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:

<table>
<thead>
<tr>
<th>Preferred Agents</th>
<th>Non-Preferred Agents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anoro Ellipta®</td>
<td>Breztri Aerosphere™</td>
</tr>
<tr>
<td>Atrovent HFA®</td>
<td>Daliresp®</td>
</tr>
<tr>
<td>Bevespi Aerosphere®</td>
<td>Duaklir® Pressair®</td>
</tr>
<tr>
<td>Combivent Respimat®</td>
<td>Incruse® Ellipta®</td>
</tr>
<tr>
<td>Ipratropium Soln</td>
<td>Lonhala® Magnair®</td>
</tr>
<tr>
<td>Ipratropium-Albuterol</td>
<td>Seebri™ Neohaler®</td>
</tr>
<tr>
<td>Spiriva HandiHaler®</td>
<td>Spiriva® Respimat®</td>
</tr>
<tr>
<td></td>
<td>Stiolto® Respimat®</td>
</tr>
<tr>
<td></td>
<td>Trelegy Ellipta</td>
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<tr>
<td></td>
<td>Tudorza® Pressair®</td>
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<tr>
<td></td>
<td>Utibron® Neohaler®</td>
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<tr>
<td></td>
<td>Yupelri®</td>
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</tbody>
</table>
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: COPD Anticholinergic Agents
- 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 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
- For Breztri Aerosphere: 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
- Claim exceeds maximum dosing limitation for the following:

<table>
<thead>
<tr>
<th>Drug Description</th>
<th>Generic Equivalent</th>
<th>Max Dosing Limitation</th>
</tr>
</thead>
<tbody>
<tr>
<td>COMBIVENT RESPIMAT</td>
<td>IPRATROPIUM/ALBUTEROL</td>
<td>6 sprays per day</td>
</tr>
</tbody>
</table>

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

5. USPDI, Micromedex; 2021.
6. Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.