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 a chloride channel activator indicated for the treatment of:
- chronic idiopathic constipation (CIC) in adults.
- 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 (note: effectiveness of Amitiza in the treatment of OIC in patients taking diphenylheptane opioids [e.g., methadone] has not been established).
- irritable bowel syndrome with constipation (IBS-C) in women ≥ 18 years old.

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.

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.

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.

COVERAGE GUIDELINES

The plan may authorize coverage of a nonpreferred gastrointestinal medication for Members when the following criteria for a particular regimen are met and limitations do not apply:

Amitiza (lubiprostone)

1. Member has a documented diagnosis of one of the following:
   a. irritable bowel syndrome with constipation (IBS-C)

b. chronic idiopathic constipation (CIC)
c. opioid-induced constipation (OIC) and member is not taking methadone

AND

2. The Member is 18 years of age or older

AND

3. The Member tried and failed therapy with at least **one** agent from at least two of the following therapeutic classes:
   a. Fiber (such as methylcellulose, psyllium, etc)
   b. Hyperosmotic laxative (such as lactulose, glycerin suppositories, polyethylene glycol, etc.)
   c. Stimulant laxative (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 has had an inadequate response, intolerance, or contraindication to Amitiza

Relistor (methylnaltrexone) 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 AND Amitiza

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

LIMITATIONS

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

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

CODES

None

REFERENCES

1. Amitiza (lubiprostone) [prescribing information]. Bedminster, NJ: Sucampo Pharma Americas, LLC; October 2019.
2. Movantik (naloxegol) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals; April 2020.
3. Relistor (methylnaltrexone) [prescribing information]. Bridgewater, NJ: Salix Pharmaceuticals; April 2020.
4. Symproic (naldemidine) [prescribing information]. Raleigh, NC: BioDelivery Services International, Inc; May 2020.

APPROVAL HISTORY

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, Adding Tufts Health RITogether to the template.
4. December 12, 2017: Decreased the number of classes of laxatives that must be trialed from three to two.
5. December 11, 2018: Removed Amitiza from the list of medications that must be used for the treatment of opioid-induced constipation. 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.
8. September 15, 2020: Effective 1/1/21, MNG is retired. Criteria for Relistor are being added to the Gastrointestinal Medications MNG.

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, adding Tufts Health RITogether to the template.
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 1/1/21, MNG is retired. Criteria for Movantik are being added to the Gastrointestinal Medications MNG.

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.

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, Adding Tufts Health RITogether to the template.
5. July 11, 2017: No changes.
6. September 18, 2018: Effective 1/1/19, removed criteria for Amitiza, Giazo, and Linzess to reflect Not Covered status. Added criteria for Trulance. Updated trial options for generic Lialda.
7. December 11, 2018: Updated criteria for mesalamine 1.2 gram to include Apriso HD in the list of medications that can be trialed. Administrative changes made to template.
8. September 10, 2019: Removed criteria for generic Lialda, as it is covered effective 10/1/19. Renamed MNG "Trulance."
9. August 11, 2020: No changes.
10. September 15, 2020: Effective 1/1/21, updated title of MNG from "Trulance" to "Gastrointestinal Medications." Updated MNG to reflect that Trulance is Not Covered. Added approval criteria for Amitiza. Added criteria for Movantik, Relistor, and Symproic to the MNG. Updated Movantik, Relistor, and Symproic criteria to require trial and failure with Amitiza.

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.