Drug/Drug Class: GI Motility Agents, Chronic, PDL Edit
First Implementation Date: April 6, 2017
Revised Date: April 2, 2020
Prepared For: MO HealthNet
Prepared By: MO HealthNet/Conduent
Criteria Status: ☒Existing Criteria
☒Revision of Existing Criteria
☐New Criteria

Executive Summary

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

Why Issue Selected: Opioid-Induced Constipation (OIC) is a common adverse effect of opioid therapy. A prophylactic bowel regimen is recommended when initiating opioid therapy. Amitiza® is indicated for OIC in adults with chronic non-cancer pain, as well as Movantik®, an opioid receptor antagonist drug. Relistor® tablets are also approved for OIC. Symproic® (also structurally related to naloxone) is the newest product to treat OIC. Relistor injection is indicated for treatment of OIC in patients with advanced illness (e.g. palliative care). Therapy with these agents is significantly more costly than with older medications.

Chronic Idiopathic Constipation (CIC) is generally defined as infrequent and difficult passage of stool. Constipation secondary to other diseases (e.g. Parkinson’s, spinal cord injury) is generally not considered CIC. FDA-indicated products Linzess®, Amitiza® and Trulance® increase fluid motility in the intestinal tract to alleviate symptoms associated with CIC.

Irritable bowel syndrome (IBS) is a functional bowel disorder that can be characterized by predominantly constipation (IBS-C) or diarrhea (IBS-D), or symptoms may be mixed (IBS-M). Drugs that are helpful for CIC are also beneficial in treating IBS-C. Amitiza is approved for treatment of IBS-C in women-only. Lotronex® and alosetron are indicated for the treatment of severe IBS-D in women-only who have failed conventional therapy. Viberzi® is an opioid receptor agonist and which is also approved to treat IBS-D.

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>• Amitiza®</td>
<td>• Alosetron</td>
</tr>
<tr>
<td>• Linzess®</td>
<td>• Lotronex®</td>
</tr>
<tr>
<td>• Movantik®</td>
<td>• Motegrity™</td>
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<tr>
<td></td>
<td>• Relistor®</td>
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<td></td>
<td>• Symprio®</td>
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<td></td>
<td>• Trulance®</td>
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<tr>
<td></td>
<td>• Viberzi®</td>
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<td></td>
<td>• Zelnorm™</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: GI Motility Agents, Chronic
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Documented compliance on a current therapy regimen OR
- For agents with diarrhea indications:
  - Therapeutic trial on at least 2 different anti-diarrheal products AND
  - For Lotronex: Documented diagnosis of IBS with diarrhea as primary bowel symptom (female)
  - For Viberzi: Documented diagnosis of IBS with severe diarrhea as primary bowel symptom
- For agents with constipation indications:
  - Therapeutic trial on at least 2 different covered laxative preparations AND
  - Failure to achieve desired therapeutic outcomes with trial on 2 or more preferred agents:
    - Documented trial period for preferred agents OR
    - Documented ADE/ADR to preferred agents AND
  - For Motegrity: Documented diagnosis of Chronic Idiopathic Constipation
  - For Movantik, Relistor, or Symprio:
    - Participant is currently on opioid therapy (1 claim in the last 45 days) AND
    - Documented diagnosis of drug induced constipation
  - For Linzess or Trulance:
    - Documented diagnosis of Chronic Idiopathic Constipation OR
    - Documented diagnosis of Irritable Bowel Syndrome with Constipation (male and female)
  - For Amitiza:
    - Documented diagnosis of Chronic Idiopathic Constipation OR
    - Documented diagnosis of Irritable Bowel Syndrome with Constipation (female) OR
    - Documented diagnosis of Opioid-Induced Constipation in adults with chronic non-cancer pain AND participant is currently on opioid therapy (1 claim in the last 45 days)
  - For Zelnorm:
    - Documented diagnosis of Irritable Bowel Syndrome with Constipation (female) AND
    - Participant aged < 65 years
Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if no approval criteria are met
- For Lotronex: dosing exceeds 2 tablets per day

Required Documentation

<table>
<thead>
<tr>
<th>Laboratory Results:</th>
<th>Progress Notes:</th>
<th>Other:</th>
</tr>
</thead>
</table>

Disposition of Edit

Denial: Exception Code “0160” (Preferred Drug List Edit)
Rule Type: PDL

Default Approval Period

1 year

References

5. USPDI, Micromedex; 2019.
6. Drug Facts and Comparisons On-line; 2019