UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1208-10
Program	Prior Authorization/Notification
Medication	Rubraca® (rucaparib)
P&T Approval Date	2/2017, 2/2018, 9/2018, 9/2019, 6/2020, 6/2021, 6/2022, 4/2023, 4/2024, 4/2025
Effective Date	7/1/2025

1. Background:

Rubraca (rucaparib) is a poly (ADP-ribose) polymerase (PARP) inhibitor 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.

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.

The National Comprehensive Cancer Network (NCCN) recommends Rubraca for castration-resistant distant metastatic prostate cancer for patients who have a pathogenic BRCA1 or BRCA2 mutation (germline and/or somatic) and have been treated with androgen receptor-directed therapy. The NCCN also recommends Rubraca as second-line therapy that may be considered for BRCA altered uterine leiomyosarcoma (uLMS). The NCCN also recommends Rubraca as maintenance therapy for metastatic pancreatic adenocarcinoma in patients with germline or somatic BRCA1/2 or PALB2 mutations if good performance status (ECOG 0-1) and no disease progression (after at least 4-6 months of chemotherapy, assuming acceptable tolerance) following the most recent platinum-based chemotherapy.

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]:

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

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

   a. Patient is less than 19 years of age

Authorization will be issued for 12 months.

B. Ovarian Cancer

1. **Initial Authorization**

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

(1) Diagnosis of **one** of the following:

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

-AND-

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

(a) Cancer has a deleterious *BRCA* mutation

-AND-

(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.

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

-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.

D. Uterine Cancer

1. **Initial Authorization**

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

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

(a) Diagnosis of *BRCA* altered uterine leiomyosarcoma (uLMS)

-AND-

(b) Disease has progressed following prior treatment with **one** of the following:

i. gemcitabine plus docetaxel
ii. doxorubicin

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.

E. Pancreatic Cancer

1. **Initial Authorization**

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

      (1) Diagnosis of pancreatic adenocarcinoma

      -AND-

      (2) Disease is metastatic

      -AND-

      (3) Presence of **one** of the following:

         (a) Deleterious or suspected deleterious germline or somatic *BRCA1/2* mutation
         (b) Deleterious or suspected deleterious germline or somatic *PALB2* mutation

      -AND-

      (4) Disease has **not** progressed while receiving at least 16 weeks of a first-line platinum-based chemotherapy regimen

   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.

F. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

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.

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]. Vienna, Austria: pharma&; June 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed March 12, 2025.

Program	Prior Authorization/Notification – Rubraca (rucaparib)
Change Control	
2/2017	New program for Rubraca approved by FDA on 12/19/2016.
2/2018	Annual review. Updated references.
9/2018	Revised coverage criteria. Updated background and references.
9/2019	Annual review. Updated background. No changes to coverage criteria. Added general NCCN recommended review criteria.
6/2020	Added review criteria for prostate cancer. Updated background and references.
6/2021	Annual review. No changes to criteria. Updated references.
6/2022	Annual review. Updated background and criteria to include indications for uterine cancer and pancreatic cancer per NCCN guidelines. Updated references.
4/2023	Updated criteria for maintenance treatment of recurrent ovarian cancer indication to limit to patients with a deleterious *BRCA* mutation per prescribing information. Updated background, added state mandate, and updated references.
4/2024	Annual review with no changes to criteria. Updated references.
4/2025	Annual review. Updated background and criteria to remove requirement for taxane-based chemotherapy for prostate cancer per NCCN. Updated references.