

### Clinical Pharmacy Program Guidelines for Alunbrig

Program	Prior Authorization
Medication	Alunbrig™ (brigatinib)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	6/2017
Pharmacy and Therapeutics Approval Date	6/2020
Effective Date	8/2020

**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.<sup>1</sup> The National Cancer Comprehensive Network (NCCN) also recommends Alunbrig as first-line therapy for ALK-positive NSCLC.

**2. Coverage Criteria:**

<p><b>A. <u>Non-Small Cell Lung Cancer (NSCLC)</u></b></p> <p><b>1. <u>Initial Authorization</u></b></p> <p>a. Alunbrig will be approved based on <b><u>all</u></b> of the following criteria:</p> <p style="margin-left: 40px;">(1) Diagnosis of non-small cell lung cancer (NSCLC)</p> <p style="text-align: center;"><b>-AND-</b></p> <p style="margin-left: 40px;">(2) Disease is <b><u>one</u></b> of the following:</p> <p style="margin-left: 80px;">(a) Metastatic</p> <p style="margin-left: 80px;">(b) Recurrent</p> <p style="text-align: center;"><b>-AND-</b></p>
--

(3) Tumor is anaplastic lymphoma kinase (ALK)-positive

**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.**

**B. NCCN Recommended Regimens**

**1. Initial Authorization**

a. **Alunbrig** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

**Authorization will be issued for 12 months.**

**2. Reauthorization**

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

(1) Documentation of positive clinical response to Alunbrig therapy

**Authorization will be issued for 12 months.**

**3. Additional Clinical Programs:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limitations may be in place

**4. References:**

Confidential and Proprietary, © 2020 UnitedHealthcare Services Inc.

1. Alunbrig [package insert]. Cambridge, MA: Ariad Pharmaceuticals, Inc.; December 2018.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at [www.nccn.org](http://www.nccn.org). Accessed May 7,2020.

Program	Prior Authorization –Alunbrig (brigatinib)
<b>Change Control</b>	
Date	Change
6/2017	New program.
6/2018	Updated background and criteria to include off-label NCCN recommendations. Updated references.
6/2019	Updated background and criteria to include NCCN recommendation for first-line therapy for ALK-positive NSCLC. Updated references.
6/2020	Annual review. Updated references. Added additional clinical notes section.