**Chronic GI Motility Agents**

**WA.PHAR.47 Chronic GI Motility Agents**

**Background:**
Chronic constipation is infrequent bowel movements or difficulty passage of stools that persist for several weeks or longer. There are many possible causes such as blockage in the colon or rectum, problems with nerves around the colon or rectum, and difficulty with the muscles involved in elimination.

Symptoms of diarrhea may consist of loose, water, bowel movements that are more frequent, greater volume of stool, and abdominal cramps. The multiple causes of chronic diarrhea include celiac disease, colon cancer, Crohn’s disease, inflammatory bowel disease (IBD), irritable bowel syndrome (IBS), and ulcerative colitis.

**Medical necessity**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alosetron (LOTRONEX®) Eluxadoline (VIBERZI™)</td>
<td>Lotronex, Viberzi may be considered medically necessary when used to treat irritative bowel syndrome with diarrhea (IBS-D)</td>
</tr>
<tr>
<td>Linaclotide (LINZESS®) Lubiprostone (AMITIZA®) Pelcanatide (TRULANCE™)</td>
<td>Linzess, Amitiza, Trulance may be considered medically necessary when used to treat irritative bowel syndrome with constipation (IBS-C), chronic idiopathic constipation, or advanced illness (or terminal illness) when receiving palliative care.</td>
</tr>
<tr>
<td>Lubiprostone (AMITIZA®) Methylaltrexone (RELISTOR®) Naldemadine (SYMPROIC®) Naloxegol (MOVANTIK®)</td>
<td>Amitiza, Relistor, Symproic, Movantik may be considered medically necessary when used to treat opioid-induced constipation for non-cancer pain.</td>
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</table>

**Clinical policy:**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Clinical Criteria (Initial Approval)</th>
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</table>
| Alosetron (LOTRONEX®) Eluxadoline (VIBERZI™) | Lotronex, and Viberzi may be covered when ALL of the following are met:  
1. Diagnosis of severe irritative bowel syndrome with diarrhea (IBS-D)  
2. Known or suspected GI obstruction has been ruled out  
3. Greater than or equal to (≥) ONE of the following:  
   a. Frequent and severe abdominal pain/discomfort  
   b. Frequent bowel urgency or fecal incontinence  
   c. Disability or restriction of daily activities due to IBS-D  
4. History of failure, contraindication or intolerance to ≥ 2 week trial of TWO of the following conventional therapies:  
   a. Antidiarrheal (e.g. loperamide)  
   b. Antispasmodics (e.g. dicyclomine, hyoscyamine)  
   c. Antibiotics  
   d. Antidepressants (e.g. amitriptyline, sertraline)  
   e. Bile acid sequestrants (e.g. cholestyramine, colestipol) |
<table>
<thead>
<tr>
<th>Medications</th>
<th>Criteria</th>
</tr>
</thead>
</table>
| Linaclotide (LINZESS®), Lubiprostone (AMITIZA®), Pelcanatide (TRULANCE™) | Linzess, Amitiza, and Trulance may be covered when ALL of the following are met:  
1. Diagnosis of ONE of the following:  
   a. Irritable bowel syndrome with constipation (IBS-C)  
   b. Chronic idiopathic constipation (CIC)  
   c. Advanced illness (or terminal illness) receiving palliative care  
2. History of failure, contraindication or intolerance to ≥ 2 week trial of TWO of the following conventional therapies:  
   a. Bulk-forming laxative (e.g. psyllium)  
   b. Stool softener (e.g. docusate sodium)  
   c. Osmolar agents (e.g. lactulose)  
   d. Stimulant laxative (e.g. sennoside)  
   e. Polyethylene glycol (e.g. Miralax)  
3. Known or suspected GI obstruction has been ruled out  
4. Greater than or equal to (≥) 18 years of age  
5. Attestation that provider confirms the patient does not have a history of any contraindications for these drugs.  

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<table>
<thead>
<tr>
<th>Medications</th>
<th>Criteria</th>
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</table>
| Lubiprostone (AMITIZA®), Methylnaltrexone (RELISTOR®), Naldemadine (SYMPROIC®), Naloxegol (MOVANTIK®) | Amitiza, Relistor, Symproic, Movantik may be covered when ALL of the following are met:  
1. Diagnosis of Opioid-Induced constipation (OIC) with chronic non-cancer pain  
2. History of failure, contraindication or intolerance to ≥ 2 week trial of TWO of the following conventional therapies:  
   a. Bulk-forming laxative (e.g. psyllium)  
   b. Stool softener (e.g. docusate sodium)  
   c. Osmolar agents (e.g. lactulose)  
   d. Stimulant laxative (e.g. sennoside)  
   e. Polyethylene glycol (e.g. Miralax)  
3. Known or suspected GI obstruction has been ruled out  
4. Greater than or equal to (≥) 18 years of age  
5. Attestation that provider confirms the patient does not have a history of any contraindications for these drugs.  

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Criteria (Reauthorization)  
Documentation of positive clinical symptomatic improvement to therapy  

Approve for 12 months
Dosage and quantity limits

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dose and Quantity Limits</th>
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<tbody>
<tr>
<td>Eluxadoline (VIBERZI™)</td>
<td>200mg per day; 60 tablets per 30-day supply</td>
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<tr>
<td>Naloxegol (MOVANTIK®)</td>
<td>25mg per day; 30 capsules per 30-day supply</td>
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<tr>
<td>Naldemadine (SYMPROIC®)</td>
<td>1 tablet (0.2mg) per day; #30 for 30-day supply</td>
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<tr>
<td>Methylnalbetrone (RELISTOR®)</td>
<td>Oral: 150mg tablet; #90 tablets per 30-day supply</td>
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<td>Injection: 12mg vial/syringe; #30 vials/syringe per 30-day supply</td>
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<td></td>
<td>8mg syringe; #30 syringes per 30-day supply</td>
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<tr>
<td>Lubiprostone (AMITIZA®)</td>
<td>CIC/OIC: 48mcg per day; 60 capsules per 30-day supply</td>
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<td>IBS-C: 16mcg per day; 60 capsules per 30-day supply</td>
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<tr>
<td>Alosetron (LOTRONEX®)</td>
<td>2mg per day; 60 tablets per 30-day supply</td>
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<tr>
<td>Linaclotide (LINZESS®)</td>
<td>CIC: 145mcg per day; 30 capsules per 30-day supply</td>
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<td>IBS-C: 290mcg per day; 30 capsules per 30-day supply</td>
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<tr>
<td>Pelcanatide (TRULANCE™)</td>
<td>CIC: 3mg per day; 30 tablets per 30-day supply</td>
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<td>IBS-C: 3mg per day; 30 tablets per 30-day supply</td>
</tr>
</tbody>
</table>

References

2. Product Information: MOVANTIK® oral tablets, naloxegol oral tablets. AstraZeneca Pharmaceuticals LP (per FDA), Wilmington, DE, 2016
6. Product Information: LINZESS® oral capsules, linaclotide oral capsules. Allergan USA Inc (per manufacturer), Irvine, CA, 2017
7. Product Information: TRULANCE™ oral tablets, plecanatide oral tablets. Synergy Pharmaceuticals Inc (per manufacturer), New York, NY, 2017