Applicable Drugs: Alunbrig (brigatinib)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 11/17/2025

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to IV are met.)

I. Documentation the following diagnoses AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

A. Non-small cell lung cancer (NSCLC)

i. Documentation disease is anaplastic lymphoma kinase positive (ALK)-positive as detected by an FDA-approved test.

ii. Documentation of advanced or metastatic disease.

iii. Alunbrig will be used as a single agent.

iv. Meets ONE of the following criteria (1 or 2):

1. Alunbrig will be used as first line therapy.

2. Documentation the patient is intolerant to or has progressed on treatment with Xalkori (crizotinib).

v. Minimum age requirement: 18 years old or older

Other Uses With Supportive Evidence

B. Central nervous system cancers

C. Histiocytic neoplasms

D. Soft Tissue sarcomas

E. T-Cell lymphomas

F. Uterine neoplasms

II. Treatment must be prescribed by or in consultation with an oncologist or hematologist.

III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

IV. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

Exclusion Criteria

- N/A

Other Criteria

- N/A

Quantity / Days Supply Restrictions

- Tablets: 180 mg, 90 mg, or 30 mg
- Maximum dose: 180 mg orally once daily
    - When starting treatment, recommended dose is 90 mg once daily for 7 days, then increase to 180 mg orally once daily
- Maximum quantity: 30-day supply

Approval Length

- **Authorization:** 1 year
- **Re-Authorization:** 1 year; An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of symptomatic disease with multiple lesions.

Appendix

N/A

References

1. Alunbrig. Prescribing Information. Takeda Pharmaceuticals America, Inc., 2024. Accessed September 18, 2025. www.alunbrig.com/sites/default/files/2022-10/prescribing-information.pdf
2. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Non-Small Cell Lung Cancer. Version 8.2025. Updated August 15, 2025. Accessed September 18, 2025. www.nccn.org/professionals/physician_gls/pdf/nscl.pdf
3. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Central Nervous System Cancers. Version 2.2025. Updated August 28, 2025. Accessed September 18, 2025. www.nccn.org/professionals/physician_gls/pdf/cns.pdf
4. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Histiocytic Neoplasms. Version 1.2025. Updated June 20, 2025. Accessed September 18, 2025. www.nccn.org/professionals/physician_gls/pdf/histiocytic_neoplasms.pdf

5. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Soft Tissue Sarcoma. Version 1.2025. Updated May 2, 2025. Accessed September 18, 2025. www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf
6. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. T-Cell Lymphomas. Version 2.2025. Updated May 28, 2025. Accessed September 18, 2025. www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf
7. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Uterine Neoplasms. Version 3.2025. Updated March 7, 2025. Accessed September 18, 2025. www.nccn.org/professionals/physician_gls/pdf/uterine.pdf

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.