Reference number(s)
1815-A

Specialty Guideline Management Alunbrig

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Alunbrig	brigatinib

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

Alunbrig 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.

Compendial Uses[2]

- Recurrent or advanced ALK rearrangement-positive NSCLC
- Brain metastases from ALK rearrangement-positive NSCLC
- Anaplastic large cell lymphoma (ALCL), ALK-positive
- Inflammatory myofibroblastic tumor (IMT) with ALK translocation
    - Uterine sarcoma
    - Soft tissue sarcoma
- Erdheim-Chester Disease (ECD) with ALK-fusion

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review: ALK mutation status

Coverage Criteria

Non-Small Cell Lung Cancer (NSCLC)[1,2]

Authorization of 12 months may be granted for treatment of recurrent, advanced, or metastatic ALK-positive NSCLC (including brain metastases from NSCLC) as a single agent.

Anaplastic Large Cell Lymphoma (ALCL)[2]

Authorization of 12 months may be granted for initial palliative intent therapy or treatment of relapsed/refractory ALK-positive ALCL as a single agent.

Inflammatory Myofibroblastic Tumor (IMT)[2]

Authorization of 12 months may be granted for treatment of ALK-positive IMT as a single agent when either of the following criteria is met:

- The member has uterine sarcoma and the disease is advanced, recurrent, metastatic, or inoperable
- The member has a soft tissue sarcoma (not including uterine sarcoma)

Erdheim-Chester Disease (ECD)[2]

Authorization of 12 months may be granted for treatment of symptomatic, or relapsed/refractory ALK-positive Erdheim-Chester Disease as a single agent.

Continuation of Therapy

Non-Small Cell Lung Cancer (NSCLC)[1,2,3]

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when there is no evidence of unacceptable toxicity while on the current regimen.

All Other Indications[2]

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for all other indications listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Alunbrig [package insert]. Cambridge, MA: Takeda Pharmaceuticals America, Inc.; October 2024.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed March 6, 2025.
3. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Non-Small Cell Lung Cancer. Version 3.2025. Accessed March 6, 2025. https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf