Amikacin Liposome Inhalation Suspension

Goal(s):

- Limit the use of amikacin liposome inhalation suspension to adult patients with 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.

Length of Authorization:

- 6-month initial approval; Up to 12 months renewal

Requires PA:

- Amikacin Liposome Inhalation Suspension (ALIS)

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Approval Criteria		
1. Is this a request for continuation of therapy previously approved by the FFS program?	**Yes**: Go to **Renewal Criteria**	**No**: Go to #2
2. Is this request for treatment of an adult ≥18 years of age with Mycobacterium avium complex (MAC) lung disease verified through sputum culture?	**Yes:** Record ICD10 code. Go to #3.	**No:** Pass to RPh. Deny; medical appropriateness.
3. Is this agent being prescribed by or in consultation with an infectious disease specialist, pulmonologist, or a specialist in the treatment of MAC lung infections?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; medical appropriateness.
4. Has the patient been adherent for the past 6-months to a course of a guideline-based 3-drug antibacterial treatment regimen including a macrolide, a rifamycin, and ethambutol?	**Yes:** List the antibiotic regimen. Go to #5	**No:** Pass to RPh. Deny; medical appropriateness. 6-month trial of guideline-based, 3-drug antibacterial regimen is required before starting amikacin liposome inhalation suspension.

Approval Criteria		
5. Will the patient be using amikacin liposome inhalation suspension as add on therapy to a guideline-based, 3-drug antibacterial MAC treatment regimen as described in question #4?	**Yes:** Approve for 6 months. Dose not to exceed 1 vial per day (590 mg/8.4 ml vial). Renewal consideration will require documentation of monthly MAC sputum cultures and regimen adherence.	**No:** Pass to RPh. Deny; medical appropriateness. Concurrent guideline-based, 3-drug antibacterial MAC regimen is required per product labeling.

Renewal Criteria		
1. Has the patient experienced evidence of respiratory adverse effects since treatment initiation such as hypersensitivity pneumonitis, hemoptysis, bronchospasm, or exacerbation of underlying pulmonary disease?	**Yes**: Pass to RPh. Deny; medical appropriateness.	**No**: Go to #2
2. Has the patient been adherent to both amikacin LIS and guideline-based background MAC antibiotic regimen?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; medical appropriateness.
3. Is there documentation of at least 3 consecutive negative monthly sputum cultures in the first 6 months of amikacin LIS therapy or a minimum of 2 consecutive negative monthly sputum cultures in the last 2 months of amikacin LIS therapy?	**Yes**: Document results of sputum culture. Approve for additional 3 months. Therapy not to exceed 12 months after converting to negative sputum status (≥3 consecutive negative MAC cultures).	**No:** Pass to RPh. Deny; medical appropriateness.