Rubraca™ (rucaparib)
(Oral)

Document Number: IC-0289

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

I. Length of Authorization

Coverage will be provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- 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) [Medical Benefit]:

- 1200 mg per day

III. Initial Approval Criteria

Coverage for drug is provided in the following conditions:

- Patient must be 18 years of age or older; **AND**
- Must be used as a single agent; **AND**

Ovarian cancer (epithelial ovarian, fallopian tube, or primary peritoneal cancer) †

- Patient must have a deleterious BRCA mutation (germline and/or somatic) as detected by an FDA-approved test (i.e., FoundationFocus CDxBRCA); **AND**
    - Patient's disease must be advanced, persistent or recurrent; **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

† FDA Approved Indication(s)

IV. Renewal Criteria

Authorizations can be renewed based on the following criteria:

- Patient continues to meet the criteria identified in section III; **AND**
  - Tumor response with 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).

V. Dosage/Administration

Indication	Dose
Ovarian cancer	600 mg (two 300 mg tablets) twice daily

VI. Billing Code/Availability Information

HCPCS:

C9399 – Unclassified drugs or biologicals (Hospital Outpatient Use ONLY)
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.; April 2018. Accessed April 2018.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) rucaparib. National Comprehensive Cancer Network, 2018. 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 April 2018.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
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
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
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
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) and Local Coverage Determinations (LCDs) 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): 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)

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