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Scope: Medicaid

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

Lubiprostone (generic for Amitiza)
Prucalopride (generic for Motegrity)
IBSRELA (tenapanor)
LINZESS (linaclotide)
MOVANTIK (naloxegol)
RELISTOR (methylnaltrexone)*
SYMPROIC (naldemedine)fpaint
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, prucalopride or Trulance
2. Member is 18 years of age or older
3. Member has attempted lifestyle changes including adequate fluid intake and maintaining a diet rich in fiber and/or fiber supplementation
4. Member 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 or Trulance and the member is 18 years of age or older OR the requested drug is for Linzess and the member is 7 years of age or older
2. Member has attempted lifestyle changes including adequate fluid intake and maintaining a diet rich in fiber and/or fiber supplementation
3. Member 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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4. If the requested drug is Ibsrela, the member 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. Member is 18 years of age or older
3. Member has been taking opioids for at least 4 weeks (supported by pharmacy claims or medical chart documentation)
4. Member 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 Symproic requests, member has experienced an inadequate treatment response, intolerance, or contraindication to Movantik
6. For Relistor tablet requests, member has experienced an inadequate treatment response, intolerance, or contraindication to Symproic and Movantik
7. For Relistor injection requests, member meets either of the following criteria:
 - a. The requested drug is being prescribed for treatment of opioid-induced constipation in a member 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. Member has experienced an inadequate treatment response, intolerance, or contraindication to Symproic and Movantik
 - ii. Rationale provided why member 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 member 6 to 17 years of age
2. Pediatric member has attempted lifestyle changes including adequate fluid intake and maintaining a diet rich in fiber and/or fiber supplementation
3. Pediatric member 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. Prucalopride – 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.; March 2025.
3. Trulance [package insert]. Bridgewater, NJ: Bausch Health US, LLC; April 2024.
4. Motegrity [package insert]. Lexington, MA: Shire US Inc.; July 2025.
5. Symproic [package insert]. Florham Park, NJ: Shionogi Inc.; December 2022.
6. Movantik [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2024.
7. Relistor [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; June 2025.
8. Ibsrela [package insert]. Fremont, CA: Ardelyx, Inc; May 2025.
9. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. <http://www.micromedexsolutions.com/>. Accessed November 2019
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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
Lubiprostone	✓	✓	✓
Ibsrela		✓	
Linzess	✓	✓	
Prucalopride	✓		
Movantik			✓
Relistor inj			✓
Relistor tab			✓
Symproic			✓
Trulance	✓	✓	

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