UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Rubraca

Program	Prior Authorization
Medication	Rubraca™ (rucaparib)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	2/2018
Pharmacy and Therapeutics Approval Date	6/2020
Effective Date	8/2020

1. Background:

Rubraca (rucaparib) is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated 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. It is also indicated for the treatment of patients with 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. Rubraca is also indicated for the treatment of adult patients with 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. This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

2. Coverage Criteria:

A. <u>Ovarian Cancer</u>

1. **<u>Initial Authorization</u>**

   a. **Rubraca** will be approved based on **<u>all</u>** of the following criteria:

      (1) Diagnosis of **<u>one</u>** of the following:

         (a) Epithelial ovarian cancer
         (b) Fallopian tube cancer
         (c) Primary peritoneal cancer

-AND-

(2) **One** of the following:

(a) **Both** of the following

i. Cancer has a deleterious *BRCA* mutation

-AND-

ii. History of failure, contraindication, or intolerance to two or more chemotherapies (e.g., carboplatin or cisplatin)

-OR-

(b) To be used as maintenance therapy in individuals who are in complete or partial response to platinum-based chemotherapy

Authorization will be issued for 12 months.

2. Reauthorization

a. **Rubraca** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Rubraca therapy

Authorization will be issued for 12 months.

B. Prostate Cancer

1. **Initial Authorization**

a. **Rubraca** will be approved based on **all** of the following criteria:

(1) Diagnosis of metastatic, castration-resistant prostate cancer

-AND-

(2) Cancer has a deleterious *BRCA* mutation

-AND-

(3) History of failure, contraindication, or intolerance to **both** of the following:

(a) Androgen receptor-directed therapy (e.g., Zytiga (abiraterone), Xtandi (enzalutamide), Erleada (apalutamide))

-AND-

(b) Taxane-based chemotherapy (e.g., docetaxel, Jevtana (cabazitaxel))

-AND-

(4) **One** of the following:

(a) Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

-OR-

(b) Patient has had bilateral orchiectomy

Authorization will be issued for 12 months.

2. Reauthorization

a. **Rubraca** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Rubraca therapy

Authorization will be issued for 12 months.

C. NCCN Recommended Regimens

1. Initial Authorization

a. **Rubraca** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

a. **Rubraca** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Rubraca therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Rubraca [package insert]. Boulder, CO: Clovis Oncology, Inc. May 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed May 18, 2020

Program	Prior Authorization- Rubraca (rucaparib)
Change Control	
Date	Change
2/2017	New program for Rubraca approved by FDA on 12/19/2016.
2/2018	Annual review. Updated references. Added a section for NCCN recommended regimens to account for NCCN updates that occur outside of scheduled policy reviews.
9/2018	Updated background and criteria to align with labeled indications. Updated references.
9/2019	Annual review. Updated background. No changes to criteria.
6/2020	Added review criteria for prostate cancer. Updated background and references. Added Additional Clinical Rules section.