

PHARMACY COVERAGE GUIDELINE

ALUNBRIG™ (brigatinib) Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):

- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively “Service”) is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider’s judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member’s benefit plan; and
- Is subject to change as new information becomes available.

Scope

- This PCG applies to Commercial and/or Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance

- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The “Criteria” section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member’s benefit plan.
- The “Description” section describes the Service.
- The “Definition” section defines certain words, terms or items within the policy and may include tables and charts.
- The “Resources” section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the [request form](#) and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Medical Necessity Requirements for ALUNBRIG (brigatinib)

Criteria for Initial Therapy:

Prescriber Qualifications

- Prescribed by an Oncologist or in consultation with an Oncologist

Indication

- Metastatic non small cell lung cancer (NSCLC) with ALK rearrangement positive disease
- Other oncologic direct treatment uses listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A

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Age Requirement

- 18 years or older

Baseline Clinical Evaluation

- ALK positive confirmed by a United States Food and Drug Administration (FDA) approved test
- Blood pressure is within normal limits or medical treatment initiated if abnormal
- Eastern Cooperative Oncology Group Performance status of 0 to 2
- Negative pregnancy test in a woman of childbearing potential

Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA

Safety

- No interstitial lung disease or pneumonitis
- No severe or recurrent systolic blood pressure greater than or equal to 160 mmHg or diastolic blood pressure greater than or equal to 100 mmHg despite use of more than one antihypertensive medication
- No severe or recurrent symptomatic bradycardia or resting heart rate less than 60 beats per minute
- No severe or recurrent visual disturbance
- No severe or recurrent hyperglycemia (greater than or equal to 250 mg/dL) despite optimal medical management

Documentation Requirements

- A completed request form must be submitted including:
 - Chart notes
 - Lab results (ALK test result, blood pressure readings, pregnancy test result, glucose levels)
 - Supporting clinical documentation

Initial Therapy Criteria Approval Duration

- 6 months OR end of plan year
-

Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy

Prescriber Qualifications

- Continues to be seen by a physician specializing in or is in consultation with an Oncologist

Clinical Response

- No evidence of disease progression or unacceptable toxicity

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Adherence

- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA

Safety

- No significant adverse drug effects such as:
 - Recurrent mild to moderate interstitial lung disease/pneumonitis or first occurrence of severe to life threatening interstitial lung disease/pneumonitis
 - Recurrent severe or life threatening hypertension despite antihypertensive therapy
 - Recurrent symptomatic bradycardia or first occurrence with life threatening consequences or urgent intervention
 - Recurrent moderate to severe visual disturbances or first occurrence of life threatening visual disturbances
 - Recurrent severe or life threatening hyperglycemia despite medical management
 - Hepatotoxicity that is moderate or greater with total bilirubin elevation greater than 2 times the upper limit of normal without cholestasis or hemolysis
 - Severe photosensitivity
 - Any severe or life threatening reaction that does not improve after dose modification
 - Any recurrence of a life threatening reaction

Additional Requirements

- Requested dose is at least 60 mg once daily

Documentation Requirements

- Chart notes
- Supporting clinical documentation with evidence of improvement in given indication
- Lab values confirming safe use (blood pressure, heart rate, glucose, bilirubin)

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

Criteria for Off-Label Use Requests:

Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. Off-Label Use of Non-Cancer Medications
2. Off-Label Use of Cancer Medications

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**ALUNBRIG™ (brigatinib)
Generic Equivalent (if available)**

Description:

Alunbrig (brigatinib) is indicated for the treatment of individuals with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC).

Alunbrig (brigatinib) is a tyrosine kinase inhibitor with activity against multiple kinases. It inhibits auto-phosphorylation of ALK and ALK-mediated phosphorylation of downstream signaling proteins thereby inhibiting proliferation of certain cell lines. Alunbrig (brigatinib) exhibits anti-tumor activity against 4 mutant forms of ALK identified in NSCLC tumors in patients who have progressed on crizotinib.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
[MedWatch Forms for FDA Safety Reporting | FDA](#)

ECOG Performance status:

Eastern Co-operative Oncology Group (ECOG) Performance Status	
Grade	ECOG description
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours
3	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
4	Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
5	Dead

Oken, M.M., Creech, R.H., Tormey, D.C., Horton, J., Davis, T.E., McFadden, E.T., Carbone, P.P.: Toxicity And Response Criteria Of The Eastern Cooperative Oncology Group. Am J Clin Oncol 5:649-655, 1982

NCCN recommendation definitions:

Category 1:

Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

Category 2A:

Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

Category 2B:

Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.

Category 3:

Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate

Common Terminology Criteria for Adverse Events (CTCAE) Version 4.0:

Grade 1	Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated
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Grade 2	Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL*
Grade 3	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care ADL**
Grade 4	Life-threatening consequences; urgent intervention indicated
Grade 5	Death related to AE
U.S. department of Health and Human Services, National Institutes of Health, and National Cancer Institute	

Resources:

Alunbrig (brigatinib) product information, revised by Takeda Pharmaceuticals America, Inc. 10-2024. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed January 29, 2026.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Non-small Cell Lung Cancer Version 4.2026 – Updated March 06, 2026. Available at <https://www.nccn.org>. Accessed March 10, 2026.

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.

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