TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: Gastrointestinal Medications

Effective: June 15, 2020

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[SM] – 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.
- 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. Motegrity is available in 1 mg and 2 mg tablets. The adult dose is 2 mg once daily, and the dose for patients with severe renal impairment (creatinine clearance < 30 mL/minute) is 1 mg once daily.
- Viberzi (eluxadoline) is a mu-opioid receptor agonist indicated in adults for the treatment of irritable bowel syndrome with diarrhea (IBS-D).

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 due to chronic, non-cancer pain or chronic pain related to prior cancer or its treatment that does not require frequent (e.g., weekly) opioid dosage escalation)
   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.)

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.)

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.)

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.)

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. The coverage of Linzess is limited to one tablet per day.
2. The coverage of Amitiza is limited to two tablets per day.
3. The coverage of Motegrity is limited to one tablet 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. Viberzi (eluxadoline) [prescribing information]. Irvine, CA: Allergan; June 2018.

APPROVAL HISTORY

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.

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