Pharmacy Medical Necessity Guidelines: Gastrointestinal Medications

Effective: May 13, 2025

Prior Authorization Required		√	Type of Review – Care Management	
Not Covered			Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit		RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan			**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

- **Amitiza (lubiprostone)** is indicated for the treatment of chronic idiopathic constipation in adults, irritable bowel syndrome with constipation in women ≥18 years of age, and opioid-induced constipation (OIC) in adults with chronic, non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation (note: effectiveness of Amitiza in the treatment of OIC in patients taking diphenylheptane opioids [e.g., methadone] has not been established).
- **Ibsrela (tenapanor)** is a sodium/hydrogen exchange 3 (NHE3) inhibitor indicated for the treatment of irritable bowel syndrome with constipation in adults.
- **Linzess (linaclotide)** is indicated in adults for the treatment of chronic idiopathic constipation and for the treatment of irritable bowel syndrome with constipation. It is also indicated for the treatment of functional constipation in patients 6 to 17 years of age.
- **Motegrity (prucalopride)** is a serotonin-4 receptor agonist indicated for the treatment of chronic idiopathic constipation in adults.
- **Movantik (naloxegol)** is an opioid antagonist indicated for the treatment of OIC in adult patients with chronic non-cancer pain, including patient with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation.
- **Symproic (naldemidine)** is an opioid antagonist indicated for the treatment of OIC in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation.
- **Viberzi (eluxadoline)** is a mu-opioid receptor agonist indicated in adults for the treatment of irritable bowel syndrome with diarrhea (IBS-D).
- **Relistor (melthylnaltrexone)** is an opioid antagonist available in injectable (pre-filled syringe and single-dose vial) and oral dosage forms. Relistor injections and tablets are approved for the treatment of OIC in adults with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation. Additionally, Relistor injection is indicated for the treatment of OIC in adults with advanced illness or pain caused by active cancer who require opioid dosage escalation for palliative care. In clinical trials, many patients with non-cancer pain had one of the following: back pain, joint/extremity pain, fibromyalgia, neurologic/neuropathic pain, and rheumatoid arthritis. Many patients with advanced illness had one of the following: incurable cancer, end-stage COPD/emphysema, cardiovascular disease/heart failure, Alzheimer's disease/dementia, HIV/AIDS, or other advanced illnesses.

COVERAGE GUIDELINES

The plan may authorize coverage of a non-preferred gastrointestinal medication for Members when **ALL** the following criteria are met:

Lubiprostone (Amitiza)

1. Documented diagnosis of one of the following:
   a. Chronic idiopathic constipation (CIC)
   b. Opioid-induced constipation (OIC) and member is not taking methadone
   c. Irritable bowel syndrome with constipation (IBS-C)

AND

2. The Member is 18 years of age or older

AND

3. The Member has had an inadequate response or adverse reaction to at least one medication from at least **two** of the following therapeutic classes, or contraindication to all agents in all of the following therapeutic classes:
   a. Fiber (such as methylcellulose, psyllium, etc)
   b. Hyperosmotic (such as lactulose, glycerin suppositories, polyethylene glycol, etc.)
   c. Stimulant Laxatives (such as Cascara, Senna, Bisacodyl, etc.)
   d. Saline laxatives (such as magnesium citrate, magnesium hydroxide, sodium phosphate)

Linzess (linaclotide)

IBS or CIC

1. Documented diagnosis of irritable bowel syndrome with constipation (IBS-C) or chronic idiopathic constipation (CIC)

AND

2. The Member is 18 years of age or older

AND

3. The Member has had an inadequate response or adverse reaction to at least one generic medication from at least **two** of the following therapeutic classes, or contraindication to all agents in all of the following therapeutic classes:
   a. Fiber (such as Methylcellulose, Psyllium, etc)
   b. Hyperosmotic (such as Lactulose, Glycerin Suppositories, Polyethylene Glycol, etc.)
   c. Stimulant Laxatives (such as Cascara, Senna, Bisacodyl, etc.)
   d. Saline laxatives (such as magnesium citrate, magnesium hydroxide, sodium phosphate)

Functional Constipation

1. Documented diagnosis of functional constipation

AND

2. The Member is 6 to 17 years of age

AND

3. Documentation the Member has had an inadequate response or adverse reaction to at least two generic laxatives or clinical rationale why other laxatives are not appropriate for the member. Examples include polyethylene glycol, lactulose, and bisacodyl

Ibsrela (tenapanor)

1. Documented diagnosis of irritable bowel syndrome with constipation (IBS-C)

AND

2. The Member is 18 years of age or older

AND

3. The Member has had an inadequate response or adverse reaction to at least one generic medication from at least **two** of the following therapeutic classes, or contraindication to all agents in all of the following therapeutic classes:
   a. Fiber (such as Methylcellulose, Psyllium, etc)
   b. Hyperosmotic (such as Lactulose, Glycerin Suppositories, Polyethylene Glycol, etc.)
   c. Stimulant Laxatives (such as Cascara, Senna, Bisacodyl, etc.)
   d. Saline laxatives (such as magnesium citrate, magnesium hydroxide, sodium phosphate)

Motegrity (prucalopride)

1. The Member has a diagnosis of chronic idiopathic constipation (CIC)

AND

2. The Member is 18 years of age or older

AND

3. The Member has had an inadequate response or adverse reaction to at least one generic medication from at least **two** of the following therapeutic classes, or contraindication to all agents in all of the following therapeutic classes:
   a. Fiber (such as Methylcellulose, Psyllium, etc)
   b. Hyperosmotic (such as Lactulose, Glycerin Suppositories, Polyethylene Glycol, etc.)
   c. Stimulant Laxatives (such as Cascara, Senna, Bisacodyl, etc.)
   d. Saline laxatives (such as magnesium citrate, magnesium hydroxide, sodium phosphate)

AND

4. The Member had an inadequate response, intolerance, or contraindication to lubiprostone (Amitiza)

Movantik (naloxegol) and Symproic (naldemidine)

1. The Member is diagnosed with opioid-induced constipation

AND

2. The Member is 18 years of age or older

AND

3. The Member had an inadequate response or adverse reaction to at least **one** agent from at least two of the following therapeutic classes, or contraindication to all agents in all of the following therapeutic classes:
   a. Osmotic Laxative (e.g., Lactulose, Glycerin Suppositories, Polyethylene Glycol, etc.)
   b. Stimulant Laxative (e.g., Cascara, Senna, Bisacodyl, etc.)
   c. Saline laxatives (e.g., magnesium citrate, magnesium hydroxide, sodium phosphate)
   d. Fiber laxatives (e.g., psyllium, methylcellulose, calcium polycarbophil)

AND

4. The Member had an inadequate response, adverse reaction, or contraindication to lubiprostone (Amitiza)

Relistor® Tablets and Injection

Initial Criteria

1. The Member is diagnosed with chronic non-cancer pain (such as back pain, arthritis, neurologic/neuropathic pain, joint/extremity pain, rheumatoid arthritis, fibromyalgia or chronic pain related to prior cancer or its treatment and does not require frequent [e.g., weekly] opioid dosage escalation)

OR

The Member is diagnosed with advanced illness requiring palliative therapy (such as incurable cancer, end-stage COPD/emphysema, cardiovascular disease/heart failure, Alzheimer's disease/dementia, HIV/AIDS, or other end-stage life-threatening disease) **(Relistor® injection only)**

AND

2. The Member is 18 years of age or older

AND

3. Member has been taking an opioid analgesic for at least 4 weeks immediately prior to the Relistor® request

AND

4. Diagnosis of opioid-induced constipation (OIC)

AND

5. The Member has had an inadequate response or adverse reaction to at least one medication from at least **two** of the following classes of laxatives, or contraindication to all agents in all of the following therapeutic classes:

   a. Saline laxatives (e.g., magnesium citrate, magnesium hydroxide sodium phosphate)
   b. Hyperosmotic laxatives (e.g., lactulose, glycerin suppositories, polyethylene glycol)
   c. Stimulant laxatives (e.g., senna, bisacodyl)
   d. Fiber laxatives (e.g., psyllium, methylcellulose, calcium polycarbophil)

AND

6. For the diagnosis of chronic non-cancer pain (including chronic pain related to prior cancer or its treatment who do not require frequent [e.g., weekly] opioid dosage escalation) only: Member has had an inadequate response, intolerance, or contraindication to Movantik™ (naloxegol) AND Amitiza (lubiprostone)

Renewal Criteria

1. Documentation that Member continues to take chronic opioids for chronic non-cancer pain, chronic pain related to prior cancer or its treatment that does not require frequent (e.g., weekly) opioid dosage escalation, or advanced illness requiring palliative therapy (**Relistor® injection only)**

AND

2. Documentation of improvement of opioid-induced constipation while taking Relistor®

Viberzi (eluxadoline)

1. Documented diagnosis of irritable bowel syndrome with diarrhea

AND

2. The member is 18 years of age or older

AND

3. Member has had an inadequate response or adverse reaction to at least **one** generic medication from at least **two** of the following therapeutic classes, or contraindication to all agents in all of the following therapeutic classes:
   a. **Anti-diarrheal medications:** loperamide, diphenoxylate/atropine
   b. **Anti-spasmodic medications:** dicyclomine
   c. **Tricyclic antidepressants:** desipramine, imipramine, amitriptyline

LIMITATIONS

1. Approval of Relistor is limited to one year.
2. Requests for brand-name products, which have AB-rated generics, will be reviewed according to Brand Name criteria.
3. The following quantity limits apply:

Medication Name	Quantity Limit
Lubiprostone capsule	2 capsules per day
Linzess tablet	1 tablet per day
Motegrity tablet	1 tablet per day

CODES

None

REFERENCES

1. Amitiza (lubiprostone) [prescribing information]. Bedminster, NJ: Sucampo Pharma Americas, LLC; November 2020.
2. Ibsrela (tenapanor) [prescribing information]. Waltham, MA: Ardelyx, Inc; April 2022.
3. Linzess (linaclotide) [prescribing Information]. North Chicago, IL: AbbVie, Inc; June 2023.
4. Motegrity (prucalopride) [prescribing information]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; November 2020.
5. Movantik (naloxegol) [prescribing information]. Chicago, IL: Valinor Pharma, LLC; March 2023.
6. Relistor [package insert]. Bridgewater, NJ: Salix Pharmaceuticals; April 2020.
7. Symproic (naldemidine) [prescribing information]. Raleigh, NC: BioDelivery Sciences International, Inc; July 2021.
8. Wald A. Treatment of irritable bowel syndrome in adults. Available at: www.uptodate.com. Accessed 18 April 2024.
9. Viberzi (eluxadoline) [prescribing information]. Madison, NJ: Allergan; June 2020.

APPROVAL HISTORY

September 13, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. December 13, 2022: Effective March 1, 2023, updated Viberzi criteria to remove hyoscyamine as a prerequisite treatment option.
2. July 11, 2023: Effective August 1, 2023, updated Linzess criteria to include the supplemental indication of functional constipation in children 6 to 17 years of age. Updated lubiprostone criteria to remove female gender requirement for IBS-C. Added the following language to the limitations section of the MNG: "requests for brand-name products, which have AB-rated generics, will be reviewed according to Brand Name criteria."
3. May 14, 2024: Effective August 1, 2024, updated RxUM fax number. Updated the previous trial language throughout the MNG.
4. May 13, 2025: No changes

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services