Zejula® (niraparib)
(Oral)

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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) [NDC Unit]:

- Zejula 100 mg capsule: 3 capsules per day

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

- 300 mg per day

III. Initial Approval Criteria [1-7]

Coverage is provided in the following conditions:

- Patient must be 18 years of age or older; **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

- Used as 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 therapy; **AND**

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        - 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 in CR/PR following primary therapy with or without bevacizumab ‡; **AND**
        - Patient has germline or somatic BRCA1/2 mutation; **OR**
    - Patient has stage III-IV high-grade serous or grade 2/3 endometrioid carcinoma ‡; **AND**
        - Patient is in complete or partial response after primary therapy with or without bevacizumab; **OR**
- Used as treatment of advanced, persistent, or recurrent disease; **AND**
    - Used as single-agent subsequent therapy after at least three 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

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

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

IV. Renewal Criteria [1-7]

Authorizations can be renewed based on 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), cardiovascular effects

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(hypertension/hypertensive crisis), posterior reversible encephalopathy syndrome (PRES), allergic-type reactions (including bronchial asthma) to FD&C Yellow No. 5 (tartrazine), etc.; **AND**

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]

Indication	Dose
Ovarian Cancer	First-Line Maintenance Treatment of Advanced Disease – 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 Maintenance Treatment of Recurrent Disease – 300 mg (3 capsules) orally once daily until disease progression or unacceptable toxicity Subsequent Treatment of Advanced Disease after Three or More Chemotherapies – 300 mg (3 capsules) orally once daily until disease progression or unacceptable toxicity Subsequent Treatment of Persistent or Recurrent Disease in combination with bevacizumab: – 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.; March 2021. Accessed March 2021.
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, 2021. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are

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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 2021.

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 1.2021. National Comprehensive Cancer Network, 2021. 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 2021.
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.

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
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

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ICD-10	ICD-10 Description
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

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: 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/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

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