UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Rubraca

Program	Prior Authorization
Medication	Rubraca™ (rucaparib)
Markets in Scope	Arizona, California, Florida-CHIP, Hawaii, Maryland, Nevada, New Mexico, New York, New York EPP, Ohio, Rhode Island, Washington, New Jersey, Louisiana
Issue Date	2/2018
Pharmacy and Therapeutics Approval Date	2/2018
Effective Date	4/2018

1. Background:

Rubraca (rucaparib) is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated as monotherapy for the treatment of patients with deleterious *BRCA* mutation (germline and/or somatic) associated advanced ovarian cancer who have been treated with two or more chemotherapies. Select patients for therapy based on an FDA-approved companion diagnostic for Rubraca.

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 ovarian cancer

      -AND-

      (2) **<u>Both</u>** of the following:

         (a) Cancer has a deleterious *BRCA* mutation as confirmed by an FDA-approved diagnostic test (e.g., FoundationFocus CDxBRCA™)
         (b) History of failure, contraindication, or intolerance to two or more chemotherapies (e.g., carboplatin or cisplatin)

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. 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. References:

1. Rubraca™ [package insert]. Boulder, CO: Clovis Oncology, Inc. February 2017.

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.