POLICY NUMBER UM ONC_1301	SUBJECT Rubraca™ (rucaparib)		DEPT/PROGRAM UM Dept	PAGE 1 OF 2
DATES COMMITTEE REVIEWED 01/11/17, 01/10/18, 01/09/19, 12/11/19, 01/08/20, 06/10/20	APPROVAL DATE June 10, 2020	EFFECTIVE DATE June 26, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 01/11/17, 01/10/18, 01/09/19, 12/11/19, 01/08/20, 06/10/20	
PRIMARY BUSINESS OWNER: UM APPROVED BY: Dr. Andrew Hertler		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
URAC STANDARDS HUM 1		NCQA STANDARDS UM 2	ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS All	

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.

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century 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

1. **PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:**
    a. When health plan Medicaid coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the **Preferred Drug Guidelines OR**
    b. When health plan Exchange coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the **Preferred Drug Guidelines OR**
    c. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the **Preferred Drug Guidelines shall follow NCH L1 Pathways** when applicable, otherwise shall follow NCH drug policies **AND**
    d. Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**
    e. When available, generic alternatives are preferred over brand name drugs.
2. **Ovarian Cancer**
    a. **NOTE: Rucaparib is a non-preferred PARP-inhibitor per NCH Policy & NCH Pathway. Please refer to the NCH Pathway document for the most current recommended PARP inhibitors for ovarian cancer**
    b. Rucaparib may be used as a single agent when **ALL** of the following criteria are met:
        i. The member has stage III/IV ovarian carcinoma **AND**
        ii. Member has relapsed or progressive disease with deleterious/suspected deleterious germline BRCA1/2 mutation **AND**
            A. Member has received at least 3 prior chemotherapy regimens OR

B. Member has completed two or more lines of platinum-based therapy with a complete or partial response

iii. Rubraca (rucaparib) will be used as a single agent and as maintenance therapy.

3. **Prostate Cancer**

a. **NOTE: The preferred agent in this setting is olaparib.**

b. Rucaparib may be used as a single agent in prostate cancer when **ALL** the following criteria are met:

i. Member has metastatic Castration-Resistant prostate Cancer **AND**

ii. Member has experienced disease progression on or after taxane based therapy (e.g. docetaxel) and Androgen Receptor Directed therapy (e.g. Abiraterone and/or Enzalutamide) **AND**

iii. 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) **AND**

iv. Member is intolerant to/has a contraindication to olaparib.

III. EXCLUSION CRITERIA

1. Disease progression while receiving Rubraca (rucaparib).
2. Lack of documented BRCA1 or 2 testing: Germline testing for members with Ovarian Cancer AND Germline and/or somatic mutation testing on the tumor tissue
3. Concurrent use with other PARP inhibitors.
4. Dosing exceeds single dose limit of Rubraca (rucaparib) 600mg.
5. Treatment exceeds the maximum limit of 120 (300 mg) tablets/month or 180 (200 mg) tablets/month.
6. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

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

V. APPROVAL AUTHORITY

1. Review – Utilization Management Department
2. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Rubraca PI prescribing information. Clovis Oncology, Inc. Boulder, CO. 2018.
2. Clinical Pharmacology Elsevier Gold Standard. 2020.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.