Executive Summary

**Purpose:** The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

**Why Issue Selected:** Leukotriene receptor antagonists work selectively and competitively on cysteinyl leukotriene receptors, which are components of slow-reacting substance of anaphylaxis. Leukotriene production and receptor occupation have been correlated with the pathophysiology of asthma and allergy, including airway edema, smooth muscle constriction and altered cellular activity associated with the inflammatory process. These agents are not recommended as first line therapy by the National Asthma Education and Prevention Program guidelines but instead alternatives for moderate persistent and mild persistent asthma for both pediatric and adult participants.

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>• Montelukast</td>
<td></td>
<td>• Accolate&lt;sup&gt;®&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Singulair&lt;sup&gt;®&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Zafirlukast</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Zileuton ER</td>
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<tr>
<td></td>
<td></td>
<td>• Zyflo&lt;sup&gt;®&lt;/sup&gt;</td>
</tr>
</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: Leukotriene Modifiers
- 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 **AND**
- **For montelukast:**
  - Documented compliance on current therapy regimen **OR**
  - For documented diagnosis of moderate to severe asthma:
    - Documented compliance on ICS/LABA (defined as 90/120 days) **OR**
    - Clinical Consultant Review
  - For documented diagnosis of allergies:
    - Documented compliance on a second generation antihistamine (defined as 120/150 days) **AND**
    - Documented compliance on intranasal corticosteroid (defined as 90/120 days) **OR**
    - Clinical Consultant Review
- **For documented diagnosis of eosinophilic gastroenteritis or obstructive sleep apnea/sleep disorder breathing**

Denial Criteria

- Lack of adequate trial on required preferred agents
- For Singulair (montelukast): documented diagnosis of suicide attempt
- 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 Unit/Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACCOLATE 10 MG TABLET</td>
<td>ZAFIRLUKAST</td>
<td>2 tablets</td>
</tr>
<tr>
<td>ACCOLATE 20 MG TABLET</td>
<td>ZAFIRLUKAST</td>
<td>2 tablets</td>
</tr>
<tr>
<td>SINGULAIR 4 MG GRANULES</td>
<td>MONTELUKAST</td>
<td>1 packet</td>
</tr>
<tr>
<td>SINGULAIR 4 MG CHEW</td>
<td>MONTELUKAST</td>
<td>1 tablet</td>
</tr>
<tr>
<td>SINGULAIR 5 MG CHEW</td>
<td>MONTELUKAST</td>
<td>1 tablet</td>
</tr>
<tr>
<td>SINGULAIR 10 MG TABLET</td>
<td>MONTELUKAST</td>
<td>1 tablet</td>
</tr>
<tr>
<td>ZYFLO 600 MG TABLET</td>
<td>ZILEUTON</td>
<td>4 tablets</td>
</tr>
<tr>
<td>ZYFLO CR 600 MG TABLET</td>
<td>ZILEUTON</td>
<td>4 tablets</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

- USPDI, Micromedex; 2022.
- Facts and Comparisons eAnswers (online); 2022 Clinical Drug Information, LLC.