

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Antibiotics, Inhaled PDL Edit
<b>First Implementation Date:</b>	January 5, 2012
<b>Revised Date:</b>	July 7, 2022
<b>Prepared For:</b>	MO HealthNet
<b>Prepared By:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input checked="" type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

## Executive Summary

**Purpose:** The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

**Why Issue Selected:** Cystic Fibrosis (CF) is the most common lethal genetic disease among Caucasians, affecting approximately 30,000 individuals residing in the United States. It has been estimated that 4 to 5 percent of all Caucasians in North America are carriers of the CF gene. CF is an autosomal recessive disorder caused by mutations of the cystic fibrosis transmembrane conductance regulator (CFTR) gene located on chromosome #7. The typical manifestation of CF involves progressive obstructive lung disease that has been associated with impaired mucous clearance, difficulty clearing pathogens, and risk of chronic pulmonary infection and inflammation. As a result, respiratory failure is the common cause of death in these patients. The median expected survival age of patients born between 2012 and 2016 has increased to 43 years. The main objectives of CF treatment are to treat and prevent infection, promote mucus clearance, and improve nutrition. Since pulmonary infection is the main source of morbidity and mortality, antibiotics play an important role in CF therapy to control the progression of the disease. In patients with pulmonary exacerbations marked by chronic infection of *Pseudomonas aeruginosa*, treatment with the combination of aminoglycoside and beta-lactam antibiotics is recommended. Chronic use of inhaled tobramycin (TOBI®) is recommended in the CF guidelines to reduce exacerbation for patients who are 6 years of age or older with persistent *P. aeruginosa* culture in the airways. Cayston® is a beta-lactamase-resistant monobactam antibiotic that has activity against aerobic gram-negative bacteria, including *P. aeruginosa*.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:	Preferred Agents	Non-Preferred Agents
	<ul style="list-style-type: none"> <li>Bethkis®</li> <li>Kitabis® Pak</li> <li>Tobramycin Amp (gen TOBI®)</li> </ul>	<ul style="list-style-type: none"> <li>Arikayce®</li> <li>Cayston®</li> <li>TOBI®</li> <li>TOBI® Podhaler®</li> <li>Tobramycin Amp (gen Bethkis®)</li> <li>Tobramycin Pak (gen Kitabis® Pak)</li> </ul>

Type of Criteria:  Increased risk of ADE  
 Appropriate Indications

Preferred Drug List  
 Clinical Edit

Data Sources:  Only Administrative Databases

Databases + Prescriber-Supplied

## Setting & Population

- Drug class for review: Antibiotics, Inhaled
- Age range: All appropriate MO HealthNet participants

## Approval Criteria

- Failure to achieve desired therapeutic outcomes with trial on 2 or more preferred agents
  - Documented trial period of preferred agents
  - Documented ADE/ADR to preferred agents

## Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met

## Required Documentation

Laboratory Results:   
MedWatch Form:

Progress Notes:   
Other:

## Disposition of Edit

Denial: Exception Code "0160" (Preferred Drug List)  
Rule Type: PDL

## Default Approval Period

1 year

## References

- Evidence-Based Medicine and Fiscal Analysis: "Inhaled Antibiotics - Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond VA; January 2022.
- Evidence-Based Medicine Analysis: "Inhaled Antibiotics", UMKC-DIC; January 2022.
- USPDI, Micromedex; 2022.
- Facts and Comparisons eAnswers (online); 2022 Clinical Drug Information, LLC.