Clinical Policy Title:	tobramycin
Policy Number:	RxA.193
Drug(s) Applied:	Bethkis®, Kitabis® Pak, TOBI®, TOBI® Podhaler®
Original Policy Date:	02/07/2020
Last Review Date:	4/1/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Cystic Fibrosis (must meet all)**:**

1. Diagnosis of CF;
2. Prescribed by or in consultation with a pulmonologist, an infection disease specialist, or an expert in treatment of cystic fibrosis;
3. *Pseudomonas aeruginosa* is present in at least one airway culture;

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. Cystic Fibrosis (must meet all)**:**

1. Member is currently receiving or has been treated with this medication within the past 90 days, excluding manufacturer samples.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. TOBI Podhaler. Package Insert. Novartis Pharmaceuticals Corporation; 2020. https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/201688s010lbl.pdf Accessed April 1, 2024.
2. Mogayzel PJ, Naureckas ET, 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): 1640-50. https://www.atsjournals.org/doi/full/10.1513/AnnalsATS.201404-166OC#.VVNmEo5Viko. Accessed April 1, 2024.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Policy description table was updated. 2. Continuation therapy criteria II.A.1. was	06/19/2020	09/14/2020

rephrased to “Member is currently receiving medication that has been authorized by RxAdvance…”. 3. Initial therapy and continued therapy approval duration for “Commercial” was updated from length of benefit to 6 months and 12 months respectively; added approval duration for “HIM”. 4. References were updated.		
Policy was reviewed: 1. Approval duration section was updated to remove HIM from initial and continued therapy approval. 2. References were updated.	04/01/2021	06/10/2021
Policy was reviewed: 1. References were reviewed and updated.	01/05/2022	04/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.2: Updated to include new prescriber criteria Prescribed by or in consultation with a pulmonologist, an infection disease specialist, or an expert in treatment of cystic fibrosis. 2. Initial Approval Criteria: Updated commercial approval duration from 6 months to 12 months. 3. References were reviewed and updated.	01/18/2023	04/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed documentation requirement for inadequate response to Cayston or tobramycin monotherapy. 2. References were reviewed and updated.		