niraparib (Zejula®)

EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO139

Description

Niraparib (Zejula) is an orally administered poly(ADP-ribose) polymerase (PARP) inhibitor indicated for the treatment, or maintenance therapy, of ovarian, fallopian tube, or primary peritoneal cancer.

Length of Authorization

- Initial: Six months
- Renewal: 12 months

Quantity limits

Product Name	Dosage Form	Indication	Quantity Limit
niraparib (Zejula)	100 mg capsules	Maintenance for: recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer; Treatment for: advanced ovarian, fallopian tube, or primary peritoneal cancer	90 capsules/30 days

Initial Evaluation

I. Niraparib (Zejula) may be considered medically necessary when the following criteria below are met:
   A. Member is 18 years of age or older; **AND**
   B. Medication is prescribed by, or in consultation with, an oncologist; **AND**
   C. Niraparib (Zejula) will be used as monotherapy; **AND**
   D. Member has not progressed on prior PARP inhibitor (e.g., olaparib [Lynparza], rucaparib [Rubraca]) therapy; **AND**
   E. A diagnosis of one of the following:
      1. **Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer**; **AND**
         i. Provider is requesting for maintenance therapy; **AND**
         ii. Member has experienced disease progression on or after at least two or more prior platinum-based chemotherapy regimens (e.g., cisplatin, carboplatin, oxaliplatin); **AND**
         iii. Member is in complete or partial response to their last platinum-based chemotherapy regimen (i.e., platinum-sensitive); **AND**
         iv. Provider attests with supporting documentation that member's recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer has not

progressed since the most recent platinum-based chemotherapy regimen; **OR**

2. **Advanced ovarian, fallopian tube, or primary peritoneal cancer**; **AND**
    i. Provider is requesting for treatment, and not maintenance therapy; **AND**
    ii. Member has been treated with three or more prior lines of chemotherapy; **AND**
        a. Member has homologous recombination deficiency (HRD) positive tumor (i.e., t*BRCAm)*; **OR**
        b. Member without *BRCA* mutations must have progressed at least six months after their last dose of platinum-based chemotherapy regimen.

II. Niraparib (Zejula) is considered investigational when used for all other conditions, including but not limited to:
    A. Used in combination with other chemotherapy or targeted therapy regimen.
    B. Breast Cancer
    C. Prostate Cancer
    D. Lung Cancer
    E. Advance Solid Tumors
    F. Melanoma
    G. Pancreatic cancer
    H. Gastroesophageal cancer

Renewal Evaluation

I. Member has received a previous prior authorization approval for this agent through this health plan; **AND**
II. Member is not continuing therapy based off being established on therapy through samples, manufacturer coupons, or otherwise. Initial policy criteria must be met for the member to qualify for renewal evaluation through this health plan; **AND**
III. Medication is prescribed by, or in consultation with, an oncologist; **AND**
IV. Member does not have evidence of disease progression.

Supporting Evidence

I. The safety and efficacy of niraparib (Zejula) in the setting of maintenance therapy for recurrent ovarian cancer was studied in a double-blind, placebo-controlled trial in adult patients with platinum-sensitive recurrent epithelial ovarian fallopian tube, or primary peritoneal cancer. The patients were randomized 2:1 niraparib (Zejula) 300 mg orally daily or matched placebo within eight weeks of the last platinum-based chemotherapy regimen. The trial demonstrated a statistically significant improvement in progression free survival (PFS) for patients randomized to niraparib (Zejula) as compared with placebo in the gBRCAmut cohort and the non-gBRCAmut cohort.

A. gBRCAmut Cohort: PFS in the niraparib (Zejula) arm was 21 and 5.5 in the placebo arm with a HR of 0.26 and 95% CI (0.17, 0.41).
B. Non-gBRCAmut Cohort: PFS in the niraparib (Zejula) arm was 9.3 and 3.9 in the placebo arm with a HR of 0.45 and 95% CI (0.34, 0.61).

II. Therapy in the maintenance setting was initiated within eight weeks after completion of the last dose of platinum-based chemotherapy. The intent is that treatment is started within a reasonable timeframe consistent with a maintenance treatment plan (i.e. as close to eight weeks as possible), but recognize that scheduling or other factors may impact the ability of a patient to start exactly within these first eight weeks.

III. The safety of niraparib (Zejula) for the treatment of advanced ovarian cancer after three or more chemotherapies was studied in a single arm trial with the investigator assessment of objective response rate (ORR) as the efficacy outcome measure. That trial included 98 patients with advanced ovarian cancer positive for homologous recombination deficiency (HRD) tumors, also known as *BRCAmut* positive tumors. Those patients were required to have been treated with three or more prior lines of chemotherapy, and those with history of PARP inhibitors were excluded. Additionally, patients without *BRCA* mutations must have progressed at least six months after their last dose of platinum-based chemotherapy regimen.
A. HRD (*BRCAmut)* positive ORR was 24% with 95% CI (16, 34)
B. Without *BRCAmut,* ORR was 20% with 95% CI (8, 37)

IV. There is a lack of strong scientific evidence from randomized controlled trials supporting safety and efficacy to support the use of a subsequent PARP inhibitor following progression of disease on another PARP inhibitor.

Investigational or Not Medically Necessary Uses

I. There is a lack of strong scientific evidence from randomized controlled trials supporting safety and efficacy for the use of niraparib (Zejula) in the following settings listed below:
A. Used in combination with other chemotherapy or targeted therapy regimen.
B. Breast Cancer
C. Prostate Cancer
D. Lung Cancer
E. Advance Solid Tumors
F. Melanoma
G. Pancreatic cancer
H. Gastroesophageal cancer

References

1. Zejula [Prescribing Information]. Waltham, MA: Tesaro, Inc. October 2019.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines). Ovarian Cancer Including: Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer & Less Common Histopathologies. Version 3.2019 [Updated November 26, 2019]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/ovarian_blocks.pdf

Policy Implementation/Update:

Date Created	May 2017
Date Effective	August 2017
Last Updated	November 2019
Last Reviewed	11/2019

Action and Summary of Changes	Date
Criteria transition into policy with the following updates made: addition of supporting evidence and investigation section, broke out the different indications (treatment versus maintenance therapy) due to the newly approved indication for late-line treatment in women with recurrent ovarian cancer, included mutation status for the treatment of recurrent ovarian cancer, included criterion around prior PARP inhibitor use, increase initial approval duration from three months to six months to be consistent with other payers, included age criterion per label, and removed the 8 weeks criterion around most recent platinum-based therapy in the setting of maintenance therapy in recurrent ovarian cancer; in place of the 8 weeks criterion, provider attestation and documentation is required instead.	11/2019