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 patients with anaplastic lymphoma (ALK)-positive metastatic non-small cell lung cancer (NSCLC), who have progressed on or are intolerant to crizotinib (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).

The safety and effectiveness of Alunbrig in pediatric patients have not been established (1).
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 is considered investigational in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

1. Metastatic non-small cell lung cancer (NSCLC)
   a. Anaplastic lymphoma kinase (ALK)-positive
   b. Presence of disease progression on or intolerance to Xalkori (crizotinib)
   c. 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

Prior – Approval Renewal Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

1. Metastatic non-small cell lung cancer (NSCLC)
a. **NO** disease progression or unacceptable toxicity  
   b. 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

### Policy Guidelines

#### Pre - PA Allowance

None

#### Prior - Approval Limits

**Quantity**

<table>
<thead>
<tr>
<th>Strength</th>
<th>Quantity per 90 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 mg</td>
<td>540 tablets per 90 days OR</td>
</tr>
<tr>
<td>90 mg</td>
<td>180 tablets per 90 days OR</td>
</tr>
<tr>
<td>One Month Initiation Pack (7 tabs of 90mg &amp; 23 tabs of 180mg) + 180 mg</td>
<td>1 Initiation Pack + 90 tablets per 90 days OR</td>
</tr>
<tr>
<td>180 mg</td>
<td>90 tablets per 90 days</td>
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</table>

**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**

<table>
<thead>
<tr>
<th>Strength</th>
<th>Quantity per 90 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 mg</td>
<td>360 tablets per 90 days OR</td>
</tr>
<tr>
<td>90 mg</td>
<td>180 tablets per 90 days OR</td>
</tr>
<tr>
<td>180 mg</td>
<td>90 tablets per 90 days</td>
</tr>
</tbody>
</table>

**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
Rationale

Summary
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

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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</thead>
<tbody>
<tr>
<td>May 2017</td>
<td>Addition to PA</td>
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<tr>
<td>September 2017</td>
<td>Annual review</td>
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<tr>
<td></td>
<td>Addition of quantity limits</td>
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<tr>
<td>January 2018</td>
<td>Addition of new strength 180 mg and the one month initiation pack</td>
</tr>
<tr>
<td>March 2018</td>
<td>Annual review</td>
</tr>
<tr>
<td>March 2019</td>
<td>Annual editorial review and reference update</td>
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</table>

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 15, 2019 and is effective on April 1, 2019.