

Policy Name:	Tobi (tobramycin), Bethkis (tobramycin), Kitabis Pak (tobramycin), Tobramycin Compound for Inhalation	Policy #:	1904P
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Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Tobi, Bethkis, Ketabis Pak, and Tobramycin Compound for Inhalation.

Statement of the Policy

Health Alliance Medical Plans and Health Alliance Northwest will approve the use of Tobi (tobramycin), Bethkis (tobramycin), Kitabis Pak (tobramycin), and Tobramycin Compound for Inhalation under the specialty pharmacy benefit when the following criteria have been met.

Criteria

1. Coverage Criteria

- 1.1 Prescription issued by a provider specializing in pediatric/adult pulmonology (lung specialist) or a doctor associated with a cystic fibrosis clinic
- 1.2 Diagnosis of cystic fibrosis
- 1.3 Diagnosis or history of airway culture positive for *Pseudomonas aeruginosa*
- 1.4 Age 6 years or older

2. Approval Period

- 2.1 Initial: 12 months
- 2.2 Reauthorization: 12 months with documented clinical benefit

CPT Codes

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HCPCS Codes

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References

1. Bethkis (tobramycin) [prescribing information]. Woodstock, IL: Chiesi USA Inc; February 2023
2. Kitabis Pak (tobramycin inhalation solution) [prescribing information]. Midlothian, VA: PARI Respiratory Equipment Inc; April 2023

3. Tobii/Podhaler (tobramycin) [prescribing information]. Morgantown, WV: Mylan Specialty LP; February 2023.
4. Kapnadak SG, Dimango E, Hempstead SE, et al. Cystic Fibrosis Foundation consensus guidelines for the care of individuals with advanced cystic fibrosis lung disease. *J Cyst Fibros*. 2020 May;19(3):344-354.
5. Mogayzel PJ Jr, Naureckas ET, Robinson KA, et al. Cystic Fibrosis Foundation pulmonary guideline. Pharmacologic approaches to prevention and eradication of initial *Pseudomonas aeruginosa* infection. *Ann Am Thorac Soc*. 2014;11(10):1640-1650.

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.