PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Zejula™ (niraparib capsules – Tesaro, Inc.)

TAC APPROVAL DATE: 02/06/2019

OVERVIEW
Zejula, a poly (ADP-ribose) polymerase (PARP) inhibitor, is 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.¹ Zejula is approved in all patients regardless of the breast cancer (BRCA) mutation status. In the pivotal study, Zejula statistically significantly improved progression-free survival in patients with a germline BRCA mutation and in patients without the BRCA mutation.

Guidelines
According to the National Comprehensive Cancer Network (NCCN) guidelines for ovarian cancer (version 2.2018 – March 9, 2018), For recurrent disease in platinum-sensitive patients, combination platinum-based chemotherapy for a total of six cycles is preferred for the first recurrence. With regards to PARP inhibitors, NCCN recommends single-agent Lynparza™ (olaparib capsules) or Rubraca™ (rucaparib tablets) as preferred agents (category 2A) for its FDA-approved use. In patients with platinum-sensitive disease who have completed two or more lines of platinum-based therapy, Zejula, Rubraca, or Lynparza are recommended for maintenance therapy if the patient has achieved a partial or complete response from the most recent chemotherapy.

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

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Zejula is recommended in those who meet the following criteria:

FDA-Approved Indications

1. 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
Zejula 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>
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<tbody>
<tr>
<td>New Policy</td>
<td>New criteria</td>
<td>04/19/2017</td>
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<tr>
<td>Early annual revision</td>
<td>Deleted criteria requiring at least two prior chemotherapy regimens to align it with FDA approved indication. Added qualifier “Maintenance Therapy” to approval condition description.</td>
<td>02/07/2018</td>
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<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>
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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.