PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Rubraca™ (rucaparib tablets – Clovis Oncology)

TAC APPROVAL DATE: 02/06/2019

OVERVIEW
Rubraca, a poly (ADP-ribose) polymerase (PARP) inhibitor, is indicated for the treatment of adult patients with deleterious Breast Cancer (BRCA) mutation (germline and/or somatic) associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies. Patients should be selected for therapy based on an FDA-approved companion diagnostic for Rubraca. Rubraca is also FDA-approved 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.

Guidelines
According to the National Comprehensive Cancer Network (NCCN) guidelines for ovarian cancer (version 2. 2018 – March 9, 2018), therapy options for patients with recurrent disease are primarily dependent on whether the patient is considered platinum-resistant or platinum-sensitive (patients who relapse ≥ 6 months after initial chemotherapy). NCCN Panel recommends single-agent Rubraca as recurrence therapy for patients with platinum-sensitive or platinum-resistant ovarian cancer that has been treated with two or more lines of chemotherapy and have BRCA mutations. The Panel feels that Rubraca is preferred for patients with platinum-resistant disease, because there are fewer good options for this setting. In patients with platinum-sensitive disease who have completed two or more lines of platinum-based therapy and are in a partial or complete response, Avastin (bevacizumab for injection) can be continued as maintenance therapy if previously treated with chemotherapy + Avastin; or Zejula™ (niraparib capsules), Lynparza™ (olaparib tablets), or Rubraca can be considered as maintenance therapy options (all category 2A).

POLICY STATEMENT
Prior authorization is recommended for prescription benefit coverage of Rubraca. All approvals are provided for 3 years in duration unless otherwise noted below.

Automation: None.
RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Rubraca is recommended in those who meet the following criteria:

FDA-Approved Indications

1. Ovarian, Fallopian Tube, or Primary Peritoneal Cancer – Treatment.
   A) Initial Therapy. Approve for 3 years if the patient meets the following criteria (i and ii):
      i. The patient has a BRCA mutation (germline or somatic) as confirmed by an approved test; AND
      ii. The patient has progressed on two or more prior lines of chemotherapy.
   B) Patient is Currently Receiving Rubraca. Approve for 3 years if the patient has a BRCA mutation (germline or somatic) as confirmed by an approved test.

2. Ovarian, Fallopian Tube, or Primary Peritoneal Cancer – Maintenance Therapy. Approve for 3 years if the patient meets the following criteria (A and B):
   A) The patient has recurrent disease; AND
   B) The patient is in complete or partial response after at least two platinum-based chemotherapy regimens (e.g., carboplatin with gemcitabine, carboplatin with paclitaxel, cisplatin with gemcitabine).

CONDITIONS NOT RECOMMENDED FOR APPROVAL
Rubraca has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

HISTORY

<table>
<thead>
<tr>
<th>Type of Revision</th>
<th>Summary of Changes*</th>
<th>TAC Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Policy</td>
<td>New criteria</td>
<td>01/11/2017</td>
</tr>
<tr>
<td>Annual revision</td>
<td>No criteria changes</td>
<td>01/24/2018</td>
</tr>
<tr>
<td>Selected revision</td>
<td>Added Maintenance therapy indication based on FDA approval. Added qualifier “Treatment” to approval criteria #1.</td>
<td>04/25/2018</td>
</tr>
<tr>
<td>Selected revision</td>
<td>Added “Fallopian Tube or Primary Peritoneal” to Ovarian Cancer – Treatment indication to match FDA label.</td>
<td>05/09/2018</td>
</tr>
<tr>
<td>Annual revision</td>
<td>Modified Maintenance Therapy criteria in recurrent disease setting to state that it is after at least two lines of platinum-based chemotherapy, based on guidelines.</td>
<td>02/06/2019</td>
</tr>
</tbody>
</table>

TAC – Therapeutic Assessment Committee; * For a further summary of criteria changes, refer to respective TAC minutes available at: http://esidepartments/sites/Dep043/Committees/TAC/Forms/AllItems.aspx.

02/06/2019
© 2019 Express Scripts Holding Company. All Rights Reserved.
This document is confidential and proprietary to Express Scripts Holding Company. Unauthorized use and distribution are prohibited.