SmartPA Criteria Proposal

Drug/Drug Class:	Antibiotics, Inhaled PDL Edit
First Implementation Date:	January 5, 2012
Proposed Date:	April 18, 2023
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☒Existing Criteria ☐Revision of Existing Criteria ☐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 a life-threatening autosomal recessive disease caused by mutations of the cystic fibrosis transmembrane conductance regulator (CFTR) gene. CF affects approximately 30,000 people in the US, with approximately 800 new cases diagnosed every year. The primary cause of death in CF is respiratory disease; median survival age in the US is 53.1 years. Since pulmonary infection is the main source of morbidity and mortality, antibiotics play a significant role in CF therapy to control the progression of the disease. In patients with pulmonary exacerbations marked by chronic infection of *Pseudomonas aeruginosa,* chronic treatment with inhaled tobramycin is a well-established first-line treatment.

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

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Bethkis® • Kitabis® Pak • Tobramycin Amp (gen TOBI®)	• Arikayce® • Cayston® • TOBI® • TOBI® Podhaler® • Tobramycin Amp (gen Bethkis®) • Tobramycin Pak (gen Kitabis® Pak)

Type of Criteria: ☒ **Increased risk of ADE** ☒ **Preferred Drug List**
☐ **Appropriate Indications** ☐ **Clinical Edit**

Data Sources: ☒ **Only Administrative Databases** ☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Antibiotic Agents, 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:	☐	Progress Notes:	☐
MedWatch Form:	☐	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: “Therapeutic Class Review: ANTI-INFECTIVES: Inhaled Antibiotics”, Gainwell Technologies; Last updated February 23, 2023.
- Evidence-Based Medicine Analysis: “Inhaled Antibiotics”, UMKC-DIC; Last updated January 2023.
- Cystic Fibrosis Foundation Patient Registry. 2021 Annual Data Report. Bethesda, Maryland. ©2022 Cystic Fibrosis Foundation.
- Cystic Fibrosis Foundation. CF Care & COVID-19: 2020 Patient Registry Data. Available at: https://www.cff.org/sites/default/files/2021-12/2020%20Patient%20Registry%20Data-CF%20Care_COVID.pdf. Accessed on November 11, 2022.
- USPDI, Micromedex; 2023.
- Facts and Comparisons eAnswers (online); 2023 Clinical Drug Information, LLC.