# 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 [1,2]**

- 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]**

- Used as maintenance therapy; **AND**
  - Patient has deleterious or suspected deleterious germline and/or somatic BRCA mutated recurrent disease †; **AND**
    - Patient is in complete or partial response to platinum-based chemotherapy (i.e., platinum-sensitive); **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**
    - Patient has stage II-IV clear cell carcinoma or carcinosarcoma (Malignant Mixed Müllerian Tumors) ‡; **AND**
        - Patient is in complete or partial response after primary therapy; **AND**
        - Patient has germline or somatic BRCA1/2 mutated 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; **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 Neoplasms ‡ [2]**

- Used as subsequent therapy for advanced, recurrent, metastatic, or inoperable disease; **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 mutation result, further genomic testing using tumor specimens as clinically indicated should be considered.*

† FDA Approved Indication(s); ‡ Compendia recommended indication(s); Φ 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.; December 2022. Accessed December 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 December 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 1.2023. 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 December 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 |

| ICD-10 | ICD-10 Description |
|---|---|
| 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 |
| 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 |