Reference number(s)
2256-A

SPECIALTY GUIDELINE MANAGEMENT

RUBRACA (rucaparib)

POLICY

I. 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.

A. FDA-Approved Indications
   1. 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.
   2. 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.

B. Compendial Uses
   1. Prostate Cancer
   2. Uterine Leiomyosarcoma (uLMS)
   3. Pancreatic Adenocarcinoma
   4. 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.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
A. Documentation of laboratory report confirming BRCA mutation status, where applicable
B. Documentation of laboratory report confirming PALB2 mutation status, where applicable

III. CRITERIA FOR INITIAL APPROVAL

A. Epithelial ovarian, fallopian tube, or primary peritoneal cancer
Authorization of 12 months may be granted for the maintenance treatment of germline or somatic BRCA-mutated epithelial ovarian, fallopian tube, or primary peritoneal cancer as a single agent when any of the following criteria are met:
   1. Member has recurrent disease and is in complete or partial response to platinum-based chemotherapy
   2. Member has advanced (stage II-IV) disease and is in complete or partial response to primary therapy

B. 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:

1. Tumor has a deleterious BRCA mutation (germline, somatic, or both)
2. Member has been treated with androgen receptor-directed therapy
3. Member has been treated with a taxane-based chemotherapy or is not fit for chemotherapy
4. Member is receiving therapy concurrently with a gonadotropin-releasing hormone (GnRH) analog or has had a bilateral orchiectomy
5. The requested medication will be used as a single agent (concurrent use with a GnRH analog is allowed)

C. 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.

D. 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:

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

IV. CONTINUATION OF THERAPY

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

V. REFERENCES

1. Rubraca [package insert]. Boulder, CO: Clovis Oncology, Inc.; December 2022.
2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed January 4, 2023.