SmartPA Criteria Proposal

Drug/Drug Class:	Antibiotic Agents – Inhaled PDL Edit
First Implementation Date:	January 5, 2012
Proposed Date:	March 19, 2020
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 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 persistant *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
• Bethkis®	• Arikayce®
• Kitabis® Pak	• Cayston®
• TOBI Podhaler™	• TOBI®
	• Tobramycin (gen TOBI®)
	• 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 1 or more preferred agents
  - Documented trial period of preferred agents
  - Documented ADE/ADR to preferred agents
- Documented compliance on current therapy regimen

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if no approval criteria are 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

1. Evidence-Based Medicine and Fiscal Analysis: “Inhaled Antibiotics - Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond VA; January 2020.
2. Evidence-Based Medicine Analysis: “Inhaled Antibiotics”, UMKC-DIC; January 2020.
3. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2020.
4. USPDI, Micromedex; 2020.
5. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.