

Reference number(s)
5866-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	<input checked="" type="checkbox"/>
Standard Control – Choice (SCCF)	<input checked="" type="checkbox"/>
Preferred Drug Plan Design (PDPD)	<input type="checkbox"/>
Advanced Control Specialty (ACSF)	<input checked="" type="checkbox"/>
Advanced Control Specialty – Choice (ACSCF)	<input checked="" type="checkbox"/>
Managed Medicaid Template (MMT)	<input type="checkbox"/>
Marketplace (MF)	<input type="checkbox"/>
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	<input type="checkbox"/>
Aetna Individual Lives (IVL)	<input type="checkbox"/>
Value (VF)	<input checked="" type="checkbox"/>

Formulary	Applies
New to Market (NTM)	<input type="checkbox"/>
Standard Formulary Chart (SFC)	<input type="checkbox"/>
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	<input type="checkbox"/>
Advanced Control Specialty Formulary Chart (ACSFC)	<input type="checkbox"/>
Value Formulary Chart (VFC)	<input checked="" type="checkbox"/>
Medical Benefit	<input type="checkbox"/>
Medical Benefit: Advanced Biosimilars First	<input type="checkbox"/>
Medical Benefit: Managed Medicaid (MMMB)	<input type="checkbox"/>
Medicare Part B	<input type="checkbox"/>
Medicare Part B: Advanced Biosimilars First	<input type="checkbox"/>

Exceptions Criteria Inhaled Antibiotics

This document informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

These criteria were developed to align with the following: Standard Control Formulary (SF), Standard Control – Choice Formulary (SCCF), Advanced Control Specialty Formulary (ACSF), Advanced Control Specialty – Choice Formulary (ACSCF), Value Formulary (VF), and Value Formulary Chart (VFC).

Plan Design Summary

This program applies to the inhaled antibiotic products specified in this document. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with Cayston for the first time. This program also applies to all members requesting treatment with Bethkis, Kitabis Pak, TOBI or TOBI Podhaler.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Inhaled Antibiotic Products

Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

	Product(s)
Preferred	<ul style="list-style-type: none"> tobramycin inhalation solution (generic)
Target	<ul style="list-style-type: none"> Bethkis (tobramycin inhalation solution) Cayston (aztreonam) Kitabis Pak (tobramycin inhalation solution) TOBI (tobramycin inhalation solution) TOBI Podhaler (tobramycin inhalation powder)

Exception Criteria

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

Cayston

Coverage for Cayston is provided when any of the following criteria is met:

- Member is currently receiving treatment with Cayston, excluding when Cayston is obtained as samples or via manufacturer's patient assistance programs.
- Member will be using Cayston in combination with the preferred product generic tobramycin inhalation solution.
- Member has had a documented inadequate response, intolerable adverse event, or contraindication with the preferred product generic tobramycin inhalation solution.

Bethkis, Kitabis Pak, TOBI, or TOBI Podhaler

Coverage for a targeted product is provided when the member has had a documented intolerable adverse event to the preferred product generic tobramycin inhalation solution, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.

References

- Bethkis [package insert]. Woodstock, IL: Chiesi USA Inc; February 2023.
- Cayston [package insert]. Foster City, CA: Gilead Sciences Inc; November 2019.
- Kitabis Pak [package insert]. Midlothian, VA: PARI Respiratory Equipment, Inc; August 2023.
- TOBI [package insert]. Morgantown, WV: Mylan Specialty L.P.; February 2023.
- TOBI Podhaler [package insert]. Morgantown, WV: Mylan Specialty L.P.; February 2023.
- Tobramycin inhalation solution [package insert]. Princeton, NJ: Dr. Reddy's Laboratories, Inc.; February 2023.