

Clinical Pharmacy Program Guidelines for Alunbrig

Program	Prior Authorization
Medication	Alunbrig™ (brigatinib)
Issue Date	6/2017
Pharmacy and Therapeutics Approval Date	6/2017
Effective Date	8/2017

1. Background:

Alunbrig™ (brigatinib) is a kinase inhibitor 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 Xalkori® (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 confirmatory trials.¹ The National Cancer Comprehensive Network (NCCN) also recommends Alunbrig for the treatment of recurrent or metastatic ALK-positive NSCLC in patients who have had disease progression while on Xalkori or Zykadia® (ceritinib) therapy.

2. Coverage Criteria:

<p>A. <u>Non-Small Cell Lung Cancer (NSCLC)</u></p> <p>1. <u>Initial Authorization</u></p> <p>a. Alunbrig will be approved based on <u>all</u> of the following criteria:</p> <p>(1) Diagnosis of non-small cell lung cancer (NSCLC)</p> <p style="text-align: center;">-AND-</p> <p>(2) Disease is <u>one</u> of the following:</p> <p style="padding-left: 40px;">(a) Metastatic (b) Recurrent</p> <p style="text-align: center;">-AND-</p> <p>(3) Tumor is anaplastic lymphoma kinase (ALK)-positive</p>
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-AND-

(4) History of failure or intolerance to **one** of the following:

- (a) Xalkori (crizotinib)
- (b) Zykadia (ceritinib)

Authorization will be issued for 12 months.

2. Reauthorization

a. **Alunbrig** will be approved based on the following criterion:

- (1) Patient does not show evidence of progressive disease while on Alunbrig therapy

Authorization will be issued for 12 months.

3. References:

- 1. Alunbrig [package insert]. Cambridge, MA: Ariad Pharmaceuticals, Inc; April 2017.
- 2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed May 25, 2017.

Program	Prior Authorization –Alunbrig (brigatinib)
Change Control	
Date	Change
6/2017	New program.