

Inhaled Antibiotics for Cystic Fibrosis (tobramycin, Tobi[®], Tobi Podhaler[™], Bethkis[®], Cayston[®])

Policy # 00519

Original Effective Date: 01/01/2017

Current Effective Date: 05/01/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider generic/brand tobramycin 300 mg per 5 mL inhalation solution (Tobi[®])[‡], generic/brand tobramycin 300 mg per 4 mL inhalation solution (Bethkis[®])[‡], tobramycin inhalation powder (Tobi[®] Podhaler[™])[‡], and aztreonam inhalation solution (Cayston[®])[‡] for the treatment of *Pseudomonas aeruginosa* lung infections in cystic fibrosis patients to be **eligible for coverage**.**

Patient Selection Criteria

Coverage eligibility for generic/brand tobramycin 300 mg per 5 mL inhalation solution (Tobi), generic/brand tobramycin 300 mg per 4 mL inhalation solution (Bethkis), tobramycin inhalation powder (Tobi Podhaler), or aztreonam inhalation solution (Cayston) will be considered when the following criteria are met:

- Patient has a diagnosis of cystic fibrosis; AND
- Patient's lungs are colonized with *Pseudomonas aeruginosa*; AND
- For brand name tobramycin 300 mg per 5 mL inhalation solution (Tobi), generic/brand tobramycin 300 mg per 4 mL inhalation solution (Bethkis), or tobramycin inhalation powder (Tobi Podhaler) requests ONLY: There is clinical evidence or patient history that suggests the use of generic tobramycin 300 mg per 5 mL inhalation solution will be/was ineffective or will/did cause an adverse reaction to the patient.

*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

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When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of brand name tobramycin 300 mg per 5 mL inhalation solution (Tobi), generic/brand tobramycin 300 mg per 4 mL inhalation solution (Bethkis), or tobramycin inhalation powder (Tobi Podhaler) WITHOUT clinical evidence or patient history that suggests the use of generic tobramycin 300 mg per 5 mL inhalation solution will be/was ineffective or will/did cause an adverse reaction to the patient to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of generic/brand tobramycin 300 mg per 5 mL inhalation solution (Tobi), generic/brand tobramycin 300 mg per 4 mL inhalation solution (Bethkis), tobramycin inhalation powder (Tobi Podhaler), or aztreonam inhalation solution (Cayston) when patient selection criteria are not met (with the exception of those denoted above as **not medically necessary****) to be **investigational.***

Background/Overview

All of the mentioned inhalations in this policy are approved for the management of cystic fibrosis patients with *Pseudomonas aeruginosa* infections. Brand Tobi has a generic equivalent available. Both the brand and the generic versions of Tobi contain 300 mg per 5 mL of tobramycin inhalation solution. Bethkis is simply a slightly more concentrated version of Tobi. Bethkis contains 300 mg of tobramycin per 4 mL of inhalation solution and has a generic equivalent available. Tobi Podhaler is an inhalation powder containing tobramycin. All of the tobramycin products are taken twice daily. None of the tobramycin branded products, nor the generic tobramycin 300 mg per 4 mL inhalation solution, show superiority over the generically available tobramycin 300 mg per 5 mL inhalation solution. Cayston is an inhaled aztreonam containing solution.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Tobi was approved in late 1997. Tobi Podhaler was approved in 2013. Bethkis was approved in 2012. Cayston was approved in 2010. There is a generic tobramycin 300 mg per 5 mL inhalation solution available as well as a generic tobramycin 300 mg per 4 mL inhalation solution. All of these products are approved for the management of cystic fibrosis patients with *Pseudomonas aeruginosa* infections.

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Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The patient selection criteria presented in this policy take into consideration clinical evidence or patient history that suggests generic tobramycin 300 mg per 5 mL inhalation solution will be ineffective or cause an adverse reaction to the patient. Based on a review of the data, in the absence of the above mentioned caveat, there is no advantage of using brand name tobramycin 300 mg per 5 mL inhalation solution (Tobi), generic/brand tobramycin 300 mg per 4 mL inhalation solution (Bethkis), or tobramycin inhalation powder (Tobi Podhaler) over the generic tobramycin 300 mg per 5 mL inhalation solution. This policy is also in place to ensure that these inhalations are being utilized for their FDA approved indication.

References

1. Cayston [package insert]. Gilead Sciences, Inc. Foster City, California. Updated September 2012.
2. Tobi Podhaler [package insert]. Novartis. East Hanover, New Jersey. Updated September 2015.
3. Bethkis [package insert]. Chiesi USA. Woodstock, Illinois. Updated May 2014.
4. Tobi [package insert]. Novartis. East Hanover, New Jersey. Updated September 2015.

Policy History

Original Effective Date: 01/01/2017

Current Effective Date: 05/01/2025

08/04/2016 Medical Policy Committee review

08/17/2016 Medical Policy Implementation Committee approval. New policy.

08/03/2017 Medical Policy Committee review

08/23/2017 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

08/09/2018 Medical Policy Committee review

08/15/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

08/01/2019 Medical Policy Committee review

08/14/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

08/06/2020 Medical Policy Committee review

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- 08/12/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 04/01/2021 Medical Policy Committee review
- 04/14/2021 Medical Policy Implementation Committee approval. Added a new generic equivalent to Bethkis, tobramycin 300 mg per 4 mL inhalation solution, to the policy.
- 04/07/2022 Medical Policy Committee review
- 04/13/2022 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 04/06/2023 Medical Policy Committee review
- 04/12/2023 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 04/04/2024 Medical Policy Committee review
- 04/10/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 04/03/2025 Medical Policy Committee review
- 04/09/2025 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 04/2026

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 - 1. Consultation with technology evaluation center(s);
 - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 - 3. Reference to federal regulations.

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****Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.