

Zejula® (niraparib) (Oral)

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I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Zejula 100 mg capsule: 3 capsules per day

B. Max Units (per dose and over time) [HCPCS Unit]:

- All indications: 300 mg per day

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria

- Patient has not received prior treatment with a PARP-inhibitor (i.e., olaparib, rucaparib, or talazoparib) prior to initiating therapy; **AND**

Ovarian Cancer (epithelial ovarian, fallopian tube, or primary peritoneal cancer) † Φ ^{1,3,5}

- Used as single agent therapy for maintenance treatment; **AND**
 - Patient has recurrent disease; **AND**
 - Patient is in complete or partial response after most recent platinum-based chemotherapy (i.e., platinum-sensitive); **AND**
 - Patient has completed two or more lines of previous platinum-based therapy; **OR**
 - Patient has advanced disease †; **AND**
 - Used as first-line therapy; **AND**
 - Patient is in a complete or partial response to first-line platinum-based chemotherapy; **AND**

- Patient will start treatment no later than 12 weeks after their most recent platinum-containing regimen; **AND**
- Laboratory value for platelet count is current (i.e., within the previous 28 days); **OR**
- Patient has stage II-IV carcinosarcoma or clear cell carcinoma; ‡; **AND**
 - Patient is in complete or partial response after primary therapy; **AND**
 - Patient has germline or somatic BRCA1/2 mutated disease; **OR**
- Patient has stage II-IV high-grade serous or grade 2/3 endometrioid carcinoma ‡; **AND**
 - Patient is in complete or partial response following primary therapy not including bevacizumab; **OR**
 - Patient has germline or somatic BRCA1/2 mutated disease and is in complete or partial response following primary therapy including bevacizumab; **OR**
- Used as subsequent therapy; **AND**
 - Patient has advanced, persistent, or recurrent disease; **AND**
 - Used as a single-agent after treatment with three or more prior chemotherapy regimens; **AND**
 - Patient has homologous recombination deficiency (HRD) positive disease as defined by one of the following:
 - Patient has a deleterious or suspected deleterious *BRCA* mutation as detected by a CLIA-compliant or FDA-approved test❖; **OR**
 - Patient has a genomic instability score (GIS) of ≥ 42 and has progressed more than 6 months after an initial response to the last platinum-based chemotherapy; **OR**
- Used in combination with bevacizumab for platinum-sensitive disease ‡; **AND**
 - Patient has persistent or recurrent disease; **AND**
 - Patient has experienced radiographic and/or clinical relapse at least 6 months after a previous complete remission from prior chemotherapy regimen

Uterine Cancer ‡^{3,8}

- Used as second-line therapy as a single-agent; **AND**
- Patient has BRCA2-altered uterine leiomyosarcoma (uLMS)

❖ *If confirmed using an immunotherapy assay-<http://www.fda.gov/companiondiagnostics>.*

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); **Φ** Orphan Drug

IV. Renewal Criteria¹

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: development of myelodysplastic syndrome/acute myeloid leukemia (MDS/AML), bone marrow suppression (e.g., thrombocytopenia, anemia, neutropenia, and/or pancytopenia), cardiovascular effects (hypertension/hypertensive crisis), posterior reversible encephalopathy syndrome (PRES), allergic-type reactions (including bronchial asthma) to FD&C Yellow No. 5 (tartrazine), etc.; **AND**

Ovarian Cancer (First-Line Maintenance Treatment of Advanced Disease)

- Laboratory value for platelet count is current (i.e., within the previous 28 days)

V. Dosage/Administration ^{1,7,8}

Indication	Dose
Ovarian Cancer	<u>First-Line Maintenance Treatment of Advanced Disease</u>
	– Weight <77 kg (170 lbs) OR a platelet count <150,000/μL: 200 mg (2 capsules) orally once daily until disease progression or unacceptable toxicity
	– Weight ≥77 kg (170 lbs) AND a platelet count ≥150,000/μL: 300 mg (3 capsules) orally once daily until disease progression or unacceptable toxicity
	<u>Maintenance Treatment of Recurrent Disease</u>
	– 300 mg (3 capsules) orally once daily until disease progression or unacceptable toxicity
Uterine Cancer	<u>Subsequent Treatment of Advanced Disease after Three or More Chemotherapies</u>
	– 300 mg (3 capsules) orally once daily until disease progression or unacceptable toxicity
	<u>Subsequent Treatment of Persistent or Recurrent Disease in combination with bevacizumab:</u>
	– 300 mg (3 capsules) orally once daily until disease progression or unacceptable toxicity

VI. Billing Code/Availability Information

HCPCS Code:

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

NDC:

- Zejula 100 mg oral capsule: 69656-0103-xx

VII. References

1. Zejula [package insert]. Waltham, MA; Tesaro Inc.; May 2021. Accessed March 2022.
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, 2022. 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 March 2022.
4. Moore KN, Secord AA, Geller MA, et al. Niraparib monotherapy for late-line treatment of ovarian cancer (QUADRA): a multicentre, open-label, single-arm, phase 2 trial. *Lancet Oncol*. 2019 May;20(5):636-648. doi: 10.1016/S1470-2045(19)30029-4. Epub 2019 Apr 1.
5. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer. Version 1.2022. National Comprehensive Cancer Network, 2022. 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 March 2022.
6. González-Martín A, Pothuri B, Vergote I, et al. Niraparib in Patients with Newly Diagnosed Advanced Ovarian Cancer. *N Engl J Med*. 2019 Dec 19;381(25):2391-2402. doi: 10.1056/NEJMoa1910962. Epub 2019 Sep 28.
7. Mirza MR, Avall Lundqvist E, Birrer MJ, et al. Niraparib plus bevacizumab versus niraparib alone for platinum-sensitive recurrent ovarian cancer (NSGO-AVANOVA2/ENGOT-ov24): a randomised, phase 2, superiority trial. *Lancet Oncol* 2019; 20:1409-1419.
8. Musacchio L, Caruso G, Pisano C, et al. PARP Inhibitors in Endometrial Cancer: Current Status and Perspectives. *Cancer Manag Res*. 2020; 12: 6123–6135. doi: 10.2147/CMAR.S221001

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C48.1	Malignant neoplasm of specified parts of peritoneum

ICD-10	ICD-10 Description
C48.2	Malignant neoplasm of peritoneum, unspecified
C54.0	Malignant neoplasm of isthmus uteri
C54.1	Malignant neoplasm of endometrium
C54.2	Malignant neoplasm of myometrium
C54.3	Malignant neoplasm of fundus uteri
C54.8	Malignant neoplasm of overlapping sites of corpus uteri
C54.9	Malignant neoplasm of corpus uteri, unspecified
C55	Malignant neoplasm of uterus, part 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
C56.3	Malignant neoplasm of bilateral ovaries
C56.9	Malignant neoplasm of ovary, unspecified
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), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at:

<https://www.cms.gov/medicare-coverage-database/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/LCA): 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	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
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