PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Alunbrig Prior Authorization Policy
- Alunbrig® (brigatinib tablets – ARIAD/Takeda)

REVIEW DATE: 08/07/2024

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.[1]

Guidelines
Alunbrig is addressed in National Comprehensive Cancer Network (NCCN) guidelines:[2-5]
- **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).[3]
- **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).[5,6]
- **NSCLC:** Guidelines (version 7.2024 – July 26, 2024) recommend testing for *ALK* rearrangements in eligible patients with NSCLC.[4] 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:

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 ≥ 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 ≥ 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 ≥ 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 ≥ 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.