Commercial/Healthcare Exchange PA Criteria

Effective: February 15, 2017

Prior Authorization: Rubraca

Products Affected: Rubraca (rucaparib) Oral Tablet

Medication Description:

Rucaparib is an inhibitor of poly (ADP-ribose) polymerase (PARP) enzymes, including PARP-1, PARP-2, and PARP3, which play a role in DNA repair. In vitro studies have shown that rucaparib-induced cytotoxicity may involve inhibition of PARP enzymatic activity and increased formation of PARP-DNA complexes resulting in DNA damage, apoptosis, and cell death.

Covered Uses:

1. Treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies
2. Maintenance treatment of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer that are in a complete or partial response to platinum-based chemotherapy
3. Metastatic Castration-Resistant Prostate Cancer with BRCA Mutations

Exclusion Criteria: N/A

Required Medical Information:

1. Diagnosis
2. Confirmed BRCA mutation (germline and/or somatic) via FDA-approved test
3. Previous medications tried/failed

Age Restrictions: 18 years of age or older

Prescriber Restriction: Prescribed by, or in consultation with, an Oncologist

Coverage Duration: 3 years

Other Criteria:

BRCA-mutated Ovarian Cancer

A. Patient is diagnosed with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer; AND
B. Patient's cancer has deleterious BRCA mutation (germline and/or somatic); AND
C. Patient has received prior treatment with at least two chemotherapies.

Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer (maintenance treatment)

A. Patient is diagnosed with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer; AND
B. Patient's disease has had a complete or partial response to platinum-based chemotherapy.

Metastatic Castration-Resistant Prostate Cancer with BRCA Mutations

A. Patient has been diagnosed with a deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC); AND
B. Patient has been treated with androgen receptor-directed therapy; AND
C. Patient has been treated with a taxane-based chemotherapy; AND
D. One of the following:
    a. Rubraca is being used concurrently with a gonadotropin-releasing hormone (GnRH) analog; OR
    b. Patient has had bilateral orchiectomy

References:

1. Product Information: RUBRACA(TM) oral tablets, rucaparib oral tablets. Clovis Oncology Inc (per manufacturer), Boulder, CO, 2016.
2. FDA Accepts Clovis Oncology's New Drug Application for Rucaparib for Priority Review for the Treatment of Advanced Mutant BRCA Ovarian Cancer. August 23, 2016. New York, NY: Businesswire. Available at: http://www.businesswire.com/news/home/20160823006191/en/FDA-Accepts-Clovis-Oncology%E2%80%99s-Drug-Application-Rucaparib. Accessed January 6, 2017.
3. Clinical Trials for Ovarian Cancer, ARIEL clinical trials. c2016. Boulder, CO: Clovis Oncology. Available at: http://arielstudy.com. Accessed January 6, 2017.
4. The National Comprehensive Cancer Network. NCCN Guidelines for Ovarian Cancer. Updated June 30, 2016. URL: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed January 6, 2017.
5. Lee-may Chen, Jonathan S Berek. Epithelial carcinoma of the ovary, fallopian tube, and peritoneum: Epidemiology and risk factors. Updated December 2016. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Available at: https://www.uptodate.com/contents/epithelial-carcinoma-of-the-ovary-fallopian-tube-and-peritoneum-epidemiology-and-risk-factors?source=see_link&sectionName=EPIDEMIOLOGY&anchor=H6092134#H6092134. Accessed January 6, 2017.

Policy Revision history:

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	Added Metastatic castration resistant prostate cancer indication and criteria Updated Ovarian cancer indication to align with package label (advanced ovarian and recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer) Updated Medication Description Added Age restriction 18 years of age or older Adopted EH Policy- Rev history: 7/2019 Removed from CCI oncology policy	All	6/8/2020