

Generic Name: N/A

Preferred: N/A

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

Non-preferred: N/A

Applicable Drugs (if Therapeutic Class):
Amitiza® (lubiprostone), Linzess®** (linaclotide),
Motegrity® (prucalopride), Trulance®
(plecanatide), Zelnorm™ (tegaserod).

Date of Origin: 5/1/2019

Date Last Reviewed / Revised: 9/14/2020

*This policy does not address patients with a diagnosis of Opioid-Induced Constipation (refer to separate policy “Chronic Constipation – Opioid-Induced”).

**Preferred and does not require prior authorization for Premium Plus formulary only. Please refer to specific health plan benefits.

GPI Code: 5245004500, 5255705000,
5256006020, 5254306000, 5255506020.

PRIOR AUTHORIZATION CRITERIA

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

- I. Patient is at least 18 years of age or older.
- II. Patient has one of the conditions listed below AND the indication is FDA-approved for the particular drug requested as delineated in Appendix 1:
 - A. Chronic Idiopathic Constipation (CIC) with symptoms lasting \geq 3 months in duration
 - B. Irritable Bowel Syndrome with Constipation (IBS-C)
- III. Patient has documented failure, intolerance or contraindication to at least 3 different standard laxative therapies from 3 different laxative classes/therapies A through C below:
 - A. Osmotic laxative (such as PEG 3350, lactulose)
 - B. Stimulant laxative (such as sennosides and bisacodyl)
 - C. Bowel regimen combination of drugs from A and B above with or without docusate

EXCLUSION CRITERIA

- This policy does not address patients with a diagnosis of Opioid-Induced Constipation (refer to separate policy “Chronic Constipation – Opioid-Induced”).
- Male patients requesting Amitiza® or Zelnorm™ for IBS-C.
- Female patients 65 years of age and older requesting Zelnorm™ for IBS-C.

OTHER CRITERIA

- 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

- Linzess®: up to 30 capsules per 30 days.
- Amitiza®: up to 60 capsules per 30 days.
- Motegrity®: up to 30 tablets per 30 days.
- Trulance®: up to 30 tablets per 30 days.
- Zelnom™: up to 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

Appendix 1. FDA-Approved Indications for Drugs for the Treatment of Chronic Constipation

	CIC	IBS-C	OIC
Amitiza®	✓	✓*	✓
Linzess®	✓	✓	
Motegrity®	✓		
Movantik®			✓
Relistor®			✓
Trulance®	✓	✓	
Symproic®			✓
Zelnom™		✓**	

*Amitiza® is FDA-approved only for FEMALE patients with IBS-C.

** Zelnom™ is FDA-approved for only for adult FEMALE patients under 65 years of age with IBS-C.

CIC = Chronic Idiopathic Constipation ≥ 3 months duration

IBS-C = Irritable Bowel Syndrome with Constipation

OIC = Opioid-Inducted Constipation

REFERENCES

1. https://www.allergan.com/assets/pdf/linzess_pi .
2. <https://general.takedapharm.com/ amitizapi> .
3. <https://www.bauschhealth.com/Portals/25/Pdf/PI/trulance-pi.pdf> .
4. https://www.shirecontent.com/PI/PDFs/MOTEGRITY_USA_ENG.pdf .
5. <https://www.symproic.com/docs/symproic-PI.pdf> .
6. https://movantik.com/wp-content/uploads/2020/06/movantik_PI.pdf .
7. <https://shared.salix.com/shared/pi/relistor-pi.pdf?id=8251081> .
8. <https://www.alfasigmausa.com/wp-content/uploads/master/zelnorm-pi.pdf> .
9. Medi-Span®.

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
9/14/2020	<ol style="list-style-type: none"> 1. Changed obsolete URL “https://www.trulance.com/prescribing-information.pdf” to https://www.bauschhealth.com/Portals/25/Pdf/PI/trulance-pi.pdf under References. 2. Changed obsolete URL “https://www.shionogi.com/pdf/pi/wp-content/themes/pdfs/symproic.pdf” to https://www.symproic.com/docs/symproic-PI.pdf under References. 3. Added URL for Movantik https://movantik.com/wp-content/uploads/2020/06/movantik_PI.pdf under References. 4. Added URL for Relistor https://shared.salix.com/shared/pi/relistor-pi.pdf?id=8251081 under References. 5. Added URL for Zelnorm https://www.alfasigmausa.com/wp-content/uploads/master/zelnorm-pi.pdf under References. 6. Added information for Zelnorm under Applicable Drugs, GPI, Exclusion Criteria, Other Criteria, Quantity/Days Supply Restrictions sections, and Appendix.
5/1/2019	<ol style="list-style-type: none"> 1. New Policy.

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.