Clinical Policy: Amikacin (Arikayce)

Reference Number: ERX.SPA.312
Effective Date: 03.01.19
Last Review Date: 02.22
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Amikacin (Arikayce®) is a liposomal formulation of amikacin – an aminoglycoside antibiotic active against aerobic gram-negative rods.

FDA Approved Indication(s)

Arikayce is 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. As only limited clinical safety and effectiveness data for Arikayce are currently available, reserve Arikayce for use in adults who have limited or no alternative treatment options. This drug is indicated for use in a limited and specific population of patients.

This indication is approved under accelerated approval based on achieving sputum culture conversion (defined as 3 consecutive negative monthly sputum cultures) by Month 6. Clinical benefit has not yet been established.

Limitation(s) of use: Arikayce has only been studied in patients with refractory MAC lung disease defined as patients who did not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy. The use of Arikayce is not recommended for patients with non-refractory MAC lung disease.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Arikayce is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Mycobacterium Avium Complex (must meet all)**:**

1. Diagnosis of MAC;
2. Prescribed by or in consultation with an infectious disease specialist or pulmonologist;
3. Age ≥ 18 years;
4. Failure, as evidenced by positive sputum culture, of at least a 6-month trial of a multidrug background regimen therapy at up to maximally indicated doses *(see Appendix B)*, unless all are contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed one vial per day.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Mycobacterium Avium Complex (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Documentation of at least 3 consecutive negative monthly sputum cultures in the first 6 months of therapy or at least 2 consecutive negative monthly sputum cultures in the last 2 months of therapy;
3. Member has not received more than 12 months of treatment following conversion to negative sputum status;
4. If request is for a dose increase, new dose does not exceed one vial per day.

Approval duration: Up to a total of 12 months of treatment after converting to negative sputum status

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
MAC: mycobacterium avium complex

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
clarithromycin (Biaxin®) or azithromycin (Zmax®) + ethambutol (Myambutol®) + rifampin (Rifadin®)	Variable dosing	Combo used for initial therapy for nodular/ bronchiectatic disease
clarithromycin (Biaxin) or azithromycin (Zmax) + ethambutol (Myambutol) + rifampin (Rifadin) + streptomycin or amikacin (Amikin®) or none	Variable dosing	Combo used for initial therapy for cavitary disease
clarithromycin (Biaxin) or azithromycin (Zmax) + ethambutol (Myambutol) + rifampin (Rifadin) or rifabutin (Mycobutin®) + streptomycin or amikacin (Amikin)	Variable dosing	Combo used for advanced (severe) or previously treated disease

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): known hypersensitivity to any aminoglycoside

- Boxed warning(s): risk of increased respiratory adverse reactions, including, hypersensitivity pneumonitis, hemoptysis, bronchospasm, and exacerbation of underlying pulmonary disease that have led to hospitalization in some cases

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
MAC	Inhalation of the contents of one 590 mg/8.4 mL vial per day	590 mg/8.4 mL per day

VI. Product Availability

Solution for inhalation: 590 mg/8.4 mL

VII. References

1. Arikayce Prescribing Information. Bridgewater, NJ: Insmed; October 2020. Available at: https://www.arikayce.com/pdf/full_prescribing_information.pdf?v=2.15.3. Accessed November 25, 2020.
2. Olivier KN, et al. Randomized Trial of Liposomal Amikacin for Inhalation in Nontuberculous Lung Disease. American Journal of Respiratory and Critical Care Medicine. 195;6. March 15, 2017: 814-823.
3. Griffith DE, et al. Amikacin Liposome Suspension for Treatment-Refractory Lung Disease Caused by Mycobacteriun Avium Complex (CONVERT): A Prospective, Open-Label, Randomized Study. American Journal of Respiratory and Critical Care Medicine. September 2018. doi: 10.1164/rccm.201807-1318OC.
4. Arikayce Drug Monograph. Clinical Pharmacology. http://www.clinicalpharmacology-ip.com. Accessed September 15, 2021.
5. Griffith DE, et al. An Official ATS/IDSA Statement: Diagnosis, Treatment, and Prevention of Nontuberculous Mycobacterial Diseases. American Journal of Respiratory and Critical Care Medicine. 2007;175:367-416.
6. Haworth CS, Banks J, Capstick T, et al. British Thoracic Society guidelines for the management of non-tuberculous mycobacterial pulmonary disease. Thorax 2017;72:ii1–ii64.
7. Daley CL, Iaccarino JM, Lange C, et al. Treatment of Nontuberculous Mycobacterial Pulmonary Disease: An Official ATS/ERS/ESCMID/IDSA Clinical Practice Guideline. Clinical Infectious Diseases 2020; 71(15 August): e1-e36.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	11.13.18	02.19
1Q 2020 annual review: no significant changes; references reviewed and updated.	10.23.19	02.20
1Q 2021 annual review: no significant changes; references reviewed and updated.	11.24.20	02.21
1Q 2022 annual review: added requirement that member has not received more than 12 months of treatment following conversion to negative sputum status to support existing continued authorization coverage duration requirements; references reviewed and updated.	09.15.21	02.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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