

**RATIONALE FOR INCLUSION IN PA PROGRAM****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).

**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



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## **ALUNBRIG (brigatinib)**

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 2025. National Comprehensive Cancer Network, Inc. Accessed on January 14, 2025.