



Arikayce Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date

03-15-2026

Date of Origin

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Arikayce	amikacin sulfate liposome inhal susp	590 MG/8.4ML	M ; N ; O ; Y	N		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Arikayce	Amikacin Sulfate Liposome Inhal Susp 590 MG/8.4ML (Base Eq)	590 MG/8.4 ML	28	Vials	28	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Arikayce	amikacin sulfate liposome inhal susp	590 MG/8.4ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Arikayce	Amikacin Sulfate Liposome Inhal Susp 590 MG/8.4ML (Base Eq)	590 MG/8.4ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p>Initial Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. The patient has a diagnosis of <i>Mycobacterium avium</i> complex (MAC) lung disease as confirmed by ALL of the following [medical records including chart notes are required]: <ol style="list-style-type: none"> A. Pulmonary or systemic symptoms AND B. Nodular or cavitory opacities on chest radiograph OR a high-resolution computed tomography scan that shows multifocal bronchiectasis with multiple small nodules AND C. ONE of the following: <ol style="list-style-type: none"> 1. Positive culture result from at least two separate expectorated sputum samples OR 2. Positive culture result from at least one bronchial wash or lavage OR 3. Transbronchial or other lung biopsy with mycobacterial histopathologic features (granulomatous inflammation or acid-fast bacilli [AFB]) AND positive culture for nontuberculous mycobacteria (NTM); biopsy showing mycobacterial histopathologic features (granulomatous inflammation or AFB) AND one or more sputum or bronchial washings that are culture positive for NTM AND D. Appropriate exclusion of other diagnoses AND 2. If the patient has an FDA labeled indication, then ONE of the following: <ol style="list-style-type: none"> A. The patient’s age is within FDA labeling for the requested indication for the requested agent OR B. There is support for using the requested agent for the patient’s age for the requested indication AND 3. The patient has positive sputum cultures despite at least 6 consecutive months of treatment with guideline-based combination antibiotic therapy for MAC lung disease (e.g., standard combination may include a macrolide [clarithromycin, azithromycin], a rifamycin [rifampin, rifabutin], and ethambutol) AND 4. The patient will continue treatment with guideline-based combination antibiotic therapy for MAC lung disease with the requested agent (e.g., combination may include a macrolide [clarithromycin, azithromycin], a rifamycin [rifampin, rifabutin], and ethambutol) AND 5. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., infectious disease, immunologist, pulmonologist, thoracic specialist), or the prescriber has consulted with a specialist in the area of the patient’s diagnosis AND

Module	Clinical Criteria for Approval
	<p>6. ONE of the following:</p> <ul style="list-style-type: none"> A. The patient is NOT currently being treated with another inhaled antibiotic (e.g., aztreonam for inhalation, tobramycin for inhalation) OR B. The patient is currently being treated with another inhaled antibiotic AND ONE of the following: <ul style="list-style-type: none"> 1. The patient will discontinue the other inhaled antibiotic prior to starting the requested agent OR 2. There is support for the use of another inhaled antibiotic concurrently with the requested agent AND <p>7. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p>The requested agent will also be approved when the following are met:</p> <ul style="list-style-type: none"> 1. The member resides in Ohio AND 2. The plan is Fully Insured or HIM Shop (SG) AND 3. The patient does NOT have any FDA labeled contraindications to the requested agent AND 4. ONE of the following: <ul style="list-style-type: none"> A. The patient has another FDA labeled indication for the requested agent and route of administration OR B. The patient has another indication that is supported in compendia for the requested agent and route of administration OR C. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] <p>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p>Oncology compendia allowed: NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria</p> <p>Renewal Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p>

Module	Clinical Criteria for Approval
	<ol style="list-style-type: none"> 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (Note: patients not previously approved for the requested agent will require initial evaluation review) AND 2. The patient has had clinical benefit with the requested agent AND 3. The patient will continue treatment with guideline-based combination antibiotic therapy for <i>Mycobacterium avium</i> complex (MAC) lung disease with the requested agent (e.g., combination may include a macrolide [clarithromycin, azithromycin], a rifamycin [rifampin, rifabutin], and ethambutol) AND 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., infectious disease, immunologist, pulmonologist, thoracic specialist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND 5. ONE of the following: <ol style="list-style-type: none"> A. The patient is NOT currently being treated with another inhaled antibiotic (e.g., aztreonam for inhalation, tobramycin for inhalation) OR B. The patient is currently being treated with another inhaled antibiotic AND ONE of the following: <ol style="list-style-type: none"> 1. The patient will discontinue the other inhaled antibiotic prior to starting the requested agent OR 2. There is support for the use of another inhaled antibiotic concurrently with the requested agent AND 6. The patient does NOT have any FDA labeled contraindications to the requested agent <p>Length of Approval:</p> <p>BCBSOK: 36 months ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p>Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the program quantity limit OR 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: <ol style="list-style-type: none"> A. BOTH of the following: <ol style="list-style-type: none"> 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication AND 2. There is support for therapy with a higher dose for the requested indication OR B. BOTH of the following: <ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication AND 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit <p>Length of Approval: 12 months</p>