

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 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.

Criteria:

- **Criteria for initial therapy:** Alunbrig (brigatinib) and/or generic equivalent (if available) is considered **medically necessary** and will be approved when **ALL** the following criteria are met:
1. Prescriber is a physician specializing in the patient’s diagnosis or is in consultation with an Oncologist
 2. Individual is 18 years of age or older
 3. Individual has a confirmed diagnosis of **ONE** of the following:
 - a. Metastatic non-small cell lung cancer (NSCLC) with ALK rearrangement-positive disease

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- b. Other request for a specific oncologic direct treatment use that is found and listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A
4. Individual has received and completed **ALL** the following **baseline tests** before initiation of treatment and with continued monitoring of the individual as clinically appropriate:
 - a. Anaplastic lymphoma kinase (ALK)-positive by an FDA-approved test
 - b. Blood pressure is within normal limits, if abnormal medical treatment is started before beginning therapy with Alunbrig (brigatinib)
 - c. Eastern Cooperative Oncology Group Performance status of 0-2
 - d. Negative pregnancy test in a woman of childbearing potential
5. **If available:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] ([see Definitions section](#))
6. Individual does not have interstitial lung disease or pneumonitis
7. Individual does not have 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
8. Individual does not have severe or recurrent symptomatic bradycardia or a resting heart rate less than 60 beats per minute
9. Individual does not have severe or recurrent of visual disturbance
10. Individual does not have severe or recurrent hyperglycemia (greater than or equal to 250 mg/dL) despite optimal medical management for hyperglycemia

Initial approval duration: 6 months

➤ **Criteria for continuation of coverage (renewal request):** Alunbrig (brigatinib) and/or generic equivalent (if available) is considered **medically necessary** and will be approved when **ALL** the following criteria are met (**samples are not considered for continuation of therapy**):

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Oncologist
2. Individual's condition has responded while on therapy with response defined as there is no evidence of disease progression or unacceptable toxicity
3. Individual has been adherent with the medication
4. Requested dose is at least 60 mg once daily

ORIGINAL EFFECTIVE DATE: 07/20/2017 | ARCHIVE DATE: | LAST REVIEW DATE: 05/15/2025 | LAST CRITERIA REVISION DATE: 05/16/2024

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5. Individual has not developed any significant adverse drug effects that may exclude continued use 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 use of antihypertensive therapy (see [Initial Criteria](#) section for value(s))
 - Recurrent symptomatic bradycardia or first occurrence of bradycardia with life-threatening consequences or urgent intervention indicated (see [Initial Criteria](#) section for value(s))
 - Recurrent moderate to severe visual disturbances or first occurrence of life-threatening visual disturbances
 - Recurrent severe or life-threatening hyperglycemia despite medical management for hyperglycemia (see [Initial Criteria](#) section for value(s))
 - Individual with hepatotoxicity that is moderate or greater in severity with concurrent total bilirubin elevation greater than 2 times the upper limit of normal in the absence of 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

Renewal duration: 12 months

- 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:

- Off-Label Use of Non-Cancer Medications**
 - Off-Label Use of Cancer Medications**
-

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](#)

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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
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 February 21, 2025.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Non-small Cell Lung Cancer Version 3.2025 – Updated January 14, 2025. Available at <https://www.nccn.org>. Accessed April 01, 2025.

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

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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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