



5.21.092

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| Section: | Prescription Drugs | Effective Date: | April 1, 2026 |
| Subsection: | Antineoplastic Agents | Original Policy Date: | May 12, 2017 |
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Last Review Date: March 6, 2026

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).

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

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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 |
|----------|----------|
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|--------|-----------------------------------|
| 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.; October 2024.
2. NCCN Drugs & Biologics Compendium[®] Brigatinib 2026. National Comprehensive Cancer Network, Inc. Accessed on January 13, 2026.

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 |

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|---------------|---|
| 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 |
| March 2025 | Annual review and reference update |
| June 2025 | Annual review and reference update |
| March 2026 | Annual review and reference update |

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.