

Louisiana Medicaid
Infectious Disorders – Antibiotics – Inhaled Antibiotics

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request prior authorization for non-preferred inhaled antibiotics.

Additional Point-of-Sale edits may apply.

NOTE: *T*Some of these agents medications may have **Black Box Warnings** and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.

Approval Criteria for Initial and Reauthorization Requests for Non-Preferred Inhaled Antibiotics

- For tobramycin oral inhalation (generic for Bethkis®) – there has been a treatment failure or intolerable side effect with or contraindication to brand Bethkis®; OR

ALL of the following are required:

- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- The requested medication has been prescribed for an approved diagnosis (if applicable); **AND**
- Previous use of a preferred product - **ONE** of the following is required:
 - The recipient has had a *treatment failure* with at least one preferred product; **OR**
 - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
 - The recipient has *documented contraindication(s)* to the preferred products that are appropriate to use for the condition being treated; **OR**
 - There is *no preferred product that is appropriate* to use for the condition being treated; **OR**
 - **The prescriber states that the request is to complete a course of treatment that was initiated while the recipient was in an inpatient facility;** **AND**
- By submitting the authorization request, the prescriber attests to the following:
 - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
 - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
 - -The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.
 - The recipient has no inappropriate concomitant drug therapies or disease states.

Duration of Initial and ReAuthorization Approval: 12 months

References

[Clinical Pharmacology \[database online\]. Tampa, FL: Gold Standard, Inc.; Retrieved from https://www.clinicalkey.com/pharmacology/](https://www.clinicalkey.com/pharmacology/)

DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. Pharmacotherapy: A Pathophysiologic Approach, 10e New York, NY: McGraw-Hill; Retrieved from https://accesspharmacy.mhmedical.com/book.aspx?bookid=1861

Arikayee (amikacin) [package insert]. Bridgewater, NJ: Insmed; October 2020September 2018. https://www.arikayee.com/pdf/full_prescribing_information.pdf

Bethkis (tobramycin) [package insert]. Woodstock, IL: Catalent Pharma Solutions, LLC; December 2019July 2017. https://resources.chiesiusa.com/Bethkis/BETHKIS_PI.pdf

Cayston (aztreonam) [package insert]. Foster City, CA: Gilead Sciences, Inc; NovemberFebruary 2019. https://www.gilead.com/-/media/files/pdfs/medicines/respiratory/cayston/cayston_pi.pdf?la=en

Kitabis (tobramycin) [package insert]. Midlothian, VA: PARI Respiratory Equipment, Inc; November 2019 May 2016. https://kitabis.com/prescribing_information

Tobi Podhaler (tobramycin) [package insert]. San Carlos, CAEast Hanover, NJ: Mylan Novartis Pharmaceuticals IncCorporation; JulyOctober 202015.

<https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?type=display&setid=6f3ffe58-f84f-4a6e-84af-49c3309a374e>

<https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?type=display&setid=625a4499-4e46-4f5a-8d0e-d104f520d97e>

<u>Revision / Date</u>	<u>Date</u> <u>Implementation Date</u>
Single PDL Implementation	May 2019
Separated “Select Anti-Infectives” into individual therapeutic class documents / November 2019	November 2019January 2020
Added specific wording regarding previous for use of Bethkis®, formatting changes, updated references / April 2021	April 2021July 2021