February 22, 2021

RE: Rubraca®, Zejula®

Rubraca®

Effective March 8, 2021, Rubraca® will require prior authorization. Members currently taking Rubraca® will be grandfathered. The prior authorization criteria for reimbursement is as follows:

Rubraca® (rucaparib) Approval Criteria [Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Diagnosis]:

- 1. Treatment of Advanced Recurrent/Refractory Disease:
 - a. Diagnosis of recurrent or refractory disease; and
 - b. Previous treatment with ≥2 prior lines of chemotherapy (prior chemotherapy regimens should be documented on the prior authorization request); and
 - c. Disease is associated with a deleterious or suspected deleterious BRCA mutation; and
 - d. Used as a single-agent; or
- 2. Maintenance Treatment of Advanced Disease:
 - a. Diagnosis of advanced or recurrent disease; and
 - b. Disease must be in a complete or partial response to platinum-based chemotherapy; and
 - c. Used as a single-agent.

Rubraca® (rucaparib) Approval Criteria [Castration-Resistant Prostate Cancer (CRPC) Diagnosis]:

- 1. Diagnosis of metastatic Castration-Resistant Prostate Cancer (CRPC); and
- 2. Member must have failed previous first-line therapy; and
- 3. Used as a single-agent except for the following:
 - a. Concomitant treatment with a gonadotropin-releasing hormone (GnRH) analog or prior history of bilateral orchiectomy; and
- 4. Disease must be positive for a mutation in BRCA1 or BRCA2.

Zejula®

Effective March 8, 2021, Zejula® will require prior authorization. Members currently taking Zejula® will be grandfathered. The prior authorization criteria for reimbursement is as follows:

Zejula® (niraparib) Approval Criteria [Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Diagnosis]:

- 1. Single-Agent Treatment of Advanced Recurrent/Refractory Disease:
 - a. Diagnosis of recurrent or refractory disease; and
 - b. Previous treatment with ≥3 prior lines of chemotherapy (prior chemotherapy regimens should be documented on the prior authorization request); and
 - c. Diagnosis is associated with homologous recombination deficiency (HRD) positive status defined by either:
 - i. A deleterious or suspected deleterious BRCA mutation; or
 - ii. Genomic instability and progression >6 months after response to last platinum-based chemotherapy; and
 - d. Used as a single-agent; or
- 2. Treatment of Advanced Recurrent/Refractory Disease in Combination with bevacizumab:
 - a. Used in combination with bevacizumab for platinum-sensitive persistent disease or recurrence; and
 - b. Meets 1 of the following:
 - i. As immediate treatment for serially rising CA-125 in members who previously received chemotherapy; or
 - ii. Evidence of radiographic and/or clinical relapse in members with previous complete remission and relapse ≥6 months after completing prior chemotherapy; or
- 3. Maintenance Treatment of Advanced Disease:
 - a. Diagnosis of advanced or recurrent disease; and
 - b. Disease must be in a complete or partial response to platinum chemotherapy; and
 - c. Used as a single-agent.

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