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

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.
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.

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

Epithelial ovarian, fallopian tube, or primary peritoneal cancer

A. Authorization of 12 months may be granted for treatment of epithelial ovarian, fallopian tube, or primary peritoneal cancer when all of the following criteria are met:
   1. Tumor has deleterious BRCA mutation (germline, somatic, or both) as detected by an FDA-approved companion diagnostic test
   2. Member has received two or more prior chemotherapies

B. Authorization of 12 months may be granted for the maintenance treatment of recurrent disease to members who are in complete or partial response to platinum based chemotherapy

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Rubraca [package insert]. Boulder, CO: Clovis Oncology, Inc.; April 2018.