

Alunbrig (brigatinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Alunbrig (brigatinib) tablets	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Alunbrig (brigatinib) may be approved if the following criteria are met:

- I. Individual has a diagnosis of recurrent, advanced or metastatic Non-Small Cell Lung Cancer (NSCLC); **AND**
- II. Disease is anaplastic lymphoma kinase (ALK)-positive (NCCN 1);
OR
- III. Individual has progressed on or is intolerant to Xalkori (crizotinib) (NCCN 2A);

OR

- IV. Individual has a diagnosis of Soft Tissue Sarcoma; **AND**
- V. Disease is ALK-positive Inflammatory Myofibroblastic Tumor (IMT) (NCCN 2A); **AND**
- VI. Individual is using as a single-agent treatment;

OR

- VII. Individual has a diagnosis of NSCLC and brain metastases (NCCN 2A); **AND**
- VIII. Individual has a primary diagnosis of ALK-positive NSCLC; **AND**
- IX. Individual is using as a single-agent treatment;

OR

- X. Individual has a diagnosis of Erdheim-Chester Disease (ECD) (NCCN 2A); **AND**
- XI. Disease is anaplastic lymphoma kinase (ALK)-positive; **AND**
- XII. Disease is symptomatic, relapsed, or refractory, **AND**
- XIII. Individual is using as single agent therapy;

OR

- XIV. Individual has a diagnosis of Uterine Sarcoma (NCCN 2A); **AND**
- XV. Disease is anaplastic lymphoma kinase (ALK)-positive; **AND**
- XVI. Individual is using as a single-agent treatment.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Updated periodically.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on September 9, 2023.
 - a. Central Nervous System Cancers. V1.2023. Revised March 24, 2023.
 - b. Non-Small Cell Lung Cancer. V3.2023. Revised April 13, 2023.
 - c. Histiocytic Neoplasms. V1.2023. Revised August 11, 2023.
 - d. Soft Tissue Sarcoma. V2.2023. Revised April 25, 2023.
 - e. Uterine Neoplasms. V2.2023. Revised April 28, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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