

Generic Name: N/A

Therapeutic Class or Brand Name: Chronic Constipation – Opioid-Induced

Applicable Drugs (if Therapeutic Class):

Amitiza® (lubiprostone), Movantik® (prucalopride), Relistor® (methylnaltrexone bromide), Symprioic® (naldemedine)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 5/1/2019

Date Last Reviewed / Revised: 9/30/2022

PRIOR AUTHORIZATION CRITERIA

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

- I. Documented diagnosis of opioid-induced constipation (OIC) with one of the following conditions:
 - A. Chronic non-cancer pain on opioid therapy.
 - B. Chronic pain related to previous cancer or its treatment who do not require frequent (eg, weekly) opioid dose escalation.
 - C. Advanced illness or pain caused by active cancer requiring opioid dosage escalation for palliative care
 1. Request is for Relistor injection.
- II. Documentation of chronic opioid use for at least 4 weeks.
- III. 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 and sennosides)
 - C. Bowel regimen combination of drugs from A and B above with or without docusate
- IV. Minimum age requirement: 18 years old.
- V. 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 medication-specific criteria.
- VI. 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 CIC or IBS-C. Refer to the Chronic Constipation – Idiopathic/IBS-C medication policy.
- Patients with known or suspected gastrointestinal obstruction or risk of recurrent obstruction.

MEDICATION POLICY:
Chronic Constipation – Opioid-induced



- The use of Amitiza in patients taking diphenylheptane opioids (e.g., methadone).
- Concurrent use of another OIC opioid antagonist.

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Amitiza: Sixty 24 mcg capsules 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.

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 Indications for Medications for the Treatment of Chronic Constipation

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

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

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

REFERENCES

1. Crockett SD, Greer KB, Heidelbaugh JJ, et al. American Gastroenterological Association Institute guideline on the medical management of opioid-induced constipation. *Gastroenterology*. 2019;156(1):218-226. doi:10.1053/j.gastro.2018.07.016
2. Amitiza. Prescribing information. Takeda; 2020. Accessed September 24, 2022. <https://general.takedapharm.com/amitizapi>
3. Movantik. Prescribing information. RedHill Biopharma Inc; 2020. Accessed September 24, 2022. <https://movantik.com/pdf/MovantikPrescribingInformation.pdf> .
4. Relistor. Prescribing information. Salix Pharmaceuticals, Inc; 2020. Accessed September 24, 2022. <https://shared.salix.com/shared/pi/Relistor-pi.pdf> .
5. Symproic. Prescribing information. BioDelivery Sciences International, Inc; 2020. Accessed September 24, 2022. <https://www.symproic.com/docs/symproic-PI.pdf>.
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7. Motegrity. Prescribing information. Takeda Pharmaceuticals U.S.A., Inc; 2020. Accessed September 24, 2022. https://www.shirecontent.com/PI/PDFs/MOTTEGRITY_USA_ENG.pdf
8. Trulance. Prescribing Information. Salix Pharmaceuticals, Inc.; 2021. Accessed September 24, 2022. <https://pi.bauschhealth.com/globalassets/BHC/PI/trulance-pi.pdf>
9. Zelnorm. Prescribing information. Alfasigma USA, Inc; 2019. Accessed September 24, 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.