

## Clinical Policy: Brigatinib (Alunbrig)

Reference Number: ERX.SPA.153

Effective Date: 09.01.17

Last Review Date: 05.20

Line of Business: Commercial, Medicaid

[Revision Log](#)

See **Important Reminder** at the end of this policy for important regulatory and legal information.

### Description

Brigatinib (Alunbrig®) is a kinase inhibitor.

### FDA Approved Indication(s)

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 (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

*Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.*

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 recurrent, advanced, or metastatic NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is ALK positive;
5. Request meets one of the following (a or b):\*
  - a. Dose does not exceed 180 mg per day;
  - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

*\*Prescribed regimen must be FDA-approved or recommended by NCCN*

##### Approval duration:

**Medicaid** – 6 months

**Commercial** – Length of Benefit

##### B. Other diagnoses/indications

1. Refer to ERX.PA.01 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 a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Alunbrig for NSCLC and has received this medication for at least 30 days;
2. Member is responding positively to therapy;

3. If request is for a dose increase, request meets one of the following (a or b):\*
  - a. New dose does not exceed 180 mg per day;
  - b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

*\*Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration:**

**Medicaid** – 12 months

**Commercial** – Length of Benefit

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.

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

2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

**IV. 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

*Appendix B: Therapeutic Alternatives*

Not applicable

*Appendix C: Contraindications/Boxed Warnings*

None reported

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
ALK-positive NSCLC	90 mg PO QD for the first 7 days; if tolerated, increase to 180 mg PO QD	180 mg/day

**VI. Product Availability**

Tablets: 30 mg, 90 mg, 180 mg

**VII. References**

1. Alunbrig Prescribing Information. Cambridge, MA: ARIAD Pharmaceuticals, Inc.; December 2018. Available at: [www.alunbrig.com](http://www.alunbrig.com). Accessed February 11, 2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at [www.nccn.org](http://www.nccn.org). Accessed February 11, 2020.
3. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer Version 2.2020. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/nscl.pdf](https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf). Accessed February 11, 2020.
4. National Comprehensive Cancer Network Guidelines. Central Nervous System Cancers Version 3.2019. Available at [www.nccn.org](http://www.nccn.org). Accessed February 11, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	05.17	08.17
2Q 2018 annual review: no significant changes; age added; NCCN and FDA approved uses summarized for improved clarity; specialist involvement in care added; continuity of care statement added; approval durations increased to length of benefit; references reviewed and updated.	02.13.18	05.18
2Q 2019 annual review: NCCN designation of advanced added to NSCLC; Xalkori and Zykadia trials removed per NCCN recommendation of Alunbrig as first-line therapy for ALK positive NSCLC; references reviewed and updated.	02.19.19	05.19
2Q 2020 annual review: no significant changes; added Medicaid line of business with 6/12 month initial/continued authorization duration; references reviewed and updated.	02.11.20	05.20

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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