UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2023 P 1219-8 |
| Program | Prior Authorization/Notification |
| Medication | Alunbrig® (brigatinib) |
| P&T Approval Date | 6/2017, 6/2018, 6/2019, 6/2020, 6/2021, 9/2021, 9/2022, 9/2023 |
| Effective Date | 12/1/2023 |

**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). The National Cancer Comprehensive Network (NCCN) also recommends Alunbrig as first-line therapy for ALK-positive recurrent, advanced, or metastatic NSCLC, for the treatment of inflammatory myofibroblastic tumor (IMT) with ALK translocation, ALK-positive metastatic brain cancer from NSCLC, and as first-line or subsequent therapy for anaplastic lymphoma kinase (ALK)-fusion targeted relapsed/refractory, symptomatic Erdheim-Chester Disease (ECD).

**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]:**

**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 **<u>one</u>** of the following:

         (a) Metastatic
         (b) Recurrent
         (c) Advanced

**-AND-**

(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.**

**C. Soft Tissue Sarcoma / Uterine Neoplasms**

1. **Initial Authorization**

a. **Alunbrig** will be approved based on **both** of the following criteria:

(1) Diagnosis of inflammatory myofibroblastic tumor (IMT)

**-AND-**

(2) Presence of ALK translocation

**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.**

**D. Histiocytic Neoplasms**

1. **Initial Authorization**

a. **Alunbrig** will be approved based on **all** of the following criteria:

(1) Diagnosis of symptomatic Erdheim-Chester Disease

**-AND-**

(2) Used as targeted therapy ALK-fusion

**-AND-**

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

(a) Relapsed
(b) Refractory

**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.**

**E. Central Nervous System (CNS) Cancers**

1. **Initial Authorization**

a. **Alunbrig** will be approved based on **both** of the following criteria:

(1) Diagnosis of metastatic brain cancer from NSCLC

**-AND-**

(2) 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.**

**F. NCCN Recommended Regimens**

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

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

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

**3. Additional Clinical Rules:**

- 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 limits may be in place.

**4. References:**


1. Alunbrig [package insert]. Lexington, MA: Ariad Pharmaceuticals, Inc; February 2022.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed April 31, 2023.


| 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. |
| 6/2019 | Updated background and criteria to include NCCN recommendation for first-line therapy for ALK-positive NSCLC. Updated references. |
| 6/2020 | Annual review. Added general NCCN recommendations for use criteria. Updated references. |
| 6/2021 | Annual review. Added advanced disease to NSCLC criteria. Added criteria for soft tissue sarcoma per NCCN. Updated background and references. |
| 9/2021 | Corrected error listing Zykadia instead of Alunbrig in reauthorization criteria. |
| 9/2022 | Annual review. Added criteria per NCCN recommendations for histiocytic neoplasms. Added state mandate and updated background and references. |
| 9/2023 | Annual review. Updated histiocytic neoplasm formatting with no change to clinical criteria. Added criteria for CNS cancer, IMT tumors, and uterine neoplasms per NCCN guidelines. |