



Kansas City

An Independent Licensee of the Blue Cross and Blue Shield Association

Alunbrig® (brigatinib)

Policy Number: 5.01.636

Last Review: 10/2018

Origination: 9/2017

Next Review: 10/2019

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for Alunbrig when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered

Alunbrig may be considered medically necessary when the following criteria are met:

Initial approval:

- Patient has a diagnosis of metastatic non-small cell lung cancer (NSCLC)
 - Patient tests positive for the abnormal anaplastic lymphoma kinase (ALK) gene
 - Presence of disease progression on or intolerance to Xalkori (crizotinib)
 - If patient or their partner are of child bearing age, the patient has been or will be instructed to practice effective contraception during therapy and for 4 months after stopping therapy

Renewal criteria:

- Patient has a diagnosis of metastatic non-small cell lung cancer (NSCLC)
 - Patient tests positive for the abnormal anaplastic lymphoma kinase (ALK) gene
 - NO disease progression or unacceptable toxicity while taking Alunbrig
 - If patient or their partner are of child bearing age, the patient has been or will be instructed to practice effective contraception during therapy and for 4 months after stopping therapy

When Policy Topic is not covered

The use of Alunbrig is considered investigational when the above criteria are not met, and for all other conditions, including but not limited to first-line therapy.

Considerations

Alunbrig requires prior authorization through the Clinical Pharmacy Department.

This Blue Cross and Blue Shield of Kansas City policy Statement was developed using available resources such as, but not limited to: Food and Drug Administration (FDA) approvals, Facts and Comparisons, National specialty guidelines, Local medical policies of other health plans, Medicare (CMS), Local providers.

Description of Procedure or Service

Background

Alunbrig 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 indicated for the treatment of patients with anaplastic lymphoma (ALK)-positive metastatic non-small cell lung cancer (NSCLC), who have progressed on or are intolerant to crizotinib (1). The safety of Alunbrig in patients with severe renal impairment (creatinine clearance (CrCl) less than 30 mL/min) or end-stage renal disease has not been studied. The safety of Alunbrig in patients with moderate to severe hepatic impairment has not been studied (1).

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

Rationale

Alunbrig 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.; April 2017

Billing Coding/Physician Documentation Information

N/A Alunbrig® (brigatinib) is specialty pharmacy benefit.

Additional Policy Key Words

5.01.636

Policy Implementation/Update Information

09/2017 New Policy titled Alunbrig (brigatinib)

10/2018 No changes made

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