BlueCross BlueShield
Federal Employee Program
Blue Cross Blue Shield Association
750 9th St NW, Suite 900
Washington, D.C. 20001
1-800-624-5060
Fax 1-877-378-4727

5.21.092

Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Antineoplastic Agents	**Original Policy Date:**	May 12, 2017
Subject:	Alunbrig	**Page:**	1 of 5

Last Review Date: December 13, 2024

Alunbrig

Description

Alunbrig (brigatinib)

Background

Alunbrig (brigatinib) is an oral medication indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive. Alunbrig is an inhibitor of receptor tyrosine kinases including ALK and ROS1. Translocations can affect the ALK gene resulting in the expression of oncogenic fusion proteins. The formation of ALK fusion proteins results in activation and dysregulation of the gene's expression and signaling which can contribute to increased cell proliferation and survival in tumors expressing these proteins. The administration of Alunbrig in tumors carrying ALK fusions may result in antitumor activity and prolonged survival. Treatment with Alunbrig should continue until disease progression or unacceptable toxicity (1).

Regulatory Status

FDA-approved indication: Alunbrig is a kinase inhibitor indicated for the treatment of adult patients with anaplastic lymphoma (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test (1).

Coadministration with moderate CYP3A inducers and with strong or moderate CYP3A inhibitors should be avoided during treatment with Alunbrig. Alunbrig dose should be reduced for patients with severe hepatic impairment or severe renal impairment (1).

Alunbrig can cause fetal harm when administered to a pregnant woman. Females of

reproductive potential should be advised to use effective non-hormonal contraception during treatment with Alunbrig and for at least 4 months after the final dose. Males with female partners of reproductive potential should be advised to use effective contraception during treatment with Alunbrig and for 3 months after the final dose (1).

The safety and effectiveness of Alunbrig in pediatric patients have not been established (1).

Related policies
Alecensa, Augtyro, Lorbrena, Xalkori, Zykadia

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Alunbrig may be considered **medically necessary** if the conditions indicated below are met.

Alunbrig may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Metastatic non-small cell lung cancer (NSCLC)
    a. Anaplastic lymphoma kinase (ALK)-positive
    b. Female patients of reproductive potential **only**: patient will be advised to use effective non-hormonal contraception during treatment with Alunbrig and for 4 months after the final dose
    c. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Alunbrig and for 3 months after the final dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Metastatic non-small cell lung cancer (NSCLC)
    a. **NO** disease progression or unacceptable toxicity
    b. Female patients of reproductive potential **only**: patient will be advised to use effective non-hormonal contraception during treatment with Alunbrig and for 4 months after the final dose
    c. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Alunbrig and for 3 months after the final dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Strength	Quantity
30 mg	540 tablets per 90 days **OR**
90 mg	180 tablets per 90 days **OR**
One Month Initiation Pack (7 tabs of 90mg & 23 tabs of 180mg) + 180 mg	1 Initiation Pack + 90 tablets per 90 days **OR**
180 mg	90 tablets per 90 days

Maximum daily limit of any combination: 180 mg

*** Quantity limits listed above must be used to achieve dose optimization**

**Utilizing the highest strengths available to achieve the dosage is recommended to minimize dosing errors and improve compliance

Duration 12 months

Prior – Approval *Renewal* Limits

Quantity

Strength	Quantity

30 mg	360 tablets per 90 days **OR**
90 mg	180 tablets per 90 days **OR**
180 mg	90 tablets per 90 days

Maximum daily limit of any combination: 180 mg

*** Quantity limits listed above must be used to achieve dose optimization**

**Utilizing the highest strengths available to achieve the dosage is recommended to minimize dosing errors and improve compliance

Duration 12 months

Rationale

Summary

Alunbrig (brigatinib) is a kinase inhibitor indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive. Treatment with Alunbrig should continue until disease progression or unacceptable toxicity. The safety and effectiveness of Alunbrig in pediatric patients have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Alunbrig while maintaining optimal therapeutic outcomes.

References

1. Alunbrig [package insert]. Lexington, MA: ARIAD Pharmaceuticals, Inc.; February 2022.
2. NCCN Drugs & Biologics Compendium® Brigatinib 2024. National Comprehensive Cancer Network, Inc. Accessed on October 28, 2024.

Policy History

Date	Action
May 2017	Addition to PA
September 2017	Annual review Addition of quantity limits
January 2018	Addition of new strength 180 mg and the one month initiation pack
March 2018	Annual review
March 2019	Annual editorial review and reference update
June 2020	Removed requirement to t/f crizotinib. Revised contraception requirements
September 2020	Annual review
March 2021	Annual editorial review
March 2022	Annual review and reference update

March 2023	Annual review and reference update. Changed policy number to 5.21.092
March 2024	Annual review and reference update
December 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.