Rubraca® (rucaparib)
(Oral)

Document Number: IC-0289

Last Review Date: 06/02/2020
Date of Origin: 1/31/2017
Dates Reviewed: 01/2017, 01/2018, 05/2018, 02/2019, 02/2020, 06/2020

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]:

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

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

- 1200 mg per day

III. Initial Approval Criteria [1]

Coverage for drug is provided in the following conditions:

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

Universal Criteria [1]

- Patient has not received prior treatment with a PARP-inhibitor inhibitor (i.e., olaparib, niraparib, talazoparib, etc.) prior to initiating therapy; **AND**
- Patient must not have untreated or symptomatic CNS metastases; **AND**
- Must be used as a single agent; **AND**

Ovarian Cancer (epithelial ovarian, fallopian tube, or primary peritoneal cancer) † Φ [1,2,3,4,5]

- Patient must have a deleterious BRCA mutation (germline and/or somatic) as detected by a CLIA-compliant or FDA-approved test*; **AND**
    - Patient has advanced, persistent or recurrent disease; **AND**
    - Patient must have received treatment with two or more prior lines of chemotherapy; **OR**

- Patient is in complete or partial response to platinum-based chemotherapy (i.e., platinum-sensitive); **AND**
    - Used for maintenance treatment of recurrent disease

Prostate Cancer † [1,2,6]

- Patient must have a deleterious BRCA mutation (germline and/or somatic) 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 acetate) and taxane-based chemotherapy; **AND**
- Patient is receiving a gonadotropin-releasing hormone (GnRH) analog concurrently or had a prior bilateral orchiectomy

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

† FDA Approved Indication(s); Φ Orphan Drug

IV. Renewal Criteria[1,2,3,4,5]

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), etc.

V. Dosage/Administration[1,2,3,4,5]

Indication	Dose
All indications	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.; May 2020. Accessed May 2020.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) rucaparib. National Comprehensive Cancer Network, 2020. 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 May 2020.
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.

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

ICD-10	ICD-10 Description
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

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

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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