

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	COPD Anticholinergic Agents PDL Edit
<b>First Implementation Date:</b>	October 26, 2018
<b>Proposed Date:</b>	March 18, 2021
<b>Prepared For:</b>	MO HealthNet
<b>Prepared By:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input type="checkbox"/> Existing Criteria <input checked="" 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:** Chronic obstructive pulmonary disease (COPD) is a lung disease that encompasses chronic bronchitis and emphysema. COPD is a major cause of death and illness throughout the world and is third leading cause of death in the United States. Cigarette smoking is the most common cause of COPD, however breathing in lung irritants, like pollution, dust or chemicals over a long period of time may also cause or contribute to the disease. There is no cure for COPD, but treatment can alleviate symptoms, decrease the frequency and severity of exacerbations and increase exercise tolerance. The 2020 Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines provide evaluation and treatment of patients with moderate to severe COPD (FEV1 < 80% of predicated normal and FEV1/FVC < 70%). Treatment includes short-acting muscarinic antagonists, long-acting beta-agonists, long-acting muscarinic agents, and inhaled corticosteroids which are the mainstays of therapy for COPD.

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>• <b>Anoro Ellipta<sup>®</sup></b></li> <li>• Atrovent HFA<sup>®</sup></li> <li>• Bevespi Aerosphere<sup>®</sup></li> <li>• Combivent Respimat<sup>®</sup></li> <li>• Ipratropium Soln</li> <li>• Ipratropium-Albuterol</li> <li>• Spiriva HandiHaler<sup>®</sup></li> </ul>	<ul style="list-style-type: none"> <li>• <b>Breztri Aerosphere<sup>™</sup></b></li> <li>• Daliresp<sup>®</sup></li> <li>• Duaklir<sup>®</sup> Pressair<sup>®</sup></li> <li>• Incruse Ellipta<sup>®</sup></li> <li>• Lonhala<sup>™</sup> Magnair<sup>™</sup></li> <li>• Seebri Neohaler<sup>®</sup></li> <li>• Spiriva Respimat<sup>®</sup></li> <li>• Stiolto Respimat<sup>®</sup></li> <li>• Trelegy Ellipta<sup>®</sup></li> <li>• Tudorza Pressair<sup>®</sup></li> <li>• Utibron Neohaler<sup>®</sup></li> <li>• Yupelri<sup>™</sup></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: COPD Anticholinergic Agents
- Age range: All appropriate MO HealthNet participants

- Documented compliance on current therapy regimen **OR**
- Failure to achieve desired therapeutic outcomes with trial on 3 or more preferred agents
  - Documented trial period of preferred agents **OR**
  - Documented ADE/ADR to preferred agents **AND**
- For Trelegy Ellipta: documented trial with 3 or more preferred agents, including 1 preferred LAMA-LABA agent **OR**
- ~~For Anoro Ellipta: documented trial with 3 or more preferred agents, including 2 preferred LAMA-LABA agents~~

## Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met
- Claim exceeds maximum dosing limitation for the following:

Drug Description	Generic Equivalent	Max Dosing Limitation
COMBIVENT RESPIMAT	IPRATROPIUM/ALBUTEROL	6 sprays per day

## 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

1. Evidence-Based Medicine and Fiscal Analysis: "COPD Anticholinergics – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; January 2021.
2. Evidence-Based Medicine Analysis: "Chronic Obstructive Pulmonary Disease (COPD) Anticholinergics", UMKC-DIC; February 2021.

SmartPA PDL Proposal Form

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3. Global initiative for chronic obstructive lung disease. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (GOLD 2020 report). Global Initiative For Chronic Obstructive Lung Disease website. <https://goldcopd.org/wp-content/uploads/2019/11/GOLD-2020-REPORT-ver1.0wms.pdf>.
4. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2021.
5. USPDI, Micromedex; 2021.
6. Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.

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