PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Rubraca™ (rucaparib tablets – Clovis Oncology)

DATE REVIEWED: 02/19/2020; 05/27/2020 selected revision

OVERVIEW

Rubraca, a poly (ADP-ribose) polymerase (PARP) inhibitor, is indicated[1]:

A) For the **treatment** of adult patients with deleterious *BReast CAncer (BRCA)* mutation (germline and/or somatic) associated epithelial **ovarian, fallopian tube, or primary pertitoneal cancer** who have been treated with two or more chemotherapies;

B) For the **maintenance treatment** of adult patients with recurrent **epithelial ovarian, fallopian tube, or primary peritoneal cancer** who are in a complete or partial response to platinum-based chemotherapy;

C) Treatment of adult patients with a deleterious *BRCA* mutation (germline and/or somatic)-associated **metastatic castration-resistant prostate cancer** (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy.

Guidelines

According to the National Comprehensive Cancer Network (NCCN) guidelines for ovarian cancer (version 3. 2019 – November 26, 2019), therapy options for patients with recurrent disease are primarily dependent on whether the patient is considered platinum-resistant or platinum-sensitive (patients who relapse ≥ 6 months after initial chemotherapy).[3] NCCN Panel recommends single-agent Rubraca as recurrence therapy for patients with platinum-sensitive or platinum-resistant ovarian cancer that has been treated with two or more lines of chemotherapy and have *BRCA* mutations. The Panel feels that Rubraca is preferred for patients with platinum-resistant disease, because there are fewer good options for this setting. In patients with platinum-sensitive disease who have completed two or more lines of platinum-based therapy and are in a partial or complete response, bevacizumab can be continued as maintenance therapy; or Zejula™ (niraparib capsules), Lynparza™ (olaparib tablets), or Rubraca can be considered as maintenance therapy options (all category 2A).

The NCCN prostate cancer guidelines (version 2.2020 – May 21, 2020) recommend Rubraca for *BRCA1* or *BRCA2* mutation (germline and/or somatic) for its FDA-approved use in mCRPC, either as second-line or subsequent therapy (category 2A). It is listed under "useful in certain circumstances". The guidelines note that if the patient is not fit for chemotherapy, Rubraca can be considered even if taxane-based therapy has not been given.

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Rubraca. All approvals are provided for 3 years in duration unless otherwise noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Rubraca is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Ovarian, Fallopian Tube, or Primary Peritoneal Cancer – Treatment.**
   - **A)** Initial Therapy. Approve for 3 years if the patient meets the following criteria (i and ii):
     - **i.** The patient has a *BRCA*-mutation (germline or somatic) as confirmed by an approved test; AND
     - **ii.** The patient has progressed on two or more prior lines of chemotherapy.
   - **B)** Patient is Currently Receiving Rubraca. Approve for 3 years if the patient has a *BRCA* mutation (germline or somatic) as confirmed by an approved test.

2. **Ovarian, Fallopian Tube, or Primary Peritoneal Cancer –Maintenance Therapy.** Approve for 3 years if the patient is in complete or partial response after at least two platinum-based chemotherapy regimens.
   Note: Examples are carboplatin with gemcitabine, carboplatin with paclitaxel, cisplatin with gemcitabine.

3. **Prostate Cancer – Castration-Resistant.** Approve for 3 years if the patient meets the following criteria (A, B, C, and D):
   - **A)** The patient has metastatic disease that is *BRCA*-mutation positive (germline and/or somatic); AND
   - **B)** The patient meets one of the following criteria (i or ii):
     - **i.** The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog.
       Note: Examples are Lupron (leuprolide for injection), Lupron Depot (leuprolide acetate for depot suspension), Trelstar (triptorelin pamoate for injectable suspension), Zoladex (goserelin acetate implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix for injection); OR
     - **ii.** The patient has had a bilateral orchiectomy; AND
   - **C)** The patient has been previously treated with at least one androgen receptor-directed therapy.
     Note: Examples are abiraterone, Xtandi (enzalutamide tablets), Yonsa® (abiraterone acetate tablets); AND
   - **D)** The patient meets one of the following criteria (i or ii):
     - **i.** The patient has been previously treated with at least one taxane-based chemotherapy.
       Note: Examples are docetaxel, cabazitaxel; OR
     - **ii.** The patient is not a candidate or is intolerant to taxane-based chemotherapy, according to the prescriber.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Rubraca has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Rubraca™ tablets [prescribing information]. Boulder, CO: Clovis Oncology, Inc.; May 2020.

2. List of cleared or approved companion diagnostic devices (*in vitro* and imaging tools). U.S. Food and Drug Administration. Available at: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm301431.htm. Last updated 12/22/2016. Accessed on January 18, 2018.
3. The NCCN Ovarian Cancer Clinical Practice Guidelines in Oncology (Version 3.2019 – November 26, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed February 14, 2020.
4. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (Version 2.2020 – May 21, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 23, 2020.