Drug Policy:

Rubraca™ (rucaparib)

POLICY NUMBER UM ONC_1301	**SUBJECT** Rubraca™ (rucaparib)		**DEPT/PROGRAM** UM Dept	**PAGE 1 of 4**
DATES COMMITTEE REVIEWED 01/11/17, 01/10/18, 01/09/19, 12/11/19, 01/08/20, 06/10/20, 05/12/21, 11/15/21, 03/09/22, 05/11/22, 10/12/22, 11/09/22, 12/14/22, 03/08/23, 05/10/23, 12/13/23, 12/12/24	**APPROVAL DATE** December 12, 2024	**EFFECTIVE DATE** December 27, 2024	**COMMITTEE APPROVAL DATES** 01/11/17, 01/10/18, 01/09/19, 12/11/19, 01/08/20, 06/10/20, 05/12/21, 11/15/21, 03/09/22, 05/11/22, 10/12/22, 11/09/22, 12/14/22, 03/08/23, 05/10/23, 12/13/23, 12/12/24	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Evolent Specialty Services Clinical Guideline Review Committee		
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**		
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid	

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

I. PURPOSE

To define and describe the accepted indications for Rubraca (rucaparib) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. Continuation requests for a not-approvable medication shall be exempt from this

Evolent policy provided:

1. The requested medication was used within the last year, AND
2. The member has not experienced disease progression and/or no intolerance to the requested medication, AND
3. Additional medication(s) are not being added to the continuation request.

B. Ovarian Cancer

1. Rucaparib may be used as single agent maintenance therapy after complete or partial response to first line platinum-based therapy for BRCA 1 or 2 positive newly diagnosed stage II-IV ovarian cancer OR
2. Rucaparib may be used as a single agent as maintenance therapy in a member with stage II-IV ovarian carcinoma who has recurrent platinum sensitive disease, with a deleterious germline BRCA 1 or 2 mutation, and after a complete or partial response to platinum-based therapy.
3. NOTE: The use of Rubraca (rucaparib) as monotherapy is not supported by Evolent Rubraca Policy for persistent disease or recurrence in members with/without deleterious germline BRCA mutation who have been treated with two or more lines of chemotherapy. This policy position is based on the FDA withdrawal of the above indication based on findings from the ARIEL-4 study (see reference below). The ARIEL-4 study showed a lack of overall survival benefit with Rubraca (rucaparib) versus standard chemotherapy in the treatment of relapsed, BRCA-mutated, high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer. Please refer to alternative agents/regimens recommended by Evolent, including but not limited to regimens available at http://pathways.newcenturyhealth.com.

C. Prostate Cancer

1. Rucaparib may be used as a single agent in prostate cancer when ALL the following criteria are met:
   a. Member has metastatic Castration-Resistant Prostate Cancer AND
   b. Member has experienced disease progression on an Androgen Receptor Directed therapy (e.g., abiraterone and/or enzalutamide) and a taxane-based chemotherapy (e.g., docetaxel, cabazitaxel + steroid) AND
   c. Member's cancer is positive for BRCA 1 or 2 mutation (on germline testing on the patient and/or somatic testing on the tumor tissue).

III. EXCLUSION CRITERIA

A. Disease progression while receiving Rubraca (rucaparib) or another PARP inhibitor [i.e., Zejula (niraparib) or Lynparza (Olaparib).

B. Use of Rubraca (rucaparib) not to exceed more than 1 line of maintenance therapy for recurrent ovarian cancer.

C. Lack of documented BRCA 1 or 2 testing: Germline testing for members with Ovarian Cancer AND Germline and/or somatic mutation testing on the tumor tissue.

D. Concurrent use with chemotherapy.

E. Dosing exceeds single dose limit of Rubraca (rucaparib) 600mg.

F. Treatment exceeds the maximum limit of 120 (300 mg), 120 (250 mg), or 120 (200 mg) tablets/month.

G. Use of Rubraca (rucaparib) not to exceed more than 1 line of maintenance therapy for recurrent

ovarian cancer.

H. Investigational use of Rubraca (rucaparib) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:

1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
4. Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

IV. CODING INFORMATION

HCPCS Code	Description
J8999	rucaparib

V. MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

VI. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VII. ATTACHMENTS

A. None

VIII. REFERENCES

A. GSK: Dear health care provider letter (niraparib): Important prescribing information. 2022. https://www.zejulahcp.com/content/dam/cf-pharma/hcp-zejulahcpv2/

en_US/pdf/ZEJULA%20(niraparib)%20Dear%20HCP%20Letter%20September%202022.pdf

B. Tew WP, Lacchetti C, Ellis A, et al: PARP inhibitors in the management of ovarian cancer: ASCO guideline. J Clin Oncol 38:3468-3493, 2020

C. Oza AM, et al. Overall survival results from ARIEL4: A phase III study assessing rucaparib vs chemotherapy in patients with advanced, relapsed ovarian carcinoma and a deleterious BRCA1/2 mutation. Ann Oncol. 2022;33(suppl 7): 518O. doi:10.1016/annonc/annonc1054.

D. Mateo J, et al. DNA-Repair Defects and Olaparib in Metastatic Prostate Cancer. N Engl J Med. 2015 Oct 29;373(18):1697-708.

E. Thiery-Vuillemin, Antoine, et al. Health-related quality of life (HRQoL) for olaparib versus enzalutamide or abiraterone in metastatic castration-resistant prostate cancer (mCRPC) with homologous recombination repair (HRR) gene alterations: PROfound. Journal of Clinical Oncology38, no. 15_suppl(May 20, 2020)5539-5539.

F. Schweizer MT, Cheng HH, Nelson PS, Montgomery RB. Two Steps Forward and One Step Back for Precision in Prostate Cancer Treatment. J Clin Oncol. 2020 Nov 10.

G. Rubraca prescribing information. pharmaand GmbH, Taborstrasse 1 1020 Vienna Austria 2023.

H. Clinical Pharmacology Elsevier Gold Standard 2024.

I. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2024.

J. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2024.

K. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2024.

L. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.

M. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.