BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

PHARMACY COVERAGE GUIDELINES	
SECTION: DRUGS	
ORIGINAL EFFECTIVE DATE:	**7/20/17**
LAST REVIEW DATE:	**8/02/18**
LAST CRITERIA REVISION DATE:	**8/02/18**
ARCHIVE DATE:	

ALUNBRIG™ (brigatinib) oral tablet

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

ALUNBRIG™ (brigatinib) oral tablet (cont.)

Criteria:

- **Criteria for initial therapy:** Alunbrig (brigatinib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Prescriber is an Oncologist
2. Individual is 18 years of age or older
3. A confirmed diagnosis of metastatic non-small cell lung cancer (NSCLC) who have progressed on crizotinib or are intolerant to crizotinib
4. **ALL** of the following baseline tests have been completed before initiation of treatment with continued monitoring as clinically appropriate:
    - Anaplastic lymphoma kinase (ALK)-positive by an FDA-approved test
    - Blood pressure
    - Comprehensive metabolic panel
    - CPK, amylase, lipase
5. Individual does not have interstitial lung disease or pneumonitis
6. Individual does not have severe or recurrent systolic blood pressure $\geq$ 160 mmHg or diastolic blood pressure $\geq$ 100 mmHg despite use of more than one antihypertensive medication
7. Individual does not have severe or recurrent symptomatic bradycardia or a resting heart rate < 60 beats per minute
8. Individual does not have severe or recurrent of visual disturbance
9. Individual does not have severe or recurrent hyperglycemia ($\geq$ 250 mg/dL) despite optimal medical management for hyperglycemia
10. Individual does not have severe renal impairment (creatinine clearance < 30 mL/min by Cockcroft-Gault method)
11. Individual does not have moderate or severe hepatic impairment (total bilirubin > 1.5 times upper limit of normal (ULN) and any AST)
12. Will not be used with strong CYP3A inducers, including but not limited to rifampin, carbamazepine, phenytoin, and St. John's Wort
13. Woman patient of child bearing potential should use a non-hormonal method of contraception during and for at least 4 months after last dose as hormonal contraceptives may be ineffective
14. Woman patient who is breast feeding an infant or child should stop breast feeding during and for 1 week after therapy

ALUNBRIG™ (brigatinib) oral tablet (cont.)

15. Male patient with a female partner of child bearing potential should use effective contraception during and for at least 3 months after the last dose

Initial approval duration: 6 months

- **Continuation of coverage (renewal request):** Alunbrig (brigatinib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Individual continues to be seen by an Oncologist

2. Individual's condition responded while on therapy
   - Response is defined as:
     - No evidence of disease progression
     - No evidence individual has developed any significant unacceptable adverse drug reactions that may exclude continued use
     - Dose is greater than 60 mg once daily

3. Individual has been adherent with the medication

4. Individual has not developed any significant level 4 adverse drug effects that may exclude continued use
   - Significant adverse effect such as:
     - Recurrent or severe Interstitial lung disease or pneumonitis
     - Recurrent or severe hypertension despite use of antihypertensive therapy
     - Recurrent or severe bradycardia
     - Recurrent or severe visual disturbances
     - Recurrent or severe hyperglycemia despite medical management for hyperglycemia

5. Individual does not have severe renal impairment (creatinine clearance < 30 mL/min by Cockcroft-Gault method)

6. Individual does not have moderate or severe hepatic impairment (total bilirubin > 1.5 times upper limit of normal (ULN) and any AST)

7. There are no significant interacting drugs

Renewal duration: 12 months

Description:

Alunbrig (brigatinib) is indicated for the treatment of individuals with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib.

ALUNBRIG™ (brigatinib) oral tablet (cont.)

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.

Resources:

Alunbrig (brigatinib). Package Insert. Revised by manufacturer 04/2017 Accessed 05-18-2017, 01-10-2018.

Alunbrig (brigatinib) product information accessed 07-14-18 at DailyMed: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=0fe9ff20-d402-41f3-bc1e-7002ea7007db

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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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:	Dosage Form:
Directions for Use:	Quantity: / Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

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Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.