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 unless otherwise specified; **AND**
- Used as a single agent therapy; **AND**

Ovarian, Fallopian Tube, and Primary Peritoneal Cancer † ‡ Φ [1-5]

- Used as maintenance therapy; **AND**
  - Patient has recurrent Epithelial Ovarian/Fallopian Tube/Primary Peritoneal Cancer, Grade 1 Endometrioid Carcinoma, Mucinous Carcinoma of the Ovary, or Low-Grade Serous Carcinoma; **AND**

- Patient has germline or somatic BRCA1/2 mutated disease as detected by an FDA-approved or CLIA-compliant test ❖; **AND**
- Patient is in complete or partial response after at least two prior lines of platinum-based chemotherapy (i.e., platinum-sensitive); **AND**
- Patient has not progressed on prior PARP-inhibitor therapy, if previously received; **OR**

o 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 is in complete or partial response following primary therapy including bevacizumab; **AND**
  - Patient has germline or somatic BRCA1/2 mutated disease as detected by an FDA-approved or CLIA-compliant test ❖; **OR**

o Patient has Clear Cell Carcinoma of the Ovary or Carcinosarcoma (Malignant Mixed Müllerian Tumors) ‡; **AND**
- Patient has germline or somatic BRCA1/2 mutated disease as detected by an FDA-approved or CLIA-compliant test ❖; **AND**
  - Patient has stage II-IV disease and is in complete or partial response after primary therapy; **OR**
  - Patient has recurrent disease and is in complete or partial response after at least two prior lines of platinum-based chemotherapy (i.e., platinum-sensitive); **AND**
    - Patient has not progressed on prior PARP-inhibitor therapy, if previously received

Prostate Cancer † ‡ [1,2,6,7,10]

- Patient has germline or somatic BRCA mutated disease as detected by an FDA-approved or CLIA-compliant test ❖ *; **AND**
- Patient has metastatic castration-resistant prostate cancer (mCRPC); **AND**
- Patient will receive concurrent treatment with a GnRH-analog or has had a bilateral orchiectomy; **AND**
- Patient has progressed on androgen receptor-directed therapy (e.g., enzalutamide, abiraterone, apalutamide, darolutamide, etc.); **AND**
  - Patient has progressed on taxane-based chemotherapy; **OR**
  - Patient is not fit for chemotherapy

Pancreatic Adenocarcinoma ‡ [2,8]

- Patient has germline or somatic BRCA1/2 or PALB2-mutated disease as detected by an FDA-approved or CLIA-compliant test❖; **AND**

- Used as maintenance treatment for metastatic disease; **AND**
- Disease has not progressed after at least 4-6 months following the most recent platinum-based chemotherapy

Uterine Sarcoma (Uterine Neoplasms) ‡ [2]

- Used as subsequent therapy for advanced, recurrent, metastatic, or inoperable disease; **AND**
- Patient has leiomyosarcoma (LMS); **AND**
- Patient has BRCA2-altered disease as detected by an FDA-approved or CLIA-compliant test❖

❖*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 [1-5]

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(s):

- 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 February 2024.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) rucaparib. National Comprehensive Cancer Network, 2024. 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 February 2024.
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 3.2024. National Comprehensive Cancer Network, 2024. 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 2024.
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

10. Abida W, Campbell D, Patnaik A, et al. Rucaparib for the Treatment of Metastatic Castration-resistant Prostate Cancer Associated with a DNA Damage Repair Gene Alteration: Final Results from the Phase 2 TRITON2 Study. Eur Urol. 2023 Sep;84(3):321-330. doi: 10.1016/j.eururo.2023.05.021. Epub 2023 Jun 3. PMID: 37277275

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
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

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
C61	Malignant neoplasm of prostate
Z85.42	Personal history of malignant neoplasm of other parts of uterus
Z85.43	Personal history of malignant neoplasm of ovary
Z85.46	Personal history of malignant neoplasm of prostate
Z85.07	Personal history of malignant neoplasm of pancreas

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

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied 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
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC