

Rubraca® (rucaparib) (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]:

- Rubraca 300 mg tablet: 4 tablets per day
- Rubraca 250 mg tablet: 4 tablets per day
- Rubraca 200 mg tablet: 4 tablets per day

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

- All indications: 1200 mg per day

III. Initial Approval Criteria ¹

Coverage for drug is provided in the following conditions:

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

Universal Criteria ¹

- Patient has not received prior treatment with a PARP-inhibitor (i.e., olaparib, niraparib, talazoparib, etc.) prior to initiating therapy; **AND**
- Used as a single agent therapy; **AND**

Ovarian Cancer (epithelial ovarian, fallopian tube, or primary peritoneal cancer) † Φ ¹⁻⁵

- Patient has deleterious germline and/or somatic BRCA mutated disease as detected by a CLIA-compliant or FDA-approved test❖; **AND**
 - Patient has advanced, persistent or recurrent disease; **AND**
 - Patient has received treatment with at least two prior lines of chemotherapy; **OR**
- Patient is in complete or partial response to platinum-based chemotherapy (i.e., platinum-sensitive); **AND**

- Used as maintenance treatment for recurrent disease

Prostate Cancer †^{1,2,6,7}

- Patient has deleterious germline and/or somatic BRCA mutated disease as detected by a CLIA-compliant or FDA-approved test❖*; **AND**
- Patient has metastatic castration-resistant prostate cancer (mCRPC); **AND**
- Patient has been previously treated with androgen receptor-directed therapy (e.g., enzalutamide, abiraterone, etc.); **AND**
- Patient will receive concurrent treatment with a GnRH-analog or has had a bilateral orchiectomy; **AND**
- Patient has been previously treated with taxane-based chemotherapy OR patient is not fit for taxane-based therapy; **AND**
 - Patient has received prior novel hormone therapy (e.g., abiraterone, enzalutamide, darolutamide, apalutamide, etc.) and no prior docetaxel; **OR**
 - Patient has received prior docetaxel and prior novel hormone therapy; **AND**
 - Patient does not have visceral metastases

Pancreatic Adenocarcinoma ‡^{2,8}

- Patient has germline or somatic BRCA1/2 or PALB2-mutated disease as detected by any FDA-approved or CLIA-compliant test❖; **AND**
- Used as maintenance treatment for metastatic disease; **AND**
- Patient has ECOG performance status of 0-1; **AND**
- Disease has not progressed after at least 4-6 months following the most recent platinum-based chemotherapy

Uterine Cancer ‡²

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

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

**Should the plasma specimen have a negative BRCA mutations result, further genomic testing using tumor specimens as clinically indicated should be considered.*

† FDA Approved Indication(s); ‡ Compendia recommended indication(s); Ⓢ Orphan Drug

IV. Renewal Criteria^{1,2,3,4,5}

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), etc.

V. Dosage/Administration ^{1,8,9}

Indication	Dose
All indications	Administer 600 mg (two 300 mg tablets) orally twice daily until disease progression or unacceptable toxicity

VI. Billing Code/Availability Information

HCPCS Code:

- J8999 – Prescription drug, oral, chemotherapeutic, nos

NDC:

- Rubraca 200 mg tablet: 69660-0201-xx
- Rubraca 250 mg tablet: 69660-0202-xx
- Rubraca 300 mg tablet: 69660-0203-xx

VII. References

1. Rubraca [package insert]. Boulder, CO; Clovis Oncology, Inc.; September 2021. Accessed March 2022.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) rucaparib. 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.
3. Coleman RL, Oza AM, Lorusso D, et al. Rucaparib maintenance treatment for recurrent ovarian carcinoma after response to platinum therapy (ARIEL3): a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet*. 2017 Oct 28;390(10106):1949-1961. doi: 10.1016/S0140-6736(17)32440-6. Epub 2017 Sep 12.
4. Kristeleit RS, Oaknin A, Ray-Coquard I, et al. Antitumor activity of the poly(ADP-ribose) polymerase inhibitor rucaparib as monotherapy in patients with platinum-sensitive, relapsed, *BRCA*-mutated, high-grade ovarian cancer, and an update on safety. *Int J Gynecol Cancer*. 2019 Nov;29(9):1396-1404. doi: 10.1136/ijgc-2019-000623.
5. Swisher EM, Lin KK, Oza AM, et al. Rucaparib in relapsed, platinum-sensitive high-grade ovarian carcinoma (ARIEL2 Part 1): an international, multicentre, open-label, phase 2 trial.

Lancet Oncol. 2017 Jan;18(1):75-87. doi: 10.1016/S1470-2045(16)30559-9. Epub 2016 Nov 29.

6. Abida W, Campbell D, Patnaik A, et al. Genomic characteristics associated with clinical activity of rucaparib in patients (pts) with BRCA1 or BRCA2 (BRCA)-mutated metastatic castration-resistant prostate cancer (mCRPC). J Clin Onco. 38, no. 6_suppl(February 20, 2020)178-178.
7. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Prostate Cancer. Version 3.2022. 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.
8. Reiss K, Mick R, O'Hara, et al. Phase II Study of Maintenance Rucaparib in Patients With Platinum-Sensitive Advanced Pancreatic Cancer and a Pathogenic Germline or Somatic Variant in BRCA1, BRCA2, or PALB2. Clinical Trial J Clin Oncol. 2021 Aug 1;39(22):2497-2505. doi: 10.1200/JCO.21.00003. Epub 2021 May 10.
9. 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
C25.0	Malignant neoplasm of head of pancreas
C25.1	Malignant neoplasm of body of pancreas
C25.2	Malignant neoplasm of tail of pancreas
C25.3	Malignant neoplasm of pancreatic duct
C25.7	Malignant neoplasm of other parts of pancreas
C25.8	Malignant neoplasm of overlapping sites of pancreas
C25.9	Malignant neoplasm of pancreas, unspecified
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
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

ICD-10	ICD-10 Description
C54.9	Malignant neoplasm of corpus uteri, unspecified
C55	Malignant neoplasm of uterus, part unspecified
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
C61	Malignant neoplasm of prostate
Z85.43	Personal history of malignant neoplasm of ovary
Z85.07	Personal history of malignant neoplasm of pancreas

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