UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3127-6
Program	Step Therapy
Medication	Rubraca® (rucaparib)
P&T Approval Date	10/2019, 10/2020, 10/2021, 4/2022, 4/2023, 4/2024
Effective Date	7/1/2024

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 is indicated for the maintenance treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. Rubraca is indicated for the maintenance treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)- associated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. Lynparza is indicated for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. The National Comprehensive Cancer Network (NCCN) recommends Lynparza, Zejula, and Rubraca for germline or somatic BRCA 1/2 mutation-associated 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,b]:

A. <u>Patients less than 19 years of age</u>

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

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

   Authorization will be issued for 12 months.

C. Other Indications

1. **Rubraca** will be approved.

   Authorization will be issued for 12 months.

[a] 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.
[b] Coverage of oncology medications 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 may be approved based on state mandates.

4. References:

1. Zejula [package insert]. Durham, NC: GlaxoSmithKline.; January 2024.
2. Lynparza [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2023.
3. Rubraca [package insert]. Rubraca [package insert]. Vienna, Austria: pharma&; June 2023.
4. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed February 22, 2024.

Program	Step Therapy – Rubraca (rucaparib)
Change Control	
10/2019	New program
10/2020	Annual review. Updated references.
10/2021	Annual review. Removed sample pack footnote which does not apply to this program and updated references.
4/2022	Updated oncology medications state mandate note.
4/2023	Updated background and references.
4/2024	Annual review with no changes to criteria. Updated references.