examples of chemotherapy regimens are carboplatin with gemcitabine, carboplatin with paclitaxel, cisplatin with gemcitabine.

2. **Ovarian, Fallopian Tube, or Primary Peritoneal Cancer –Treatment.** Approve for 3 years if the patient meets the following criteria (A and B):
   A) The patient has tried at least three prior chemotherapy regimens.
   Note: Examples of chemotherapy regimens are carboplatin/gemcitabine, carboplatin/liposomal doxorubicin, carboplatin/paclitaxel, cisplatin/gemcitabine, capecitabine, irinotecan; AND
   B) The 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.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Zejula has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

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]. Waltham, MA: Tesaro, Inc.; April 2020.
2. The NCCN Ovarian Cancer Clinical Practice Guidelines in Oncology (Version 1.2020 – March 11, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 11, 2020.