UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

<table>
<thead>
<tr>
<th>Program Number</th>
<th>2019 P 3127-1</th>
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<tr>
<td>Program</td>
<td>Step Therapy</td>
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<tr>
<td>Medication</td>
<td>Rubraca® (rucaparib)</td>
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<tr>
<td>P&amp;T Approval Date</td>
<td>10/2019</td>
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<tr>
<td>Effective Date</td>
<td>1/1/2020; Oxford only: 1/1/2020</td>
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1. **Background:**

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to try Lynparza® (olaparib) or Zejula™ (niraparib) before providing coverage for Rubraca® (rucaparib) for the maintenance treatment of recurrent ovarian cancer.

Zejula, Rubraca, and Lynparza are 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.

Members currently on Rubraca therapy as documented in claims history will be allowed to continue on their current therapy. Members new to therapy will be required to meet the coverage criteria below.

**Coverage Information:**

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. **Coverage Criteria**

   **A. Patients less than 19 years of age**

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

         a. Member is less than 19 years of age

         **Authorization will be issued for 12 months.**

   **B. Maintenance Treatment of Recurrent Ovarian Cancer**

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1. **Rubraca** will be approved based on the following criteria:

   a. **One** of the following:

      (1) Patient has a contraindication, or history of intolerance to **one** of the following:

         (a) Lynparza (olaparib)

         -OR-

         (b) Zejula (niraparib)

         -OR-

      (2) Provider attests that the patient is not an appropriate candidate for either Lynparza (olaparib) or Zejula (niraparib)

         -OR-

      (3) **Both** of the following:

         (a) As continuation of therapy

         -AND-

         (b) Patient has **not** received a manufacturer supplied sample at no cost from a prescriber’s office, or any form of assistance from Rubraca Connections (e.g. sample card which can be redeemed at a pharmacy for a free supply of medication) or a 30 day free trial from a pharmacy as a means to establish as a current user of Rubraca

*Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber’s office or any form of assistance from Rubraca Connections **shall be required** to meet initial authorization criteria as if patient were new to therapy.

**Authorization will be issued for 12 months.**

C. **Other Indications**

1. **Rubraca** will be approved.

   **Authorization will be issued for 12 months.**

   *State mandates may apply. Any federal regulatory requirements and the member
specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Coverage of oncology medications used to treat stage four advanced metastatic cancer may be approved based on state mandates.

### 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 and/or Notification may be in place.
- Coverage of oncology medications used to treat stage IV advanced metastatic cancer may be approved based on state mandates.

### 4. References:

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<th>Program</th>
<th>Step Therapy – Rubraca® (rucaparib)</th>
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<td></td>
<td>Change Control</td>
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<tr>
<td>10/2019</td>
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