



## 5.21.92

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2021
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	May 12, 2017
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**Last Review Date:** March 12, 2021

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## 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

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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).

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### Related policies

Alecensa, 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** in patients age 18 years or age or older for ALK-Positive Metastatic non-small cell lung cancer (NSCLC) and if the conditions indicated below are met.

Alunbrig may be considered **investigational** in patients less than 18 years of age and 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

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## 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 <b>OR</b>
90 mg	180 tablets per 90 days <b>OR</b>
One Month Initiation Pack (7 tabs of 90mg & 23 tabs of 180mg) + 180 mg	1 Initiation Pack + 90 tablets per 90 days <b>OR</b>
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

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**Quantity**

Strength	Quantity
30 mg	360 tablets per 90 days <b>OR</b>
90 mg	180 tablets per 90 days <b>OR</b>
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]. Cambridge, MA: ARIAD Pharmaceuticals, Inc.; May 2020.

**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

**Keywords**

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**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.**