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| Effective Date: 3/2020 |
| Reviewed: 12/2019 |
| Scope: Medicaid |

Constipation – CIC/IBS-C/OIC

AMITIZA (lubiprostone)
LINZESS (linaclotide)
MOTEGRITY (prucalopride)
MOVANTIK (naloxegol)
RELISTOR (methylnaltrexone)
SYMPROIC (naldemedine)
TRULANCE (plecanatide)

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:

- A. The requested drug is Amitiza, Linzess, Motegrity or Trulance
- B. Patient is 18 years of age or older
- C. Patient has attempted lifestyle changes including adequate fluid intake and maintaining a diet rich in fiber and/or fiber supplementation
- D. 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)
- E. Patient does not have a known or suspected gastrointestinal (GI) obstruction or is not at increased risk for recurrent GI obstruction

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 Amitiza, 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)
5. Patient does not have a known or suspected gastrointestinal (GI) obstruction or is not at increased risk for recurrent GI obstruction

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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 Amitiza
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. Patient does not have a known or suspected gastrointestinal (GI) obstruction or is not at increased risk for recurrent GI obstruction
6. For Movantik requests, patient has experienced an inadequate treatment response, intolerance, or contraindication to Symproic
7. For Relistor tablet requests, patient has experienced an inadequate treatment response, intolerance, or contraindication to Symproic and Movantik
8. 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 incurable cancer, 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

II. CONTINUATION OF THERAPY

Authorization may be granted for members with CIC, IBS-C 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.

III. COVERAGE DURATION

- A. CIC, IBS-C, 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. Amitiza – 2 capsules per day
- B. Linzess - 1 tablet per day

- C. Motegrity – 1 tablet per day
- D. Movantik – 1 tablet per day
- E. Relistor tablet - 3 tablets per day
- F. Relistor injection – 1 prefilled syringe/vial per day
- G. Symproic - 1 tablet per day
- H. Trulance – 1 tablet per day

V. REFERENCES

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7. Relistor [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; July 2016.
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10. Ford AC, Moayyedi P, Chey WD, et al. American College of Gastroenterology Monograph on Management of Irritable Bowel Syndrome. Gastroenterology 2018; supplement 1-18.
11. 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 | ✓ | ✓ | ✓ |
| Linzess | ✓ | ✓ | |
| Motegrity | ✓ | | |
| Movantik | | | ✓ |
| Relistor inj | | | ✓ |
| Relistor tab | | | ✓ |
| Symproic | | | ✓ |
| Trulance | ✓ | ✓ | |

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