Executive Summary

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

**Why Issue Selected:** Ulcerative colitis (UC) is a chronic, inflammatory bowel disease that affects roughly one million people in the United States. There is currently no cure for this disease state but the 2018 American Gastroenterological Association guidelines on the management of mild-to-moderate UC offer recommendations on providing symptom relief and improving quality of life through long-term remission. The treatment recommendations include the 5-amino salicyllic class of medication which consists of balsalazide, mesalamine, olsalazine and sulfasalazine which are generally indicated for the treatment of active mild-to-moderate UC and/or induction or maintenance of remission. Oral budesonide is indicated only for the induction of remission in patients with active mild-to-moderate UC as there is limited efficacy or safety data for the use of budesonide for maintenance of remission.

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>
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<tbody>
<tr>
<td>Balsalazide</td>
<td>Apriso®</td>
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<td>Lialda®</td>
<td>Asacol HD®</td>
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<tr>
<td>Pentasa®</td>
<td>Azulfidine®</td>
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<tr>
<td>Sulfasalazine DR &amp; IR</td>
<td>Azulfidine EN®</td>
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<td>Budesonide (gen Uceris®)</td>
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<td>Colazal®</td>
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<td>Delzico®</td>
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<td>Dipentum®</td>
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<td>Giazo®</td>
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<td>Mesalamine (gen Apriso®)</td>
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<td>Mesalamine (gen Delzico®)</td>
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<td>Mesalamine (gen Lialda®)</td>
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<td>Uceris®</td>
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Type of Criteria: ☒ Increased risk of ADE  ☑ Preferred Drug List
☐ Appropriate Indications  ☐ Clinical Edit

Data Sources:  ☑ Databases + Prescriber-Supplied  ☐ Only Administrative Databases

**Setting & Population**

- Drug class for review: Ulcerative Colitis Agents, Oral
- Age range: 2 years of age or older: sulfasalazine IR, sulfasalazine DR, Azulfidine®, Azulfidine EN®
- Age range: 5 years of age or older: balsalazide, Colazal®, Delzicol®, mesalamine (gen Delzicol®, gen Lialda®), Lialda®
- Age range: 18 years of age or older: Apriso®, Asacol HD®, budesonide (gen Uceris®) Dipentum ®, mesalamine (gen Apriso®, gen Asacol HD®), Pentasa®, Uceris®

**Approval Criteria**

- Participant is of appropriate age per agent (see above) AND
- Failure to achieve desired therapeutic outcomes with trial on 3 preferred agents
  - Documented trial period of preferred agents OR
  - Documented ADE/ADR to preferred agents

**Denial Criteria**

- Lack of adequate trial on required preferred agents
- Therapy will be denied if no approval criteria are 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

**References**

6. USPDI, Micromedex; 2020.
7. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.

*SmartPA PDL Proposal Form*

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