



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

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

Clinical policy:

Drug	Clinical Criteria (Initial Approval)
Alosetron (LOTROXEX ®) Eluxadoline (VIBERZI ™)	Lotronex, and Viberzi may be covered when ALL of the following are met: 1. Diagnosis of severe irritable 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)

	<p>5. Greater than or equal to (\geq) 18 years of age</p> <p>6. Attestation that provider confirms the patient does not have a history of any contraindications for these drugs.</p> <p>Approve for 12 months</p>
<p>Linaclotide (LINZESS[®]) Lubiprostone (AMITIZA[®]) Pelcanatide (TRULANCE[™])</p>	<p>Linzess, Amitiza, and Trulance may be covered when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. Diagnosis of ONE of the following: <ol style="list-style-type: none"> a. Irritable bowel syndrome with constipation (IBS-C) a. Chronic idiopathic constipation (CIC) b. Advanced illness (or terminal illness) receiving palliative care 2. History of failure, contraindication or intolerance to \geq 2 week trial of TWO of the following conventional therapies: <ol style="list-style-type: none"> 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 (\geq) 18 years of age 5. Attestation that provider confirms the patient does not have a history of any contraindications for these drugs. <p>Approve for 12 months</p>
<p>Lubiprostone (AMITIZA[®]) Methylnaltrexone (RELISTOR[®]) Naldemadine (SYMPROIC[®]) Naloxegol (MOVANTIK[®])</p>	<p>Amitiza, Relistor, Symproic, Movantik may be covered when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. Diagnosis of Opioid-Induced constipation (OIC) with chronic non-cancer pain 2. History of failure, contraindication or intolerance to \geq 2 week trial of TWO of the following conventional therapies: <ol style="list-style-type: none"> 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 (\geq) 18 years of age 5. Attestation that provider confirms the patient does not have a history of any contraindications for these drugs. <p>Approve for 12 months</p> <p>Criteria (Reauthorization)</p> <p>Documentation of positive clinical symptomatic improvement to therapy</p> <p>Approve for 12 months</p>

Dosage and quantity limits

Drug Name	Dose and Quantity Limits
Eluxadoline (VIBERZI™)	200mg per day; 60 tablets per 30-day supply
Naloxegol (MOVANTIK®)	25mg per day; 30 capsules per 30-day supply
Naldemadine (SYMPROIC®)	1 tablet (0.2mg) per day; #30 for 30-day supply
Methylnaltrexone (RELISTOR®)	Oral: <ul style="list-style-type: none"> 150mg tablet; #90 tablets per 30-day supply Injection: <ul style="list-style-type: none"> 12mg vial/syringe; #30 vials/syringe per 30-day supply 8mg syringe; #30 syringes per 30-day supply
Lubiprostone (AMITIZA®)	CIC/OIC: 48mcg per day; 60 capsules per 30-day supply IBS-C: 16mcg per day; 60 capsules per 30-day supply
Alosetron (LOTRONEX®)	2mg per day; 60 tablets per 30-day supply
Linaclotide (LINZESS®)	CIC: 145mcg per day; 30 capsules per 30-day supply IBS-C: 290mcg per day; 30 capsules per 30-day supply
Pelcanatide (TRULANCE™)	CIC: 3mg per day; 30 tablets per 30-day supply IBS-C: 3mg per day; 30 tablets per 30-day supply

References

1. Product Information: VIBERZI™ oral tablets, eluxadoline oral tablets. Allergan USA, Inc (per FDA), Irvine, CA, 2017.
2. Product Information: MOVANTIK® oral tablets, naloxegol oral tablets. AstraZeneca Pharmaceuticals LP (per FDA), Wilmington, DE, 2016
3. Product Information: RELISTOR® oral tablets, subcutaneous injection, methylnaltrexone bromide oral tablets, subcutaneous injection. Salix Pharmaceuticals (per FDA), Bridgewater, NJ, 2016
4. Product Information: AMITIZA® oral capsules, lubiprostone oral capsules. Sucampo Pharma Americas, LLC and Takeda Pharmaceuticals America, Inc. (per Manufacturer), Rockville, MD, 2016.
5. Product Information: LOTRONEX® oral tablets, alosetron HCl oral tablets. Prometheus Laboratories Inc. (per FDA), San Diego, CA, 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
8. Micromedex® 2.0, (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: <http://www.micromedexsolutions.com/> (cited: 01/31/2018).
9. Product Information: SYMPROIC® oral tablets, naldemedine oral tablets. Shionogi Inc (per manufacturer), Florham Park, NJ, 2017.