

## Clinical Policy: Brigatinib (Alunbrig)

Reference Number: PA.CP.PHAR342

Effective Date: 01/18

Last Review Date: 04/18

[Revision Log](#)

### Description

Brigatinib (Alunbrig™) is a kinase inhibitor.

### FDA approved indication

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

This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

### Policy/Criteria

Provider must submit documentation (which may require office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with PA Health & Wellness Corporation® that Alunbrig is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Non-Small Cell Lung Cancer (must meet all):

1. Diagnosis of NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age  $\geq$  18 years;
4. Disease is characterized as both of the following (a and b):
  - a. Recurrent or metastatic;
  - b. ALK-positive;
5. Failure of crizotinib (Xalkori)\* or ceritinib (Zykadia)\* unless contraindicated or clinically significant adverse effects are experienced;  
*\*Prior authorization is (or may be) required*
6. Dose does not exceed 180 mg/day (2 tablets/day).

**Approval duration: 6 months**

##### B. Other diagnoses/indications

1. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

#### II. Continued Therapy

##### A. Non-Small Cell Lung Cancer (must meet all):

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;

2. Member is responding positively to therapy, including no disease progression;
3. If request is for a dose increase, new dose does not exceed 180 mg/day (2 tablets/day).

**Approval duration: 6 months**

**B. Other diagnoses/indications (1 or 2):**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.

**Approval duration: Duration of request or 6 months (whichever is less); or**

2. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**III. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

ALK: anaplastic lymphoma kinase

FDA: Food and Drug Administration

NCCN: National Comprehensive Cancer Network

NSCLC: non-small cell lung cancer

**IV. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
ALK+ NSCLC	90 mg orally once daily for the first 7 days; if tolerated, increase to 180 mg orally once daily	180 mg/day

**V. Product Availability**

Tablets: 30 mg, 90 mg

**VI. Workflow Document**

N/A

**VII. References**

1. Alunbrig Prescribing Information. Cambridge, MA: ARIAD Pharmaceuticals, Inc.; April 2017. Available at: [www.alunbrig.com](http://www.alunbrig.com). Accessed January 2018.
2. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer Version 2.2018. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/nscl.pdf](https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf). Accessed January 2018.
3. Brigatinib. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at NCCN.org. Accessed January 2018.

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2018 annual review: added age; approval duration for commercial changed to length of benefit; summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; references reviewed and updated.	02.13.18	

