SENTARA HEALTH PLANS

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-800-750-9692**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process may be delayed.**

Drug Requested: Arikayce® (amikacin liposome inhalation suspension)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy:** _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

Quantity Limit: One vial (590mg) via inhalation route once daily. Quantity Limit: 590mg/8.4ml; 28 vials/28days.

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization Approval: 6 months

- ❑ Patient must be 18 years of age or older

AND

- ❑ Medication must be prescribed by or in consultation with an infectious disease specialist or infectious disease specialist

AND

- ❑ Member must have a confirmed diagnosis of Mycobacterium avium complex (MAC) lung disease confirmed by **BOTH** of the following criteria supported from the American Thoracic Society **(chart notes and labs must be submitted)**:

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A. Must submit chart notes documenting the patient has ONE of the following clinical findings:
   - ❑ Pulmonary symptoms **OR**
   - ❑ Nodular or cavitary opacities on chest radiograph **OR**
   - ❑ A high-resolution computed tomography (HRCT) scan that shows multifocal bronchiectasis with multiple small nodules

AND

B. Must submit chart notes documenting the patient has **ONE** of the following **microbiological** findings:
   - ❑ Positive culture results from at least two separate expectorated sputum samples **OR**
   - ❑ Bronchoscopic culture positive for nontuberculosis mycobacterium (NTM) **OR**
   - ❑ Lung biopsy showing granulomatous inflammation or positive acid-fast bacilli (AFB) staining and positive culture for nontuberculosis mycobacterium (NTM)

AND

- ❑ Must submit documentation of **at least 2 positive sputum cultures** despite **at least 6 months** of multidrug background guideline-based therapy (GBT). GBT therapy may include a macrolide (clarithromycin, azithromycin), rifampin and ethambutol. **(Must attach lab results)**

AND

- ❑ There is documentation the member has positive sputum cultures within the past 60 days

AND

- ❑ Other diagnoses such as tuberculosis and lung malignancy has been ruled out

AND

- ❑ Member will continue Arikayce in combination with guideline-based therapy (a macrolide; clarithromycin or azithromycin, rifampin and ethambutol **(will be verified through pharmacy paid claims)**

Reauthorization Approval: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member has demonstrated response to therapy with the addition of Arikayce, defined by 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 **(Must submit labs)**

Renewal criteria: up to 12 months of treatment after converting to negative sputum status. Treatment beyond the first reauthorization approval (after 18 months) will require documentation of a positive sputum culture to demonstrate the need for continued treatment.

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Exclusion: will not be approved if member has history of any of the following:

- ❑ The member is using in combination with an intravenous aminoglycoside (such as amikacin or streptomycin **OR**
- ❑ The member has MAC isolates with amikacin resistance (minimum inhibitory concentration [MIC] >64ug/ml)

Medication being provided by a Specialty Pharmacy - PropriumRx

Not all drugs may be covered under every Plan

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pha rmacy paid claims or submitted chart notes.****