

## PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology – Alunbrig Prior Authorization Policy

- Alunbrig® (brigatinib tablets – ARIAD/Takeda)

**REVIEW DATE:** 08/07/2024

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### OVERVIEW

Alunbrig, a kinase inhibitor, is indicated for the treatment of anaplastic lymphoma kinase (ALK)-positive, metastatic **non-small cell lung cancer (NSCLC)** in adults, as detected by an FDA-approved test.<sup>1</sup>

### Guidelines

Alunbrig is addressed in National Comprehensive Cancer Network (NCCN) guidelines:<sup>2-5</sup>

- **Histiocytic Neoplasms:** Guidelines (version 2.2024 – July 19, 2024) recommend Alunbrig as a “Useful in Certain Circumstances” treatment option for *ALK*-positive Erdheim-Chester disease (category 2A).<sup>3</sup>
- **Inflammatory Myofibroblastic Tumor (IMT):** NCCN Soft Tissue Sarcoma guidelines (version 2.2024 – July 31, 2024) recommend Alunbrig as a “Preferred” treatment option for IMT with *ALK* translocation (category 2A). The NCCN Uterine Neoplasms guidelines (version 2.2024 – March 6, 2024) recommend Alunbrig as “Useful in Certain Circumstances” for first-line therapy for advanced, recurrent/metastatic, or inoperable IMT with *ALK* translocation for uterine sarcoma (category 2A).<sup>5,6</sup>
- **NSCLC:** Guidelines (version 7.2024 – July 26, 2024) recommend testing for *ALK* rearrangements in eligible patients with NSCLC.<sup>4</sup> If *ALK* rearrangement is discovered prior to first-line systemic therapy, Alunbrig is a “Preferred” first-line treatment option (category 1). If *ALK* rearrangement is discovered during first-line systemic therapy, options are to complete the planned systemic therapy (including maintenance therapy) or to interrupt the systemic therapy and treat with Alunbrig (“Preferred”, category 2A) or another *ALK* inhibitor. NCCN recommendations for patients with disease progression often include continuing the first-line targeted therapy, depending on type of progression.
- **T-Cell Lymphomas:** Guidelines (version 4.2024 – May 28, 2024) recommend Alunbrig for *ALK*-positive anaplastic large-cell lymphoma (ALCL) under “other recommended regimens” (category 2A) for initial palliative-intent therapy and for second-line/subsequent therapy (regardless of intention to transplant).

### 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 one of the following criteria:

08/07/2024

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### FDA-Approved Indication

1. **Non-Small Cell Lung Cancer.** Approve for 1 year if the patients meets ALL of the following (A, B, C, and D):
  - A) Patient is  $\geq 18$  years of age; AND
  - B) Patient has advanced or metastatic disease; AND
  - C) Patient has anaplastic lymphoma kinase (*ALK*)-positive disease; AND
  - D) The mutation was detected by an approved test.

### Other Uses with Supportive Evidence

2. **Erdheim-Chester Disease.** Approve for 1 year if the patient meets BOTH of the following (A and B):
  - A) Patient is  $\geq 18$  years of age; AND
  - B) Patient has anaplastic lymphoma kinase (*ALK*) rearrangement/fusion-positive disease.
3. **Inflammatory Myofibroblastic Tumor.** Approve for 1 year if the patients meets ALL of the following (A, B, and C):
  - A) Patient is  $\geq 18$  years of age; AND
  - B) Patient has anaplastic lymphoma kinase (*ALK*)-positive disease; AND
  - C) Patient meets ONE of the following (i or ii):
    - i. Patient has advanced, recurrent, or metastatic disease; OR
    - ii. The tumor is inoperable.
4. **Peripheral T-Cell Lymphomas.** Approve for 1 year if the patient meets BOTH of the following (A and B):
  - A) Patient is  $\geq 18$  years of age; AND
  - B) Patient has anaplastic lymphoma kinase (*ALK*)-positive anaplastic large cell lymphoma (ALCL).

### 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; February 2022.
2. The NCCN Drugs & Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on August 1, 2024. Search terms: brigatinib.
3. The NCCN Histiocytic Neoplasms Clinical Practice Guidelines in Oncology (version 2.2024 – July 19, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on August 1, 2024.
4. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 7.2024 – June 26, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed August 1, 2024.
5. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 2.2024 – July 31, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on August 1, 2024.
6. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 2.2024 – March 6, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on August 1, 2024.
7. The NCCN T-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 4.2024 – May 28, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on August 1, 2024.



