

Generic Name: N/A

Preferred: N/A*

Therapeutic Class or Brand Name: Chronic Constipation – Idiopathic and IBS-C

Non-preferred: Amitiza® (lubiprostone), lbsrela® (tenapanor), Linzess®* (linaclotide), Motegrity® (prucalopride), Trulance® (plecanatide), Zelnorm™ (tegaserod).

Applicable Drugs (if Therapeutic Class):

Amitiza® (lubiprostone), lbsrela® (tenapanor), Linzess®* (linaclotide), Motegrity® (prucalopride), Trulance® (plecanatide), Zelnorm™ (tegaserod).

Date of Origin: 5/1/2019

Date Last Reviewed / Revised: 2/28/2023

*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 V are met)

- I. Documented diagnosis of one of the following:
 - A. Chronic idiopathic constipation (CIC) with symptoms lasting \geq 3 months in duration
 - B. Irritable bowel syndrome with constipation (IBS-C)
- II. Documented treatment failure or contraindication to at least 3 standard laxative therapies, with at least one from each the following regimens A through C below:
 - A. Osmotic laxative (eg, lactulose, magnesium salts, PEG 3350)
 - B. Stimulant laxative (eg, bisacodyl, sennosides)
 - C. Bowel regimen combination of drugs from A and B above with or without docusate
- III. Minimum age requirement: 18 years old.
- IV. 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.
- V. 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

- Treatment of Opioid-Induced Constipation (OIC). Refer to the Chronic Constipation – Opioid-Induced medication policy.
- Patients with known or suspected gastrointestinal obstruction or risk of recurrent obstruction.
- Concurrent use of another OIC opioid antagonist.

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.
- Zelnorm is contraindicated in patients with the following conditions:
 - A history of myocardial infarction, stroke, transient ischemic attack, or angina.
 - A history of ischemic colitis or other forms of intestinal ischemia.
 - Severe renal impairment (eGFR < 15 mL/min/1.73 m²) or end-stage renal disease.
 - Moderate or severe hepatic impairment (Child-Pugh B or C).
 - A history of bowel obstruction, symptomatic gallbladder disease, suspected sphincter of Oddi dysfunction, or abdominal adhesions.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Amitiza: CIC: Sixty 24 mcg capsules per 30 days
IBS-C: Sixty 8 mcg capsules per 30 days
- Ibsrela: 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
- Motegrity: 30 tablets per 30 days.
- Trulance: 30 tablets per 30 days.
- Zelnorm: 60 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

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

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

- a. Amitiza is FDA-approved for women ≥ 18 years of age with IBS-C.
- b. Relistor prefilled syringe is FDA-approved for patients with advanced illness or pain caused by active cancer requiring opioid dosage escalation for palliative care.
- c. Zelnorm is FDA-approved for adult women < 65 years of age with IBS-C.

REFERENCES

1. Lembo A, Sultan S, Chang L, Heidelbaugh JJ, Smalley W, Verne GN. AGA clinical practice guideline on the pharmacological management of irritable bowel syndrome with diarrhea. *Gastroenterology*. 2022;163(1):137-151. doi:10.1053/j.gastro.2022.04.017
2. Amitiza. Prescribing information. Takeda; 2020. Accessed August 27, 2022. <https://general.takedapharm.com/amtizapi>
3. Ibsrela. Prescribing information. Ardelyx, Inc; 2022. Accessed February 28, 2023. <https://ardelyx.com/wp-content/uploads/2021/11/IBSRELA-Prescribing-Information-1.pdf>
4. Linzess. Prescribing information. Allergan; 2021. Accessed August 27, 2022. https://www.rxabbvie.com/pdf/linzess_pi.pdf
5. Motegrity. Prescribing information. Takeda Pharmaceuticals U.S.A., Inc; 2020. Accessed August 27, 2022. https://www.shirecontent.com/PI/PDFs/MOTEGRITY_USA_ENG.pdf
6. Movantik. Prescribing information. RedHill Biopharma Inc; 2020. Accessed August 27, 2022. <https://movantik.com/pdf/MovantikPrescribingInformation.pdf> .
7. Relistor. Prescribing information. Salix Pharmaceuticals, Inc; 2020. Accessed August 27, 2022. <https://shared.salix.com/shared/pi/Relistor-pi.pdf> .
8. Symproic. Prescribing information. BioDelivery Sciences International, Inc; 2020. Accessed August 27, 2022. <https://www.symproic.com/docs/symproic-PI.pdf>.
9. Trulance. Prescribing Information. Salix Pharmaceuticals, Inc; 2021. Accessed August 27, 2022. <https://pi.bauschhealth.com/globalassets/BHC/PI/trulance-pi.pdf>

10. Zelnorm. Prescribing information. Alfasigma USA, Inc; 2019. Accessed August 27, 2022.

https://www.myzelnorm.com/assets/pdfs/PM-000413_ZELNORM_PI-MG_160x850mm_v6FNL_ND.pdf

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.