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:	10/19/2023
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. Age ≥ 6 years;
4. *Pseudomonas aeruginosa* is present in at least one airway culture;
5. If tobramycin is prescribed concurrently (or for alternating use) with Cayston®, documentation supports inadequate response to either agent alone (e.g., deteriorating pulmonary status, recurrent pulmonary exacerbations);
6. Dose does not exceed one of the following (a or b):
   a. Inhalation solution (Bethkis®, Kitabis® Pak, TOBI®): 600 mg per day administered on a 28 days on/28 days off cycle;
   b. Inhalation powder (TOBI® Podhaler®): 224 mg per day administered on a 28 days on/28 days off cycle.

Approval Duration
Commercial: 12 months
Medicaid: 6 months

II. Continued Therapy Approval

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

1. Member is currently receiving tobramycin that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If tobramycin is prescribed concurrently (or for alternating use) with Cayston®, documentation supports inadequate response to either agent alone (e.g., deteriorating pulmonary status, recurrent pulmonary exacerbations);
4. If request is for a dose increase, new dose does not exceed one of the following (a or b):
   a. Inhalation solution (Bethkis®, Kitabis® Pak, TOBI®): 600 mg per day administered on a 28 days on/28 days off cycle;
   b. Inhalation powder (TOBI® Podhaler®): 224 mg per day administered on a 28 days on/28 days off cycle.

Approval Duration

Commercial: 12 months
Medicaid: 12 months

References

1. Flume PA, Mogayzel PJ, Robinson KA, et al. Cystic fibrosis pulmonary guidelines. Treatment of pulmonary exacerbations. Am J Respir Crit Care Med. 2009; 180: 802-808. Available at: https://pubmed.ncbi.nlm.nih.gov/19729669/. Accessed January 18, 2023.
2. Mogayzel PJ, Naureckas ET, Robinson KA, et al. Cystic fibrosis pulmonary guidelines: Chronic medications for maintenance of lung health. Am J Respir Crit Care Med. April 1, 2013; 187 (7): 680-689. Available at: https://pubmed.ncbi.nlm.nih.gov/23540878/. Accessed January 18, 2023.

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 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.	06/19/2020	09/14/2020
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