PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Alunbrig™ (brigatinib tablets – ARIAD/Takeda)

TAC APPROVAL DATE: 05/22/2019

OVERVIEW
Alunbrig, a kinase inhibitor, is indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to Xalkori® (crizotinib capsules). Alunbrig targets ALK, c-ros oncogene 1 (ROS1), insulin-like growth factor-1 receptor (IGF-1R), FLT-3, epidermal growth factor receptor (EGFR) deletion and point mutations.

Guidelines
The National Comprehensive Cancer Network (NCCN) guidelines on NSCLC (version 4.2019 – April 29, 2019) recommend testing for ALK gene rearrangements in all patients with non-squamous NSCLC (category 1). Testing is a prerequisite before treatment. Alecensa® (alectinib capsules) [preferred], Xalkori, Zykadia™ (ceritinib capsules), and Alunbrig [all category 1] are all of the recommended first-line therapies in patients with ALK-positive NSCLC. For subsequent therapy with progression on Xalkori, Xalkori can be continued, or therapy can be switched to Alecensa, Alunbrig, or Zykadia if not previously [all category 2A]. For patients who progress on Alecensa, Zykadia, or Alunbrig, local therapy can be considered in addition to continuing the kinase inhibitors or therapy can be switched to Lorbrena (lorlatinib tablets) for multiple systemic lesions.

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

Automation: None.

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

FDA-Approved Indications

1. Non-Small Cell Lung Cancer (NSCLC). Approve for 3 years if the patient has metastatic NSCLC that is anaplastic lymphoma kinase (ALK)-positive as detected by an approved test.
CONDITIONS NOT RECOMMENDED FOR APPROVAL
Alunbrig 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>--</td>
<td>05/17/2017</td>
</tr>
<tr>
<td>Selected revision</td>
<td>Modified criteria for approval in patients who have tried any one of the first-line therapies for ALK-positive non-small cell lung cancer, based on guidelines and reviewer feedback.</td>
<td>07/12/2017</td>
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<tr>
<td>Annual revision</td>
<td>No criteria changes</td>
<td>05/02/2018</td>
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<tr>
<td>Annual revision</td>
<td>The guidelines support the use of Alunbrig first-line for ALK-positive lung cancer. The requirement of another ALK inhibitor prior to Alunbrig approval has been deleted.</td>
<td>05/22/2019</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. ALK – Anaplastic lymphoma kinase.