Rubraca

Description

Rubraca (rucaparib)

Background
Rucaparib is an inhibitor of poly (ADP-ribose) polymerase (PARP) enzymes, including PARP-1, PARP-2, and PARP-3, which (when uninhibited) play a role in DNA repair. In vitro studies have shown that rucaparib-induced cytotoxicity may involve inhibition of PARP enzymatic activity and increased formation of PARP-DNA complexes resulting in DNA damage, apoptosis, and cell death. Increased rucaparib-induced cytotoxicity was observed in tumor cell lines with deficiencies in BRCA 1/2 (BRCA mutations) and other DNA repair genes (1).

Regulatory Status
FDA-approved indications: Rubraca is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated (1):

1. As monotherapy for the treatment of patients with deleterious BRCA mutation (germline and/or somatic) associated advanced ovarian cancer who have been treated with two or more chemotherapies.
2. For the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.

Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML) occurs in patients exposed to Rubraca. Monitor patients for hematological toxicity at baseline and monthly thereafter (i.e. monitor complete blood count testing at baseline and monthly thereafter). Discontinue if MDS/AML is confirmed or until disease progression or unacceptable toxicity (1).
Rubraca can cause fetal harm when administered to a pregnant woman based on its mechanism of action and findings from animal studies. Advise females of reproductive potential to use effective contraception during treatment and for 6 months following the last dose of Rubraca (1).

The safety and effectiveness of Rubraca in pediatric patients have not been established (1).

Related policies
Lynparza, Zejula

**Policy**
This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Rubraca may be considered **medically necessary** in patients with advanced ovarian cancer or as maintenance therapy for patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer and if the conditions indicated below are met.

Rubraca may be considered **investigational** in patients less than 18 years of age and for all other indications.

**Prior-Approval Requirements**

**Age**
18 years of age or older

**Diagnoses**

Patient must have **ONE** of the following:

1. Advanced Ovarian Cancer
   a. *BRCA* mutation as detected by an approved FDA laboratory test
   b. Treatment previously by two or more chemotherapies
   c. Used as monotherapy

2. Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer
   a. Complete or partial response to platinum based chemotherapy

**AND ALL** of the following for **BOTH** indications:
1. Agreement of provider to do a complete blood count (CBC) done at baseline and monthly thereafter
2. Women of reproductive potential:
   a. Use of effective contraception during therapy and for 6 months after the last dose

Prior – Approval Renewal Requirements

Age
18 years of age or older

Diagnoses

Patient must have ONE of the following:

1. Advanced Ovarian Cancer
   a. Used as monotherapy

2. Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer

AND ALL of the following for BOTH indications:
1. Agreement of provider to monthly complete blood counts (CBCs)
2. NO disease progression or unacceptable toxicity
3. Women of reproductive potential:
   a. Use of effective contraception during therapy and for 6 months after the last dose

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

Quantity

<table>
<thead>
<tr>
<th>Strength</th>
<th>Quantity per 90 days</th>
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<tbody>
<tr>
<td>200 mg</td>
<td>360 tablets per 90 days OR</td>
</tr>
<tr>
<td>250 mg</td>
<td>360 tablets per 90 days OR</td>
</tr>
<tr>
<td>300 mg</td>
<td>360 tablets per 90 days</td>
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Duration 12 months

Prior – Approval Renewal Limits
Same as above

Rationale

Summary
Rubraca is an inhibitor of poly (ADP-ribose) polymerase (PARP) enzymes, including PARP-1, PARP-2, and PARP-3, which (when uninhibited) play a role in DNA repair. Rubraca is indicated as monotherapy for the treatment of patients with deleterious BRCA mutation (germline and/or somatic) associated advanced ovarian cancer who have been treated with two or more chemotherapies. Rubraca is also indicated for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. MDS/AML occurred in patients exposed to Rubraca, therefore monthly testing for hematological toxicity is required during treatment with Rubraca (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Rubraca while maintaining optimal therapeutic outcomes.

References

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>January 2017</td>
<td>Addition to PA</td>
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<tr>
<td>March 2017</td>
<td>Annual review</td>
</tr>
<tr>
<td>June 2017</td>
<td>Annual review</td>
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<tr>
<td>September 2017</td>
<td>Annual review</td>
</tr>
<tr>
<td></td>
<td>Addition of quantity limits</td>
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<tr>
<td>May 2018</td>
<td>Addition of the diagnosis of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer to criteria</td>
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<tr>
<td>June 2018</td>
<td>Annual review</td>
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<tr>
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Keywords
This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 15, 2019 and is effective on April 1, 2019.