Pharmacy Medical Necessity Guidelines: Gastrointestinal Medications

Effective: January 1, 2021

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:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
• CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

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 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 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.
- Motegrity (prucalopride) is a serotonin-4 receptor agonist indicated for the treatment of chronic idiopathic constipation in adults. Motegrity is contraindicated in patients with intestinal perforation or obstruction due to structural or functional disorder of the gut wall, obstructive ileus, severe inflammatory conditions of the intestinal tract such as Crohn's disease, ulcerative colitis, and toxic megacolon/megarectum.
- Movantik (naloxegol) is an opioid antagonist indicated for the treatment of opioid-induced constipation (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 opioid-induced constipation (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 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. Additionally, Relistor® injection is indicated for the treatment of OIC in adults with advanced illness who are receiving 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.
  Use of Relistor® injections beyond four months of treatment has not been studied in the advanced illness population.

COVERAGE GUIDELINES

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

Amitiza (lubiprostone)

1. Documented diagnosis of one of the following:
   a. Chronic idiopathic constipation
   b. Opioid-induced constipation and member is not taking methadone
   c. Female Member with irritable bowel syndrome with constipation

AND

2. The Member is 18 years of age or older

AND

3. The Member tried and failed therapy with at least **two** 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)

1. Documented diagnosis of irritable bowel syndrome with constipation or chronic idiopathic constipation

AND

2. The Member is 18 years of age or older

AND

3. The Member tried and failed therapy with at least **two** 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)

Isbrela (tenapanor)

1. Documented diagnosis of irritable bowel syndrome with constipation

AND

2. The Member is 18 years of age or older

AND

3. The Member tried and failed therapy with at least **two** 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 tried and failed therapy with at least one generic medication from at least **two** 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)

Movantik (naloxegol) and Symproic (naldemidine)

1. The Member is diagnosed with opioid-induced constipation

AND

2. The Member had an inadequate response or intolerance to at least one agent from at least two of the following classes of laxatives:
   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

3. The Member had an inadequate response, intolerance, or contraindication to 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. Member has been taking an opioid analgesic for at least 4 weeks immediately prior to the Relistor® request

AND

3. Diagnosis of opioid-induced constipation (OIC)

AND

4. The Member has had an inadequate response, intolerance, or contraindication to at least one medication from at least two of the following classes of laxatives:
   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

5. **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 intolerance to at least **one** generic medication from at least **two** of the following therapeutic classes:
   a. **Anti-diarrheal medications:** loperamide, diphenoxylate/atropine
   b. **Anti-spasmodic medications:** dicyclomine, hyoscyamine
   c. **Tricyclic antidepressants:** desipramine, imipramine, amitriptyline

LIMITATIONS

1. Approval of Relistor is limited to one year.
2. The following quantity limits apply:

Medication Name	Quantity Limit
Amitiza capsule	2 capsules per day
Linzess tablet	1 tablet per day
Motegrity tablet	1 tablet per day
Relistor 8 and 12 mg prefilled syringes	1 prefilled syringe per day
Relistor 12 mg vial	1 vial per day
Relistor 150 mg tablet	3 tablets per day

CODES

None

REFERENCES

1. Amitiza (lubiprostone) [prescribing information]. Bedminster, NJ: Sucampo Pharma Americas, LLC; October 2018.
2. Isbrela (tenapanor) [prescribing information]. Fremont, CA: Ardelyx, Inc; September 2019.
3. Linzess (linaclotide) [prescribing Information]. Madison, NJ: Allergan; October 2018.
4. Motegrity (prucalopride) [prescribing information]. Lexington, MA: Shire US Inc.; December 2018.
5. Movantik (naloxegol) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals; May 2019.
6. Relistor [package insert]. Bridgewater, NJ: Salix Pharmaceuticals; November 2018.
7. Symproic (naldemidine) [prescribing information]. Raleigh, NC: BioDelivery Sciences International, Inc; April 2019.
8. Viberzi (eluxadoline) [prescribing information]. Irvine, CA: Allergan; June 2018.

APPROVAL HISTORY

Movantik:

July 14, 2015: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. September 16, 2015: Approval duration modified to life of plan.
2. January 1, 2016: Administrative change to rebranded template.
3. August 9, 2016: No changes
4. April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
5. August 8, 2017: No changes.
6. October 18, 2018: Administrative changes made to template.
7. February 12, 2019: Updated criteria to include saline laxatives and fiber laxatives as previous trial options.
8. January 14, 2020: No changes.
9. September 15, 2020: Effective 1/1/2021, MNG is retired. Movantik criteria being added to "Gastrointestinal Medications" MNG.

Relistor:

July 8, 2014: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. September 13, 2016: Defined "advanced illness requiring palliative therapy". Added approval criteria for the indication of chronic non-cancer pain. Defined opioid-induced constipation as having taken opioids for at least four weeks immediately prior to the request. Added fiber laxatives as a class of laxatives may have tried and failed. For the diagnosis of chronic non-cancer pain, included trial and failure of Amitiza and Movantik™.
2. October 18, 2016: Added Relistor® tablets to criteria.
3. May 9, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
4. December 12, 2017: Decreased the number of classes of laxatives that must be trialed from three to two.
5. December 11, 2018: Updated the definition of chronic non-cancer pain. Administrative changes made to template.
6. April 9, 2019: Updated the renewal criteria to include diagnosis of chronic pain related to prior cancer or its treatment that does not require frequent (e.g., weekly) opioid dosage escalation.
7. April 14, 2020: Effective 4/20/20, updated the criteria for chronic non-cancer pain and advanced illness.

Symproic:

February 13, 2018: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
1. February 12, 2019: Administrative changes made to template.
2. January 14, 2020: No changes.
3. September 15, 2020: Effective 1/1/2021, MNG is retired. Adding Symproic to "Gastrointestinal Medications" MNG.

Gastrointestinal Medications:

April 14, 2015: Reviewed by Pharmacy & Therapeutics Committee; new consolidated criteria; modified duration approval for 2 years. Subsequent endorsement date(s) and changes made:

Subsequent endorsement date(s) and changes made:
1. September 16, 2015: Approval duration approved for life of plan
2. January 1, 2016: Administrative change to rebranded template.
3. July 12, 2016: Removed the Lotronex prior authorization criteria from the guideline.
4. May 9, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether. Added criteria for Viberzi.
5. July 11, 2017: Updated approvable diagnosis for Viberzi.
6. October 16, 2018: Effective 1/1/19, removed criteria for Giazo to reflect Not Covered status. Effective 10/22/18, updated diagnosis information for Amitiza. Administrative update to template.
7. December 11, 2018: Effective 1/1/19, updated generic Lialda criteria to remove Dipentum as a trial option and updated the mesalamine product examples.
8. August 13, 2019: Added Motegrity (prucalopride) to the Medical Necessity Guideline
9. September 10, 2019: Removed generic Lialda from the MNG, as it is now covered.
10. June 9, 2020: Added criteria for Isbrela to the MNG.
11. September 15, 2020: Effective January 1, 2021, consolidated MNGs to include Movantik, Symproic, and Relistor. Updated Movantik and Symproic criteria to require trial with Amitiza for the treatment of opioid-induced constipation. Updated criteria for Amitiza, Linzess, Isbrela, and Motegrity to include saline laxatives as a previous trial option. Updated Amitiza to clarify for the diagnosis of opioid induced-constipation that the member is not taking methadone.

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.