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.

<table>
<thead>
<tr>
<th>Program-Specific Information:</th>
<th>Preferred Agents</th>
<th>Non-Preferred Agents</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N/A</td>
<td>Breztri Aerosphere®</td>
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<tr>
<td></td>
<td></td>
<td>Daliresp®</td>
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<tr>
<td></td>
<td></td>
<td>Trelegy Ellipta</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: 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:  
MedWatch Form:  
Progress Notes:  
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

<table>
<thead>
<tr>
<th>Drug Description</th>
<th>Generic Equivalent</th>
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<tbody>
<tr>
<td>DUONEB 0.5 MG-3 MG/3 ML SOLN</td>
<td>IPRATROPIUM/ALBUTEROL SULFATE</td>
</tr>
<tr>
<td>SPIRIVA 18 MCG CP-HANDIHALER</td>
<td>TIOTROPIUM BROMIDE</td>
</tr>
<tr>
<td>ATROVENT HFA INHALER</td>
<td>IPRATROPIUM BROMIDE</td>
</tr>
<tr>
<td>COMBIVENT RESPIMAT INHALER</td>
<td>IPRATROPIUM/ALBUTEROL SULFATE</td>
</tr>
<tr>
<td>ANORO ELLIPTA 62.5-25 MCG INH</td>
<td>UMECLINDIUM BROMIDE/VILANTEROL TRIFENATATE</td>
</tr>
<tr>
<td>SPIRIVA RESPIMAT 1.25 MCG INH</td>
<td>TIOTROPIUM BROMIDE</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>--------------------</td>
</tr>
<tr>
<td>IPRATROPIUM BR 0.02% SOLN</td>
<td>IPRATROPIUM BROMIDE</td>
</tr>
<tr>
<td>SPIRIVA RESPIMAT INHAL SPRAY</td>
<td>TIOTROPIUM BROMIDE</td>
</tr>
</tbody>
</table>

**References**

- Evidence-Based Medicine Analysis: “Chronic Obstructive Pulmonary Disease (COPD) Anticholinergics”, UMKC-DIC; October 2021.
- USPDI, Micromedex; 2022.
- Facts and Comparisons eAnswers (online); 2022 Clinical Drug Information, LLC.