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.

FDA-Approved Indication

A. Ovarian Cancer

1. Treatment of adult patients with deleterious BRCA mutation (germline and/or somatic) associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies. Select for therapy based on an FDA-approved companion diagnostic test for Rubraca.
2. Maintenance treatment for adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.

B. 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.

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: Documentation of laboratory report confirming BRCA mutation status, where applicable.

III. CRITERIA FOR INITIAL APPROVAL

A. Epithelial ovarian, fallopian tube, or primary peritoneal cancer

1. Authorization of 12 months may be granted for treatment of epithelial ovarian, fallopian tube, or primary peritoneal cancer as a single agent when all of the following criteria are met:
   a. Tumor has deleterious BRCA mutation (germline, somatic, or both)
   b. Member has received two or more prior chemotherapies
2. Authorization of 12 months may be granted for the maintenance treatment of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer as a single agent when all of the following criteria are met:
   a. Members is in complete or partial response to platinum-based chemotherapy
   b. Member has received at least two prior platinum-containing regimens

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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)

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.; October 2020.
2. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed January 5, 2021.

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