

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Alunbrig Prior Authorization Policy

- Alunbrig® (brigatinib tablets – ARIAD/Takeda)

REVIEW DATE: 06/30/2021

OVERVIEW

Alunbrig, a kinase inhibitor, is indicated for the treatment of adult patients with **anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC)** as detected by an FDA-approved test.¹

Guidelines

Alunbrig is addressed in National Comprehensive Cancer Network (NCCN) guidelines:²⁻⁴

- **NSCLC.** The NCCN NSCLC guidelines (version 5.2021 – June 15, 2021) recommend testing for ALK fusions in patients with metastatic nonsquamous NSCLC.² NCCN recommends Alecensa® (alectinib capsules), Alunbrig® (brigatinib tablets), and Lorbrina® (lorlatinib tablets) as first-line treatment options (all are category 1 recommendations) for patients with ALK rearrangement-positive NSCLC.
- **Soft Tissue Sarcoma.** The NCCN Soft Tissue Sarcoma guidelines (version 2.2021 – April 28, 2021) recommend Alunbrig, Zykadia® (ceritinib capsules), and Xalkori® (crizotinib capsules) as preferred treatment options for inflammatory myofibroblastic tumor with ALK translocation (all are category 2A recommendations).³

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Alunbrig. All approvals are provided for the duration 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 patients meets the following criteria (A and B):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has metastatic anaplastic lymphoma kinase (ALK)-positive NSCLC as detected by an approved test.

Other Uses with Supportive Evidence

2. **Soft Tissue Sarcoma – Inflammatory Myofibroblastic Tumor (IMT).** Approve for 3 years if the patients meets the following criteria (A and B):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has IMT with anaplastic lymphoma kinase (ALK) translocation.
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CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Alunbrig is not recommended in the following situations:

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 5.2021 – June 15, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed June 25, 2021.
3. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 2.2021 – April 28, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on June 25, 2021.
4. The NCCN Drugs & Biologics Compendium. © 2021 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on June 25, 2021. Search terms: brigatinib.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	06/10/2020
Annual Revision	Non-Small Cell Lung Cancer: A requirement was added that the patient is ≥ 18 years of age. Soft Tissue Sarcoma – Inflammatory Myofibroblastic Tumor: This new condition of approval was added to the policy.	06/30/2021