Commercial/Healthcare Exchange PA Criteria

Effective: May 3, 2017

Prior Authorization: Zejula

Products Affected: Zejula (niraparib) oral tablet

Medication Description:

Niraparib is a poly (ADP-ribose) polymerase (PARP) enzyme inhibitor, which is highly selective for PARP-1 and PARP-2. PARP-1 and PARP-2 are involved in detecting DNA damage and promote repair. Inhibiting PARP enzymatic activity results in DNA damage, apoptosis and cell death.

Covered Uses:

1. First-Line Maintenance Treatment of Advanced Ovarian Cancer
2. Maintenance Treatment of Recurrent Ovarian Cancer
3. Treatment of Advanced Ovarian Cancer after Three or More Chemotherapies

Exclusion Criteria: N/A

Required Medical Information:

1. Diagnosis
2. Previous medications tried/failed

Prescriber Restriction: Prescribed by, or in consultation with, an Oncologist

Age Restriction: 18 years of age or older

Coverage Duration: 3 years

Other Criteria:

First-Line Maintenance Treatment of Advanced Ovarian Cancer

A. Patient has advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer; **AND**
B. Patient has had complete or partial response to first-line platinum-based chemotherapy.

Maintenance Treatment of Recurrent Ovarian Cancer

A. Patient has recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer; **AND**
B. Patient has had a complete or partial response to platinum-based chemotherapy.

Treatment of Advanced Ovarian Cancer after Three or More Chemotherapies

A. Patient has a diagnosis of advanced ovarian, fallopian tube, or primary peritoneal cancer; **AND**
B. Patient has been treated with three or more prior chemotherapy regimens; **AND**
C. Patients 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 patient has progressed more than six months after response to the last platinum-based chemotherapy.

References:

1. Product Information: ZEJULA(TM) oral capsules, niraparib oral capsules. Tesaro Inc (per FDA), Waltham, MA, 2017. Accessed April 10, 2017.
2. Mirza MR, Monk BJ, Herrstedt J, et al. Niraparib Maintenance Therapy in Platinum-Sensitive, Recurrent Ovarian Cancer. N Engl J Med. 2016 Dec 1;375(22):2154-2164. doi: 10.1056/NEJMoa1611310. Accessed April 10, 2017.
3. Tesaro Niraparib Clinical Trials. May 2010. Waltham, MA. Information about clinical trials for Niraparib. Tesaro, Inc. Available at: http://www.tesarobio.com/en/pipeline/niraparib/clinical-trials. Accessed April 10, 2017.
4. U.S. Food and Drug Administration. FDA News Release. March 2017. Silver Spring, MD. FDA approves maintenance treatment for recurrent epithelial ovarian, fallopian tube or primary peritoneal cancers. Available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm548948.htm. Accessed April 10, 2017
5. The National Comprehensive Cancer Network. NCCN Guidelines for Ovarian Cancer. Updated June 30, 2016. URL: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed April 10, 2017.
6. Lee-may Chen, Jonathan S Berek. Epithelial carcinoma of the ovary, fallopian tube, and peritoneum: Epidemiology and risk factors. Updated December 2016. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Available at: https://www.uptodate.com/contents/epithelial-carcinoma-of-the-ovary-fallopian-tube-and-peritoneum-epidemiology-and-risk-factors?source=see_link&sectionName=EPIDEMIOLOGY&anchor=H6092134#H6092134. Accessed April 10, 2017.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	4/14/2017
2	Update	Update	Coverage Duration: Update to 3 years	07/01/2019
3	Update	Added new indication per FDA label (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. 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; Added age restriction of 18 years of age and older to match FDA label	Medication Description Covered Uses Age Restriction Required Medical Information Other Criteria	8/4/2020