

This policy applies to the following:

✓	Standard Control (SF)	Managed Medicaid Template (MMT)	ACSF Chart (ACSFC)	Medical Benefit	Medicare Part B	Reference #
	Preferred Drug Plan Design (PDPD)	Marketplace (MF)	SF Chart (SFC)	Medical Benefit: Biosimilars First	Medicare Part B: Biosimilars First	5866-D
✓	Advanced Control Specialty (ACSF)	New to Market (NTM)	VF Chart (VFC)	Medical Benefit: Add-on	Medicare Part B: Advanced Biosimilars First	
✓	Value (VF)	Aetna Health Exchange (AHE)		Medical Benefit: Managed Medicaid		
		IVL				

EXCEPTIONS CRITERIA INHALED ANTIBIOTIC PRODUCTS

PREFERRED PRODUCT: TOBRAMYCIN INHALATION SOLUTION

POLICY

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

I. PLAN DESIGN SUMMARY

This program applies to the inhaled antibiotic products specified in this policy. 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 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

Preferred*	Product(s)
Preferred*	<ul style="list-style-type: none"> tobramycin inhalation solution
Targeted	<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)

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

II. EXCEPTION CRITERIA

A. Cayston

Coverage for a targeted product is provided when any of the following criteria is met:

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

B. Bethkis, Kitabis Pak, TOBI, or TOBI Podhaler

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	Preferred Drug Plan Design (PDPD)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First		Medicare Part B: Biosimilars First	5866-D
✓	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on		Medicare Part B: Advanced Biosimilars First	
✓	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid			
			IVL							

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

REFERENCES

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