

Specialty Guideline Management

Rubraca

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Rubraca	rucaparib

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications

Ovarian Cancer

Maintenance treatment of adult patients with 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.

Prostate Cancer

Treatment of adult patients with a 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. Select patients for therapy based on an FDA-approved companion diagnostic test for Rubraca.

Compendial Uses

- Prostate Cancer
- Uterine Leiomyosarcoma (uLMS)
- Pancreatic Adenocarcinoma
- Ovarian, Fallopian Tube, Primary Peritoneal Cancer – maintenance therapy for stage II-IV disease with germline or somatic BRCA mutation in complete or partial response to primary therapy

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Documentation of laboratory report confirming BRCA mutation status, where applicable
- Documentation of laboratory report confirming PALB2 mutation status, where applicable

Coverage Criteria

Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

Authorization of 12 months may be granted for the maintenance treatment of epithelial ovarian, fallopian tube, or primary peritoneal cancer as a single agent when any of the following criteria are met:

- Member has germline or somatic BRCA-mutated recurrent disease and is in complete or partial response to platinum-based chemotherapy
- Member has advanced (stage II-IV) disease and is in complete or partial response to primary therapy and either of the following criteria are met:
 - Primary therapy included bevacizumab and member has germline or somatic BRCA-mutated disease, or
 - Primary therapy did not include bevacizumab.

Prostate Cancer

Authorization of 12 months may be granted for treatment of metastatic castration-resistant prostate cancer when all of the following criteria are met:

- Tumor has a deleterious BRCA mutation (germline, somatic, or both)
- Member has been treated with androgen receptor-directed therapy
- Member has been treated with a taxane-based chemotherapy or is not fit for chemotherapy

Reference number(s)
2256-A

- Member is receiving therapy concurrently with a luteinizing hormone-releasing hormone (LHRH) agonist (e.g., goserelin, leuprolide) or antagonist (e.g., degarelix, relugolix) or has had a bilateral orchiectomy
- The requested medication will be used as a single agent (concurrent use with a LHRH agonist (e.g., goserelin, leuprolide) or antagonist (e.g., degarelix, relugolix) is allowed)

Uterine Leiomyosarcoma

Authorization of 12 months may be granted for subsequent treatment of BRCA2-altered uterine leiomyosarcoma (uLMS) when used as a single agent for advanced, recurrent, metastatic, or inoperable disease.

Pancreatic Adenocarcinoma

Authorization of 12 months may be granted for the maintenance treatment of metastatic pancreatic adenocarcinoma when all of the following criteria are met:

- Tumor has BRCA-mutations (germline or somatic) or PALB2-mutations
- Disease has not progressed on at least 16 weeks of a platinum-based chemotherapy
- The requested medication will be used as a single agent

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Rubraca [package insert]. Lee's Summit, MO: Summit SD, LLC; September 2023.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed August 18, 2024.
3. National Comprehensive Cancer Network (NCCN) Guidelines: Prostate Cancer V4.2024. National Comprehensive Cancer Network, Inc. Available at: https://nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed August 13, 2024.
4. National Comprehensive Cancer Network (NCCN) Guidelines: Pancreatic Adenocarcinoma V3.2024. National Comprehensive Cancer Network, Inc. Available at: https://nccn.org/professionals/physician_gls/pdf/pancreatic.pdf. Accessed August 13, 2024.