

Generic Name: N/A

Therapeutic Class or Brand Name: N/A

Applicable Drugs (if Therapeutic Class): Amitiza (lubiprostone), Ibsrela® (tenapanor), Linzess®* (linaclotide), Motegrity® (prucalopride), Movantik® (naloxegol), Relistor® (methylnaltrexone bromide), Symproic® (naldemedine), Trulance® (plecanatide)

Preferred: generic lubiprostone

Non-preferred: Amitiza (lubiprostone), Ibsrela (tenapanor), Linzess* (linaclotide), Motegrity (prucalopride), Movantik (naloxegol), Relistor (methylnaltrexone bromide), Symproic (naldemedine), Trulance (plecanatide)

Date of Origin: 2/2/2024

Date Last Reviewed / Revised: 2/7/2024

*Linzess is preferred and does not require prior authorization on the Premium Plus formulary.

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through III are met)

- I. Documented diagnosis of one of the following A through D AND must meet all criteria listed under applicable diagnosis:
 - A. Chronic idiopathic constipation (CIC) with symptoms lasting at least 3 months in duration
 1. Documented treatment failure or contraindication to polyethylene glycol (PEG).
 2. Documented treatment failure or contraindication to a stimulant laxative (eg, bisacodyl, sennosides).
 3. Minimum age requirement: 18 years old
 - B. Functional constipation (FC)
 1. Documented treatment failure or contraindication to polyethylene glycol (PEG).
 2. Request is for Linzess 72 mcg.
 3. Age requirement: 6 to 17 years old
 - C. Irritable bowel syndrome with constipation (IBS-C)
 1. Documented treatment failure or contraindication to polyethylene glycol (PEG).
 2. Minimum age requirement: 18 years old
 - D. Opioid-induced constipation (OIC)
 1. Documentation of one of the following a or b:
 - a) Chronic pain requiring scheduled opioid use for at least 4 weeks.
 - b) Advanced illness or pain caused by active cancer requiring opioid dosage escalation for palliative care.
 - (1) Request is for Relistor injection.

2. Documented treatment failure or contraindication to at least 2 types of laxatives used in combination, at least one of which is scheduled daily, from each of the following classes a and b:
 - a) Osmotic laxative (eg, lactulose, PEG 3350)
 - b) Stimulant laxative (eg, bisacodyl and sennosides)
 3. Minimum age requirement: 18 years old
- II. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines. Refer to Table 1 for FDA-approved indications.
- III. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Patients with known or suspected gastrointestinal obstruction or risk of recurrent obstruction.
- Treatment of OIC for patients with infrequent or as-needed use of opioids.

OTHER CRITERIA

- Amitiza is contraindicated in patients taking diphenylheptane opioids (eg, methadone).
- 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.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Amitiza: CIC: Sixty 24 mcg capsules per 30 days
 IBS-C: Sixty 8 mcg capsules per 30 days
 OIC: Sixty 24 mcg capsules per 30 days
- lbsrela: 60 tablets per 30 days
- Linzess: CIC: thirty 72 mcg or 145 mcg capsules per 30 days
 IBS-C: thirty 290 mcg capsules per 30 days
 FC: thirty 72 mcg capsules per 30 days
- Motegrity: 30 tablets per 30 days
- Movantik: 30 tablets per 30 days
- Relistor: OIC for patients with chronic non-cancer pain: 90 tablets per 30 days.
 OIC for patients with advanced illness or active cancer pain: 30 prefilled syringes per 30 days

- Symproic: 30 tablets per 30 days
- Trulance: 30 tablets per 30 days

APPROVAL LENGTH

- **Authorization:** 1 year.
- Re-Authorization:** An updated letter of medical necessity or progress notes confirming the current medical necessity criteria are met and showing the medication is effective.

APPENDIX

Table 1. FDA-Approved Indications for Medications for the Treatment of Chronic Constipation

Medication	CIC	IBS-C	OIC	FC
Amitiza	✓	✓ ^a	✓	
Ibsrela		✓		
Linzess	✓	✓		✓ ^b
Motegrity	✓			
Movantik			✓	
Relistor			✓ ^c	
Symproic			✓	
Trulance	✓	✓		

Abbreviations: CIC, chronic idiopathic constipation; FC, functional constipation; IBS-C, irritable bowel syndrome with constipation; OIC, opioid-induced constipation

- Lubiprostone is FDA-approved for women ≥ 18 years of age with IBS-C.
- Linzess is FDA-approved for pediatric patients 6 to 17 years of age with FC.
- Relistor prefilled syringe is FDA-approved for patients with advanced illness or pain caused by active cancer requiring opioid dosage escalation for palliative care.

REFERENCES

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DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.