

## Zejula™ (niraparib) (Oral)

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Last Review Date: 5/30/2017

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### I. Length of Authorization

Coverage will be provided for six months and may be renewed.

### II. Dosing Limits

#### A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- 90 capsules per 30 days (3 capsules per day)

#### B. Max Units (per dose and over time) [Medical Benefit]:

- 300 mg per day

### III. Initial Approval Criteria

Coverage for drug is provided in the following conditions:

#### Ovarian cancer (epithelial ovarian, fallopian tube, or primary peritoneal cancer) †

- Patient must be 18 years of age or older; **AND**
- Patient must have recurrent disease; **AND**
- Patient is in complete or partial response to platinum-based chemotherapy (i.e., platinum-sensitive); **AND**
- Must be used for maintenance treatment as a single agent; **AND**
- Patient will start treatment no later than 8 weeks after their most recent platinum-containing regimen

† FDA Approved Indication(s)

### IV. Renewal Criteria

Authorizations can be renewed based on the following criteria:

- Patient continues to meet the criteria identified in section III; **AND**

- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug (e.g., myelodysplastic syndrome/acute myeloid leukemia, bone marrow suppression, cardiovascular effects, etc.); **AND**
- Patient has not developed myelodysplastic syndrome/acute myeloid leukemia (MDS/AML)

## V. Dosage/Administration

Indication	Dose
All Indications	300 mg (3 capsules) orally daily

## VI. Billing Code/Availability Information

Jcode:

J8999 – Prescription drug, oral, chemotherapeutic, Not Otherwise Specified

NDC:

Zejula 100 mg oral capsule (90 count bottle): 69656-0103-xx

## VII. References

1. Zejula [package insert]. Waltham, MA; Tesaro Inc.; March 2017. Accessed May 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.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) niraparib. National Comprehensive Cancer Network, 2017. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed May 2017.

## Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C48.1	Malignant neoplasm of specified parts of peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
C56.1	Malignant neoplasm of ovary, right ovary
C56.2	Malignant neoplasm of ovary, left ovary
C56.9	Malignant neoplasm of ovary, unspecified

ICD-10	ICD-10 Description
C57.00	Malignant neoplasm of unspecified fallopian tube
C57.01	Malignant neoplasm of right fallopian tube
C57.02	Malignant neoplasm of left fallopian tube
C57.10	Malignant neoplasm of unspecified broad ligament
C57.11	Malignant neoplasm of right broad ligament
C57.12	Malignant neoplasm of left broad ligament
C57.20	Malignant neoplasm of unspecified round ligament
C57.21	Malignant neoplasm of right round ligament
C57.22	Malignant neoplasm of left round ligament
C57.3	Malignant neoplasm of parametrium
C57.4	Malignant neoplasm of uterine adnexa, unspecified
C57.7	Malignant neoplasm of other specified female genital organs
C57.8	Malignant neoplasm of overlapping sites of female genital organs
C57.9	Malignant neoplasm of female genital organ, unspecified
Z85.43	Personal history of malignant neoplasm of ovary

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Cahaba Government Benefit Administrators, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC

**Medicare Part B Administrative Contractor (MAC) Jurisdictions**

<b>Jurisdiction</b>	<b>Applicable State/US Territory</b>	<b>Contractor</b>
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC