



Proposal

Drug/Drug Class:	Anticholinergics, Long Acting Beta Adrenergic (LABA)/Inhaled Corticosteroid (ICS) Combinations and Phosphodiesterase 4 (PDE4) Inhibitors PDL Edit
First Implementation Date:	October 26, 2018
Revised Date:	November 3, 2022
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	<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: Asthma is a chronic inflammatory disorder of the airways characterized by reversible episodes of chest tightness, shortness of breath, cough or wheezing. Severity is determined by multiple factors including frequency of symptoms, FEV₁ and FEV₁/FVC measurements, and frequency of exacerbations. Approximately 25 million individuals are impacted by asthma, including 6 million children under the age of 18. The condition, although often manageable with lifestyle changes, pharmacologic therapies, and trigger avoidance, continues to be a significant health and economic burden.

Chronic obstructive pulmonary disease (COPD) is a common, preventable, and treatable disease that is characterized by persistent respiratory symptoms and airflow limitation that is due to airway and/or alveolar abnormalities. It continues to be a leading cause of morbidity and mortality worldwide. Pharmacological therapy is used to reduce COPD symptoms and reduce the frequency and severity of exacerbations. Treatment regimens are individualized based on symptom severity, exacerbation risk, comorbidities, and patient ability to effectively manage and utilize the various drug delivery devices.

Many of the currently available pharmacologic therapies utilized for the treatment and management of asthma and COPD overlap in their FDA-approved indications. Choice of therapy is guided by disease severity, prior therapies utilized, product cost, patient ability to properly use the various delivery devices, potential side effects, concomitant disease states, and ability to maintain adherence to the therapy regimen.

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"> N/A 	<ul style="list-style-type: none"> Breztri Aerosphere® Daliresp® Roflumilast

	• Trelegy Ellipta
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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: Anticholinergics, Long Acting Beta Adrenergic (LABA)/Inhaled Corticosteroid (ICS) Combinations and Phosphodiesterase 4 (PDE4) Inhibitors
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Documented compliance on current therapy regimen **OR**
- Failure to achieve desired therapeutic outcomes with trial on 2 or more preferred inhaled respiratory agents (See Appendix A)
 - Documented trial period of preferred agents **OR**
 - Documented ADE/ADR to preferred agents **AND**
- For Trelegy Ellipta: documented trial with 2 or more preferred agents, including 1 preferred LAMA-LABA agent
- For Breztri Aerosphere and Daliresp: documented trial of Trelegy Ellipta

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

Appendix A – Preferred Inhaled Respiratory Agents

Drug Description	Generic Equivalent
DUONEB 0.5 MG-3 MG/3 ML SOLN	IPRATROPIUM/ALBUTEROL SULFATE
SPIRIVA 18 MCG CP-HANDIHALER	TIOTROPIUM BROMIDE
ATROVENT HFA INHALER	IPRATROPIUM BROMIDE
COMBIVENT RESPIMAT INHALER	IPRATROPIUM/ALBUTEROL SULFATE

ANORO ELLIPTA 62.5-25 MCG INH	UMECLINDIUM BROMIDE/VILANTEROL TRIFENATATE
SPIRIVA RESPIMAT 1.25 MCG INH	TIOTROPIUM BROMIDE
IPRATROPIUM BR 0.02% SOLN	IPRATROPIUM BROMIDE
SPIRIVA RESPIMAT INHAL SPRAY	TIOTROPIUM BROMIDE

References

- Evidence-Based Medicine and Fiscal Analysis: “COPD Anticholinergics – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; January 2022.
- Evidence-Based Medicine Analysis: “Chronic Obstructive Pulmonary Disease (COPD) Anticholinergics”, UMKC-DIC; October 2021.
- Global Initiative for Chronic Obstructive Lung Disease: Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (GOLD 2021 report). <https://goldcopd.org/wp-content/uploads/2019/11/GOLD-2020-REPORT-ver1.0wms.pdf>.
- USPDI, Micromedex; 2022.
- Update on Selected Topics in Asthma Management: A Report from the NAEPPCC Expert Panel Working Group (2020 Focused Update to the Asthma Management Guidelines). <file:///C:/Users/mfast/Downloads/AsthmaManagementGuidelinesReport-2-4-21.pdf>.
- Facts and Comparisons eAnswers (online); 2022 Clinical Drug Information, LLC.