UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 1219-2
Program	Prior Authorization/Notification
Medication	Alunbrig™ (brigatinib)
P&T Approval Date	6/2017, 6/2018
Effective Date	9/1/2018; Oxford only: 9/1/2018

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 brain metastastes in patients with ALK-positive NSCLC.

Coverage Information:

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria:

A. <u>Patients less than 19 years of age</u>

1. Alunbrig will be approved based on the following criterion:

a. Member is less than 19 years of age

Authorization will be issued for 12 months.

B. <u>Non-Small Cell Lung Cancer (NSCLC)</u>

1. <u>Initial Authorization</u>

a. Alunbrig will be approved based on **<u>all</u>** of the following criteria:

(1) Diagnosis of non-small cell lung cancer (NSCLC)

-AND-

(2) Disease is **one** of the following:

(a) Metastatic
(b) Recurrent

-AND-

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

-AND-

(4) **One** of the following:

(a) History of failure or intolerance to Xalkori (crizotinib)
(b) Patient has recurrent brain metastases

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. Additional Clinical Rules:

- Supply limits may be in place.

4. 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 April 13, 2018.

Program	Prior Authorization/Notification - Alunbrig (brigatinib)
Change Control	
6/2017	New program.
6/2018	Updated background and criteria to include off label NCCN recommendations. Updated reference.