

Title: *tobramycin (Tobi®)*

Origination: 02/25/09	Revised:	Annual Review: 12/15/11
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Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Background Information:

Medication Summary

- TOBI® (tobramycin solution for inhalation) is a bactericidal antibiotic that interferes with bacterial protein synthesis when appropriate antibiotic concentration is achieved. Aerosol delivery of tobramycin allows the penetration directly to the lungs, while minimizing systemic exposure and potential side effects; ototoxicity and nephrotoxicity. Tobramycin nebulization is indicated for the management of cystic fibrosis (CF) or bronchiectasis with confirmed *Pseudomonas aeruginosa*.
- TOBI® is administered twice daily in alternating periods of 28 days. After 28 days of therapy, patients should stop TOBI® therapy for the next 28 days, and then resume therapy for the next 28 day on/28 day off cycle.

Reference Statement

- Guidelines will be compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

Eligibility Criteria

- Member must be eligible and have applicable benefits.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

Additional Information

- This procedure doesn't include a continuation therapy section as the medication typically isn't continued beyond the requested initial therapy.

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Procedure:

- 1.0 Request for *initial therapy* requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying ALL of the following:
 - 1.1 Member is at least six (6) years old (safety and efficacy of TOBI® have not been studied in pediatric Members under 6 years of age);
 - 1.2 Member has a diagnosis of cystic fibrosis (CF) or bronchiectasis with confirmed *Pseudomonas aeruginosa* (per culture and sensitivity report or clinical progress notes provided from requesting physician);
 - 1.3 If the Member meets all of the criteria, may approve up to 300mg twice daily for 28 day cycles (carton of 56 ampules) for a total of 6 months, which will equate to three (3) cycles (each cycle is 28 days on treatment then 28 days off treatment).

References:

1. TOBI® (Tobramycin Inhalation Solution). Full Prescribing Information. East Hanover, NJ: Novartis, Revised July 2008.
2. Gold Standard, Clinical Pharmacology: TOBI® (tobramycin) monograph, accessed on March 2009.
3. Shawar RM, MacLeod DL, Garber RL, et al. Activities of Tobramycin and Six Other Antibiotics Against *Pseudomonas aeruginosa* Isolates from Patients with Cystic Fibrosis. *Antimicrobial Agents and Chemotherapy*; 2877-80 December 1999.
4. Burns JL, Van Dalfsen JM, Shawar RM, et al. Effect of Chronic Intermittent Administration of Inhaled Tobramycin on Respiratory Microbial Flora in Patients with Cystic Fibrosis. *J Infect Dis* 179:1190-6 1999.
5. Ramsey BW, Pepe MS, Quan JM, et al. Intermittent Administration of Inhaled Tobramycin in Patients with Cystic Fibrosis. *N Engl Journ Med* 340:23-30 1999.
6. Barker AF, Couch L, Fiel SB, et al. Tobramycin Solution for Inhalation Reduces Sputum *Pseudomonas aeruginosa* Density in Bronchiectasis. *American Journal of Respiratory and Critical Care Medicine* 162(2): 481-6. August 2000.

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Disclaimer Information:

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.