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Reviewed: 12/2019, 7/2020, 4/2021, 3/2022, 6/2022, 5/2023, 9/2023
Scope: Medicaid

Constipation – CIC/IBS-C/OIC NON-ONCOLOGY POLICY

Lubiprostone
IBSRELA (tenapanor)
LINZESS (linaclotide)
MOTTEGRITY (prucalopride)
MOVANTIK (naloxegol)
RELISTOR (methylnaltrexone)*
SYMPROIC (naldemedine)
TRULANCE (plecanatide)

*For oncology indications, please refer to NHPRI Oncology Policy

I. CRITERIA FOR APPROVAL

A. Chronic Idiopathic Constipation (CIC)

Authorization may be granted for treatment of CIC when all of the following criteria are met:

1. The requested drug is lubiprostone, Linzess, Motegrity or Trulance
2. Patient is 18 years of age or older
3. Patient has attempted lifestyle changes including adequate fluid intake and maintaining a diet rich in fiber and/or fiber supplementation
4. Patient has experienced an inadequate treatment response, intolerance, or contraindication to at least one agent with or without docusate from both of the following classes of laxatives (a) and (b) below:
 - a. Osmotic laxative (e.g., polyethylene glycol, lactulose, magnesium hydroxide, magnesium citrate)
 - b. Stimulant laxative (e.g., senna, bisacodyl)

B. Irritable Bowel Syndrome with Constipation (IBS-C)

Authorization may be granted for treatment of IBS-C when all of the following criteria are met:

1. The requested drug is lubiprostone, Ibsrela, Linzess or Trulance
2. Patient is 18 years of age or older
3. Patient has attempted lifestyle changes including adequate fluid intake and maintaining a diet rich in fiber and/or fiber supplementation
4. Patient has experienced an inadequate treatment response, intolerance, or contraindication to at least one agent with or without docusate from both of the following classes of laxatives (a) and (b) below:
 - a. Osmotic laxative (e.g., polyethylene glycol, lactulose, magnesium hydroxide, magnesium citrate)
 - b. Stimulant laxative (e.g., senna, bisacodyl)

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5. If the requested drug is Ibsrela, the patient has also experienced an inadequate treatment response, intolerance, or contraindication to at least two other agents indicated for IBS-C (e.g. lubiprostone, Linzess, Trulance, etc.)

C. Opioid-Induced Constipation (OIC)

Authorization may be granted for treatment of OIC when all of the following criteria are met:

1. The requested drug is Symproic, Movantik, Relistor or lubiprostone
2. Patient is 18 years of age or older
3. Patient has been taking opioids for at least 4 weeks (supported by pharmacy claims or medical chart documentation)
4. Patient has experienced an inadequate treatment response, intolerance, or contraindication to therapy of 2 different types of laxatives concomitantly on a scheduled basis (not use “as needed”) with or without docusate from the laxative classes (a) and (b) below:
 - a. Osmotic laxative (e.g., polyethylene glycol, lactulose, magnesium hydroxide, magnesium citrate)
 - b. Stimulant laxative (e.g., senna, bisacodyl)
5. For Movantik requests, patient has experienced an inadequate treatment response, intolerance, or contraindication to Symproic
6. For Relistor tablet requests, patient has experienced an inadequate treatment response, intolerance, or contraindication to Symproic and Movantik
7. For Relistor injection requests, patient meets either of the following criteria:
 - a. The requested drug is being prescribed for treatment of opioid-induced constipation in a patient with advanced illness (defined as end-stage COPD/emphysema, cardiovascular disease/heart failure, Alzheimer’s disease/dementia, HIV/AIDS, or other end-stage life-threatening disease) receiving palliative care
 - b. Both of the following criteria are met:
 - i. Patient has experienced an inadequate treatment response, intolerance, or contraindication to Symproic and Movantik
 - ii. Rationale provided why patient is unable to take oral formulation of Relistor

D. Functional Constipation (FC)- Linzess only

Authorization of Linzess may be granted for treatment of FC when all of the following criteria are met:

1. Linzess is prescribed for the treatment of functional constipation (FC) in a pediatric patient 6 to 17 years of age
2. Pediatric patient has attempted lifestyle changes including adequate fluid intake and maintaining a diet rich in fiber and/or fiber supplementation
3. Pediatric patient has experienced an inadequate treatment response, intolerance, or contraindication to at least one osmotic laxative (e.g., polyethylene glycol, lactulose, magnesium hydroxide, magnesium citrate)

II. CONTINUATION OF THERAPY

Authorization may be granted for members with CIC, IBS-C, FC or OIC who meet the initial criteria and have experienced positive clinical response (e.g., greater frequency of spontaneous bowel movements, reduced abdominal pain/bloating) with requested therapy.

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III. COVERAGE DURATION

- A. CIC, IBS-C, FC and OIC not related to advanced illness – 12 months for initial and continuation of therapy
- B. OIC with advanced illness – 4 months for initial and continuation of therapy

IV. QUANTITY LIMITS

- A. Lubiprostone – 2 capsules per day
- B. Ibsrela – 2 tablets per day
- C. Linzess - 1 tablet per day
- D. Motegrity – 1 tablet per day
- E. Movantik – 1 tablet per day
- F. Relistor tablet - 3 tablets per day
- G. Relistor injection – 1 prefilled syringe/vial per day
- H. Symproic - 1 tablet per day
- I. Trulance – 1 tablet per day

V. REFERENCES

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2. Amitiza [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; December 2022.
3. Trulance [package insert]. Bridgewater, NJ: Bausch Health US, LLC; April 2021.
4. Motegrity [package insert]. Lexington, MA: Shire US Inc.; October 2022.
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6. Movantik [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2022.
7. Relistor [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; April 2020.
8. Ibsrela [package insert]. Fremont, CA: Ardelyx, Inc; April 2022.
9. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. <http://www.micromedexsolutions.com/>. Accessed November 2019
10. Crockett SD, Greer KB, Heidelbaugh JJ, et al. American Gastroenterological Association Institute Guideline on the Medical Management of Opioid-Induced Constipation. *Gastroenterology* 2019; 156:218-226.
11. Ford AC, Moayyedi P, Chey WD, et al. American College of Gastroenterology Monograph on Management of Irritable Bowel Syndrome. *Gastroenterology* 2018; supplement 1-18.
12. Tse Y, Armstrong D, Andrews CN, et al. Treatment Algorithm for Chronic Idiopathic Constipation and Constipation-Predominant Irritable Bowel Syndrome Derived from a Canadian National Survey and Needs Assessment on Choices of Therapeutic Agents. *Canadian Journal of Gastroenterology and Hepatology* 2017; Article ID 8612189.

VI. APPENDIX

FDA-Approved Indications

	CIC	IBS-C	OIC
Amitiza	✓	✓	✓
Ibsrela		✓	
Linzess	✓	✓	
Motegrity	✓		
Movantik			✓
Relistor inj			✓
Relistor tab			✓
Symproic			✓
Trulance	✓	✓	

CIC = chronic idiopathic constipation; IBS-C = irritable bowel syndrome with constipation;
OIC = opioid-induced constipation