Policy and Procedure	
PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCGAS004.1225	**GASTROINTESTINAL AGENTS CONSTIPATION AGENTS** See Table 1 for Applicable Medication
Effective Date: 3/1/2026	**Review/Revised Date**: 02/03, 12/03, 09/04, 09/05, 04/06, 10/06, 02/07, 04/07, 02/08, 08/08, 08/09, 08/10, 08/11, 02/12, 12/12, 04/13, 10/13, 12/14, 12/15, 10/16, 07/17, 10/17, 08/18, 10/18, 10/19, 02/20, 10/20, 03/21, 10/21, 08/22, 11/22, 10/23, 10/23, 10/24, 10/25 (MTW)
Original Effective Date: 02/03	**P&T Committee Meeting Date**: 02/03, 12/03, 09/04, 09/05, 04/06, 10/06, 02/07, 04/07, 02/08, 08/08, 08/09, 08/10, 08/11, 02/12, 12/12, 04/13, 12/13, 12/14, 12/15, 12/16, 08/17, 12/17, 09/18 (cv), 12/18, 06/19, 10/19, 12/19, 12/20, 04/21, 12/21, 08/22, 12/22, 02/23, 10/23, 12/23, 12/24, 12/25
Approved by: Oregon Region Pharmacy and Therapeutics Committee	

SCOPE:
Providence Health Plan and Providence Health Assurance as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:
Commercial: lubiprostone (Amitiza®), Linzess®, and prucalopride (Motegrity®) do not require prior authorization

POLICY CRITERIA

COVERED USES:
All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

REQUIRED MEDICAL INFORMATION:
1. **For all requests**, the patient must have an FDA labeled indication for the requested agent.

2. **For all requests**, medication will not be used concomitantly with other intestinal secretagogues, selective 5-HT agonists or peripherally acting mu-opioid receptor antagonists covered by this policy

3. For patients *already established* on the requested product (Note: medications obtained as samples, coupons, or any other method of obtaining medications outside of an established health plan benefit are NOT considered established on therapy):
    a. Documentation of response to therapy (such as less straining, less pain on defecation, improved stool consistency, increased number of stools per week or reduction in the number of days between stools)

4. For patients *not established* on the requested product must meet ALL the following indication-specific criteria:
    a. For **chronic idiopathic constipation (CIC) or functional constipation (FC):**

i. Documentation of two or more of the following occurring over the last three months:
    1) Fewer than three spontaneous bowel movements per week
    2) Straining during defecations
    3) Lumpy or hard stools (Bristol Stool Form Scale 1-2)
    4) Sensation of incomplete evacuation
    5) Sensation of anorectal obstruction/blockage
    6) Manual maneuvers to facilitate defecations (such as digital evacuation, support of the pelvic floor)
ii. Screen for constipation-inducing medications and medical rationale provided for continuing these medications, if applicable
iii. Documentation of inadequate response or contraindication to a reasonable trial (at least two weeks treatment) to ALL the following:
    1) Regular use of dietary fiber supplementation (such as cereal, citrus, fruits or legumes) or use of bulking agents (such as psyllium or methylcellulose taken with adequate fluids),
    2) A stimulant laxative (such as senna, bisacodyl)
    3) Routine laxative therapy, with a different mechanism of action than the laxative(s) listed above (such as lactulose, Miralax®)
    4) Lubiprostone (Amitiza®) OR prucalopride (Motegrity®)
    5) Linaclotide (Linzess®)

b. For **irritable bowel syndrome with constipation (IBS-C):**
    i. Documentation of recurrent abdominal pain occurring, on average, at least one day per week during the previous three months with two or more of the following criteria:
        1) Related to defecation (either increased or improved pain)
        2) Associated with a change in stool frequency
        3) Associated with a change in stool form (appearance)
    ii. Documentation of inadequate response or contraindication to a reasonable trial (at least two weeks treatment) to ALL the following:
        1) Regular use of dietary fiber supplementation (such as cereal, citrus, fruits or legumes) or use of bulking agents (such as psyllium or methylcellulose taken with adequate fluids)
        2) Routine laxative therapy with polyethylene glycol (Miralax®)
        3) Linaclotide (Linzess®)

c. For **opioid-induced constipation (OIC)**:
    i. Patient is on chronic opioid therapy
    ii. Documentation of less than three spontaneous bowel movements per week
    iii. Documentation of inadequate response or contraindication to a reasonable trial (at least two weeks treatment) of ALL the following:

1) A stimulant laxative (such as senna, bisacodyl)
2) Routine laxative therapy, with a different mechanism of action than the laxative above (such as lactulose, Miralax®)
3) **For Relistor®:** Failure, contraindication, or intolerance to one of the following medications:
    a) Naloxegol (Movantik®)
    b) Lubiprostone (Amitiza®)
    c) Naldemedine (Symproic®)

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS:
Age must be appropriate based on FDA-approved indication

PRESCRIBER RESTRICTIONS: N/A

COVERAGE DURATION:
For OIC: Initial authorization will be approved for six months. Reauthorization will be approved for one year
For CIC, FC or IBS: Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

QUANTITY LIMIT:
- **Ibsrela:** two tablets per day
- **Movantik:** one tablet per day
- **Relistor:**
    - 8-mg syringe: one single use syringe per day (12 ml per 30 days)
    - 12-mg syringe or vial: one single use syringe or vial per day (18 ml per 30 days)
    - 150-mg tablet: three tablets per day
- **Symproic:** one tablet per day
- **Trulance:** one tablet per day

Requests for indications that were approved by the FDA within the previous six (6) months may not have been reviewed by the health plan for safety and effectiveness and inclusion on this policy document. These requests will be reviewed using the New Drug and or Indication Awaiting P&T Review; Prior Authorization Request ORPTCOPS047.

Requests for a non-FDA approved (off-label) indication requires the proposed indication be listed in either the American Hospital Formulary System (AHFS), Drugdex, or the National Comprehensive Cancer Network (NCCN) and is considered subject to evaluation of the prescriber's medical rationale, formulary alternatives, the available published evidence-based research and whether the proposed use is determined to be experimental/investigational.

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

INTRODUCTION:

Lubiprostone (Amitiza®) is a locally acting chloride channel activator that enhances a chloride-rich intestinal fluid secretion without altering sodium or potassium concentrations in the serum. By increasing intestinal fluid secretion, lubiprostone increases the passage of stool and alleviates symptoms associated with constipation.

Linaclotide (Linzess®) and plecanatide (Trulance®) are guanylate cyclase-C (GC-C) agonists. Linaclotide and plecanatide bind to GC-C of the luminal surface of intestinal epithelium. Binding activates GC-C, which in turn, increases intracellular and extracellular levels of cyclic guanosine monophosphate (cGMP). Elevated intracellular cGMP stimulates the secretion of chloride and bicarbonate into the intestinal lumen, causing an increase in intestinal fluid and faster transit time.

Naloxegol (Movantik®) is an opioid antagonist that binds the mu-opioid receptor. It functions as a peripherally-acting mu-opioid receptor antagonist in tissues such as the gastrointestinal tract to decrease the constipating effects of opioids. Naloxegol is a PEGylated derivative of naloxone and is a substrate for the P-glycoprotein transporter (P-gp). The PEG moiety of naloxegol reduces passive permeability across the blood-brain barrier (BBB), and the P-gp substrate properties increase efflux across the BBB. Central nervous system penetration of naloxegol is expected to be negligible which limits the potential for interference with centrally mediated opioid analgesia.

Methylnaltrexone bromide (Relistor®) is a selective antagonist of opioid binding at the mu-opioid receptor. Use of opioids induces slowing of gastrointestinal motility and transit. It is theorized that this effect is mediated through peripheral mu-opioid receptors. Antagonism of these gastrointestinal mu-opioid receptors by methylnaltrexone bromide inhibits opioid-induced delay of gastrointestinal transit time. As a quaternary amine, the ability of methylnaltrexone bromide to cross the blood-brain barrier is restricted. This allows antagonism in tissues such as the gastrointestinal tract without affecting opioid-mediated effects on the central nervous system.

Naldemedine (Symproic®) is an opioid antagonist that binds the mu-opioid receptor. It functions as a peripherally-acting mu-opioid receptor antagonist in tissues such as the gastrointestinal tract to decrease the constipating effects of opioids. Naldemedine is a derivative of naltrexone with an additional side chain that

increases the molecular weight and the polar surface area, thereby reducing its ability to cross the BBB. Naldemedine is also a substrate of the P-glycoprotein (P-gp) efflux transporter. Based on these properties, the central nervous system (CNS) penetration of naldemedine is expected to be negligible at the recommended dose levels, limiting the potential for interference with centrally-mediated opioid analgesia.

Prucalopride (Motegrity®) is a selective, high affinity 5-HT4 receptor agonist

Tenapanor (Ibsrela®), is a sodium/hydrogen exchanger-3 inhibitor that reduces sodium absorption in the small intestine and colon. This results in increased water secretion into the intestinal lumen and thus a faster transit time with a softer stool consistency.

FDA APPROVED INDICATIONS:

Amitiza®

- Chronic Idiopathic Constipation (CIC) in adults
- Irritable Bowel Syndrome with Constipation (IBS-C) in women who are age 18 years and older
- Opioid-induced constipation (OIC) in adults with chronic, non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation
    - Limitation of use: Effectiveness in the treatment of OIC in patients taking diphenylheptane opioids (e.g., methadone) has not been established

Linzess®

- CIC in adults
- IBS-C in adults
- Functional Constipation (FC) in pediatric patients 6 to 17 years of age

Trulance®

- CIC in adults
- IBS-C in adults

Movantik® and Symproic®

- OIC in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation

Motegrity®

- CIC in adults

Relistor®

- Injection only - treatment of opioid-induced constipation in patients with advanced illness or pain caused by active cancer and receiving palliative care
- Treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g. weekly) opioid dosage escalation

Ibsrela®

- IBS-C in adults

POSITION STATEMENT:

Chronic Idiopathic Constipation (CIC) and Functional Constipation (FC):

Diagnosis of CIC and FC is primarily based upon symptoms. Based on epidemiological studies, constipation has been defined as a stool frequency of less than three per week. More recently the Rome IV diagnostic criteria for functional constipation has been published. Diagnosis requires symptom onset at least six months before diagnosis and the presence of the following occurring over the last three months.

1. Must include two or more of the following:
    a. Straining during more than ¼ (25%) of defecations
    b. Lumpy or hard stools (Bristol Stool Form Scale 1-2) more than ¼ (25%) of defecations
    c. Sensation of incomplete evacuation more than ¼ (25%) of defecations
    d. Sensation of anorectal obstruction/blockage more than ¼ (25%) of defecations
    e. Manual maneuvers to facilitate more than ¼ (25%) of defecations (e.g., digital evacuation, support of the pelvic floor)
    f. Fewer than three spontaneous bowel movements per week
2. Loose stools are rarely present without the use of laxatives
3. Insufficient criteria for irritable bowel syndrome

The 2023 American Gastroenterological Association and American College of Gastroenterology guideline[31] and the 2024 American Society of Colon and Rectal Surgeons guideline[34] both recommend an initial step of non-pharmacological interventions including dietary changes (such as increased fluid intake and increased dietary fiber) and behavioral changes (such as exercise). Among evaluated fiber supplements, only psyllium has demonstrated efficacy. After an initial trial of fiber supplementation, or even in combination with fiber supplementation, polyethylene glycol (PEG) is recommended. Magnesium oxide is recommended as another first-line option in individuals with CIC. In adults who fail or are intolerant to OTC therapies, lactulose can be considered. Stimulant laxatives (such as bisacodyl, sodium picosulfate, and senna), are recommended for short term use (up to four

weeks) or as rescue therapy. While longer use is likely appropriate, the guidelines state that more data is needed to better understand tolerance and side effects. While not mentioned in the American Society of Colon and Rectal Surgeons guideline, the American Gastroenterological Association and American College of Gastroenterology guideline[31] recommends lubiprostone (Amitiza®), linaclotide (Linzess®), plecanatide (Trulance®), prucalopride (Motegrity®) for adults who do not respond to OTC agents, either as a replacement or as an adjunct to OTC agents. All four of these agents are noted to have limited duration of treatment in clinical trials (ranging from four to 24 weeks), however the drugs labels do not provide a limit on use.

Irritable Bowel Syndrome with Constipation (IBS-C):
The diagnosis of IBS is made based on patient history, key symptoms, physical exam and limited diagnostic testing. The diagnostic criteria, Rome IV, was developed to help diagnose IBS-C utilizing more expansive criteria:

Recurrent abdominal pain on average at least one day/week in the last three months, associated with two or more of the following criteria:
1. Related to defecation
2. Associated with a change in frequency of stool
3. Associated with a change in form (appearance) of stool

IBS is categorized into four main subtypes according to the predominant bowel habit: IBS with predominant constipation, IBS with predominant diarrhea, IBS with mixed symptomology and unclassified IBS[24].

The American Gastroenterological Association (2022)[23] have provided recommendations in support of use of linaclotide, lubiprostone, plecanatide, tenapanor, tegaserod, and PEG laxatives over no drug treatment in patient with ISB-C. For IBS regardless of subtype, the guidelines suggest using TCAs and antispasmodics (*conditional recommendation, low certainty)*. Use of nonpharmaceutical agents (fiber) and other interventions (dietary modification, biofeedback, acupuncture) used in the treatment of patients with IBS were not addressed in the guideline. In the AGA *Clinical Decision Support Tool:* IBS Treatment[23], lifestyle and dietary modifications are recommended for all IBS patients. Specifically for IBS-C, osmotic laxatives are suggested as first-line or for mild IBS symptoms with the secretagogues (linaclotide, lubiprostone, plecanatide and tenapanor) as second line (moderate IBS symptoms).

The American College of Gastroenterology guideline (2021)[24] on the management of IBS notes soluble fiber remains an evidence-based treatment for IBS. The low cost and lack of significant side effects makes soluble fiber a reasonable first-line therapy

for IBS patients and, in combination with the moderate quality of evidence, is the basis of a strong recommendation. In addition, the guidelines give a strong recommendation for the use of the prosecretory agents linaclotide, plecanatide and lubiprostone to treat global IBS-C symptoms.

Opioid Induced Constipation (OIC):
The effect of opioids on gastrointestinal motility includes increased segmental motility and decreased peristalsis, often resulting in constipation. Diagnostic criteria for OIC are outlined in the ROME IV criteria[19]:

1. New, or worsening, symptoms of constipation when initiating, changing, or increasing opioid therapy, that must include two or more of the following:
    a. Straining during more than ¼ (25%) of defecations
    b. Lumpy or hard stools (Bristol Stool Form Scale 1-2) more than ¼ (25%) of defecations
    c. Sensation of incomplete evacuation more than ¼ (25%) of defecations
    d. Sensation of anorectal obstruction/blockage more than ¼ (25%) of defecations
    e. Manual maneuvers to facilitate more than ¼ (25%) of defecations (e.g., digital evacuation, support of the pelvic floor)
    f. Fewer than three spontaneous bowel movements per week
2. Loose stools are rarely present without the use of laxatives.

The American Gastroenterological Association (2019)[19], strongly recommends traditional laxative therapy as first-line agents, given established efficacy and benefits of safety and cost. When an adequate trial of laxatives results in suboptimal symptom control, the AGA recommends escalation of therapy to peripherally acting μ-opioid receptor antagonists (PAMORA) drugs with high- or moderate-quality evidence of efficacy, namely naldemedine and naloxegol. The AGA also conditionally recommends use of methylnaltrexone. Due to insufficient evidence, the AGA did not issue a recommendation regarding use of either lubiprostone or prucalopride in OIC.

National Comprehensive Cancer Network (2025)[17] guidelines on palliative care and adult cancer pain provide recommendations on OIC in adult patients with cancer-related pain. Preventative measures include maintaining adequate fluid and dietary fiber, exercise (if appropriate), and prophylactic medications such as stimulant laxatives and polyethylene glycol. If constipation persists, consider adding another laxative, such as magnesium hydroxide, rectal bisacodyl, lactulose, magnesium citrate, or polyethylene glycol. When response to standard laxative therapy has not been sufficient, then as needed enemas can be used and also consider a peripherally acting mu-opioid receptor antagonist such as methylnaltrexone, naldemedine or naloxegol.

Gastroparesis:
Gastroparesis is the presence of delayed gastric emptying of solids in the absence of mechanical obstruction. It is characterized by nausea, vomiting, postprandial fullness and upper abdominal pain. The ACG clinical guidelines on gastroparesis[30] treatment algorithm starts with dietary modifications then moves to pharmacological treatment. Pharmacological treatments highlighted include prokinetics (metoclopramide, erythromycin, domperidone, others) and antiemetics (histamine H1 or 5-HT3 antagonists). Prucalopride (Motegrity®), a 5-HT4 receptor agonist, is a gastrointestinal prokinetic agent that stimulates colonic peristalsis. Available evidence for the use of prucalopride in gastroparesis comes from two small trials[30]. The ACG guideline[28] suggests use of selective serotonin type 4 (5-HT4) receptor agonists over no treatment to improve gastric emptying (conditional recommendation, low quality of evidence). The AGA Clinical Practice Update on Management of Medically Refractory Gastroparesis Prucalopride[29] acknowledge prucalopride accelerated gastric emptying and improved symptoms in a small RCT but that larger trials are needed to confirm these findings. Currently there is limited evidence for use of prucalopride in gastroparesis. Prucalopride does not have FDA approval nor compendia support for treatment of gastroparesis.

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TABLE 1: Constipation agents covered by this policy

Brand Name	Generic Name
Ibsrela®	tenapanor tablet
Movantik®	naloxegol tablet
Relistor®	methylnaltrexone tablet, injection
Symproic®	naldemedine tablet
Trulance®	plecanatide tablet