Description

Arikayce (amikacin liposome inhalation suspension)

Background
Arikayce (amikacin liposome inhalation suspension) is an antibacterial drug. It is an aminoglycoside antibiotic that is inhaled into the lungs once daily through a specialized device, the Lamira Nebulizer System. It is indicated for use in combination with other antibacterial drugs to treat adult patients with a rare lung disease caused by Mycobacterium avium complex (MAC) despite six months or longer of standard multidrug treatment (1).

Regulatory Status
FDA-approved indication: Arikayce is an aminoglycoside antibacterial indicated in adults who have limited or no alternative treatment options, for the treatment of Mycobacterium avium complex (MAC) lung disease as part of a combination antibacterial drug regimen in patients who do not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy (1).

Arikayce has a boxed warning for risk of increased respiratory adverse reactions. Arikayce may cause respiratory adverse reactions including hypersensitivity pneumonitis, hemoptysis, bronchospasm, and exacerbation of underlying pulmonary disease. Patients should be monitored and if any of these reactions occurs, patients should be treated as medically appropriate (1).

Other warnings for Arikayce include ototoxicity, nephrotoxicity, neuromuscular blockade, and embryo-fetal toxicity. Patients should be closely monitored if they have known or suspected
auditory or vestibular dysfunction, suspected renal dysfunction, or suspected neuromuscular disorders such as myasthenia gravis (1).

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

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Arikayce may be considered medically necessary in patients 18 years of age and older with Mycobacterium avium complex (MAC) lung disease and if the conditions indicated below are met.

Arikayce 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:

Mycobacterium avium complex (MAC) lung disease

AND ALL of the following:

1. Diagnosis has been confirmed by at least 2 sputum cultures
2. Inadequate response to at least 6 consecutive months of a multidrug regimen
3. Alternative treatment options have been ruled out
4. Culture shows that the MAC bacteria is sensitive to aminoglycosides
5. Arikayce will be given with other antibacterial drugs
6. Patients with a history of hyperactive airway disease will pre-treat with an inhaled bronchodilator
7. Prescriber agrees to monitor for respiratory adverse reactions
8. Pregnant patients and patients of childbearing potential will be advised of the potential adverse effects to the fetus

Prior – Approval **Renewal Requirements**

**Age**
18 years of age and older

**Diagnosis**

Patient must have the following:

*Mycobacterium avium* complex (MAC) lung disease

AND ALL of the following:
1. Patient has not achieved consecutive monthly negative sputum cultures in 6 months
2. Arikayce will be given with other antibacterial drugs
3. Patients with a history of hyperactive airway disease will pre-treat with an inhaled bronchodilator
4. Prescriber agrees to monitor for respiratory adverse reactions
5. Pregnant patients and patients of childbearing potential will be advised of the potential adverse effects to the fetus

**Policy Guidelines**

**Pre - PA Allowance**
None

**Prior - Approval Limits**

<table>
<thead>
<tr>
<th>Quantity</th>
<th>84 vials* per 84 days</th>
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</thead>
<tbody>
<tr>
<td>Duration</td>
<td>168 days</td>
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</tbody>
</table>

*Vials supplied with Lamira Nebulizer System

**Prior – Approval Renewal Limits**

<table>
<thead>
<tr>
<th>Quantity</th>
<th>84 vials per 84 days</th>
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<tbody>
<tr>
<td>Duration</td>
<td>168 days (One renewal only)</td>
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</table>
Rationale

Summary
Arikayce (amikacin liposome inhalation suspension) is an antibacterial drug. It is an aminoglycoside antibiotic that is inhaled into the lungs once daily through a specialized device, the Lamira Nebulizer System. It is indicated for use in combination with other antibacterial drugs to treat adult patients with a rare lung disease caused by *Mycobacterium avium* complex (MAC) despite six months or longer of standard multidrug treatment. The safety and effectiveness of Arikayce in pediatric patients have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Arikayce while maintaining optimal therapeutic outcomes.

References

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>October 2018</td>
<td>Addition to PA</td>
</tr>
<tr>
<td>November 2018</td>
<td>Annual review</td>
</tr>
<tr>
<td>March 2019</td>
<td>Annual review. Changed renewal requirement to “patient has not achieved consecutive monthly negative sputum cultures in 6 months” and added requirement that cultures shows MAC sensitivity to aminoglycosides per SME</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.