PRIOR AUTHORIZATION POLICY

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

DATE REVIEWED: 06/10/2020

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) as detected by an FDA-approved test.[1] 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 5.2020 – May 27, 2020) recommend testing for ALK gene rearrangements in all patients with non-squamous NSCLC (category 1).[2] Testing is a prerequisite before treatment. Alecensa® (alectinib capsules) is the "Preferred" first-line therapy. Alecensa and Zykadia™ (ceritinib capsules) are category 1 recommended regiments under "Other Recommended" first-line therapies. Xalkori® (crizotinib capsules) is a category 1 therapy noted as "useful in certain circumstances". 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

1. Alunbrig™ tablets [prescribing information]. Cambridge, MA: ARIAD/Takeda Pharmaceuticals; May 2020.
2. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (Version 5.2020 – May 27, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed June 8, 2020.
3. Food and Drug Administration. Lists of cleared or approved companion diagnostic devices (in vitro and imaging tools). Available at: https://www.fda.gov/medical-devices/vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-vitro-and-imaging-tools. Accessed on May 21, 2019.