



Original Effective Date: 02/25/2023
Current Effective Date: 03/28/2024
Last P&T Approval/Version: 01/31/2024
Next Review Due By: 01/2025
Policy Number: C24671-A

Constipation Agents

PRODUCTS AFFECTED

Amitiza (lubiprostone), Ibsrela (tenapanor), Linzess (linaclotide), lubiprostone, Motegrity (prucalopride), Movantik (naloxegol), Relistor (methylnaltrexone), Symproic (naldemedine), Trulance (plecanatide)
*Xphozah (tenapanor) – SEE XPHOZAH (TENAPANOR) MHI

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:

Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:

Irritable bowel syndrome with constipation, Chronic idiopathic constipation, Opioid-induced constipation, Opioid-induced constipation in advanced illness

REQUIRED MEDICAL INFORMATION:

This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

FOR ALL INDICATIONS:

1. Prescriber attests the requested agent will not be used in combination with other functional gastro-

Molina Healthcare, Inc. confidential and proprietary © 2024

This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.

Drug and Biologic Coverage Criteria

intestinal disorder drugs

AND

2. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to **Amitiza** (lubiprostone), lubiprostone include: Patients with known or suspected mechanical gastrointestinal obstruction. Contraindications to **Ibsrela** (tenapanor) include: Pediatric patients less than 6 years of age, and patients with known or suspected mechanical gastrointestinal obstruction. Contraindications to **Linzess** (linaclotide) include: Patients with known or suspected mechanical gastrointestinal obstruction, patients less than 2 years of age. Contraindications to **Motegrity** (prucalopride) include: hypersensitivity to Motegrity, Intestinal perforation or obstruction due to structural or functional disorder of the gut wall, obstructive ileus, severe inflammatory conditions of the intestinal tract such as Crohn's disease, ulcerative colitis, and toxic megacolon/megarectum. Contraindications to **Movantik** (naloxegol) include: Patients with known or suspected gastrointestinal obstruction and at risk of recurrent obstruction, concomitant use with strong CYP3A4 inhibitors (e.g., clarithromycin, ketoconazole), and known serious or severe hypersensitivity reaction to Movantik or any of its excipients. Contraindications to **Relistor** (methylnaltrexone) include: Patients with known or suspected mechanical gastrointestinal obstruction and at increased risk of recurrent obstruction. Contraindications to **Symproic** (naldemedine) include: Patients with known or suspected gastrointestinal obstruction or at increased risk of recurrent obstruction, and patients with a history of a hypersensitivity reaction to naldemedine. Contraindications to **Trulance** (plecanatide) include: Patients less than 6 years of age due to the risk of serious dehydration, and patients with known or suspected mechanical gastrointestinal obstruction.]
AND
3. IF NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or serious side effects to a majority (not more than 3) of the preferred formulary alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s).

A. IRRITABLE BOWEL SYNDROME WITH CONSTIPATION (IBS-C) – AMITIZA, LUBIPROSTONE, IBSRELA, LINZESS, TRULANCE ONLY

1. Documented diagnosis of IBS-C
AND
2. Documentation ruling out IBS-C organic disease (alarm symptoms), dys-synergic defecation, IBS-D or slow colonic transit.
AND
3. Documentation of trial/failure (2 week trial for each agent), FDA labeled contraindication, or serious side effects to at least 2 of the following with or without a stool softener in the past 3 months: At least one stimulant laxative (e.g. bisacodyl); OR At least one osmotic laxative (e.g. PEG 3350); OR At least one saline laxative (e.g. magnesium citrate) OR At least one bulk-forming laxative (e.g. psyllium)

B. CHRONIC IDIOPATHIC CONSTIPATION (CIC) – AMITIZA, LUBIPROSTONE, LINZESS, MOTEGRITY, TRULANCE ONLY

1. Documented diagnosis of chronic idiopathic constipation
AND
2. Documentation of a minimum of TWO of the following symptoms for the last 3 months:
 - (a) Straining during at least 25% of defecations
 - (b) Sensation of anorectal obstruction/blockage for at least 25% of defecations
 - (c) Lumpy or hard stools in at least 25% of defecations
 - (d) Manual maneuvers to facilitate at least 25% of defecations (e.g., digital evacuation, support of the pelvic floor)
 - (e) Sensation of incomplete evacuation for at least 25% of defecations

Molina Healthcare, Inc. confidential and proprietary © 2024

This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.

Drug and Biologic Coverage Criteria

(f) Fewer than three spontaneous bowel movements per week

(g) Loose stools are rarely present without the use of laxatives

AND

3. Prescriber attests to ruling out secondary causes of chronic constipation (e.g., drug-induced constipation, IBS-C, Inflammatory bowel disease, colorectal cancer, hypothyroidism, electrolyte imbalances)

AND

4. Documentation of trial/failure (2 week trial for each agent), FDA labeled contraindication, or serious side effects to at least 2 of the following with or without a stool softener in the past 3 months: At least one stimulant laxative (e.g. bisacodyl); OR At least one osmotic laxative (e.g. PEG 3350, magnesium oxide, lactulose); OR At least one bulk- forming laxative (e.g. psyllium or methylcellulose)

C. OPIOID INDUCED CONSTIPATION (OIC) – AMITIZA, LUBIPROSTONE, MOVANTIK, RELISTOR, SYMPROIC ONLY

1. Documented diagnosis of opioid-induced constipation

AND

2. Documentation that member has chronic use of an opioid agent in the past 30 days as documented within claims history OR if member is new to Molina, a documented medical chart note of last fill date and/or prescription drug monitoring report

AND

3. FOR AMITIZA REQUESTS: Prescriber attests that member is not currently receiving a diphenylheptane opioid (e.g., methadone)

AND

4. Documentation of trial/failure (2 week trial for each agent), FDA labeled contraindication, or serious side effects to at least 2 of the following with or without a stool softener in the past 3 months: At least one stimulant laxative (e.g. bisacodyl); OR At least one osmotic laxative (e.g. PEG 3350); OR At least one saline laxative (e.g. magnesium citrate)

AND

5. FOR RELISTOR ONLY: Prescriber attests or pharmacy claim history supports that member is not on other opioid antagonists

D. OPIOID INDUCED CONSTIPATION WITH ADVANCED ILLNESS – RELISTOR INJ ONLY

1. Documented diagnosis of opioid-induced constipation

AND

2. Documentation that member has chronic use of an opioid agent in the past 30 days as documented within claims history OR if member is new to Molina, a documented medical chart note of last fill date and/or prescription drug monitoring report

AND

3. Documented diagnosis of an advanced illness and member is receiving palliative care

AND

4. Documentation of trial/failure (2 week trial for each agent), FDA labeled contraindication, or serious side effects to at least 2 of the following with or without a stool softener in the past 3 months: At least one stimulant laxative (e.g. bisacodyl); OR At least one osmotic laxative (e.g. PEG 3350); OR At least one saline laxative (e.g. magnesium citrate)

AND

5. Prescriber attests or pharmacy claim history supports that member is not on other opioid antagonists

E. FUNCTIONAL CONSTIPATION (FC) IN PEDIATRICS - LINZESS ONLY:

1. Documented diagnosis of functional constipation

AND

2. Prescriber attests to ruling out other causes of constipation (e.g., organic causes of constipation, IBS-C, etc.)

Drug and Biologic Coverage Criteria

AND

3. Documentation of trial/failure (2 week trial for each agent), FDA labeled contraindication, or serious side effects to at least 2 of the following: PEG 3350 OR lactulose OR milk of magnesia OR at least one stimulant laxative (e.g., bisacodyl, senna) OR at least one lubricant laxative (e.g., mineral oil)

CONTINUATION OF THERAPY:

A. ALL INDICATIONS:

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms per the prescribing physician
AND
4. FOR OIC: Documentation of continued opioid use

DURATION OF APPROVAL:

Initial authorization: 12 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

N/A

AGE RESTRICTIONS:

Functional Constipation (Linzess only): 6 to 17 years of age

All other indications: 18 years of age and older

QUANTITY:

Amitiza, lubiprostone:

CIC and OIC: 24mcg twice daily

IBS-C: 8mcg twice daily

lbsrela:

IBS-C: 50mg twice daily

Linzess:

IBS-C: 290 mcg once daily

CIC: 145 mcg or 72 mcg once daily

FC: 72 mcg once daily

Motegrity:

CIC: 2mg once daily

Movantik:

OIC: 25 mg once daily

Relistor:

OIC Chronic Non-cancer Pain: 450 mg (tablet) once daily OR 12 mg (subcutaneously) once daily

OIC Advanced Illness (injection only): Recommended dose every other day, no more frequently than one dose every 24 hours

<38kg: 0.15 mg/kg

Molina Healthcare, Inc. confidential and proprietary © 2024

This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.

Drug and Biologic Coverage Criteria

38 kg to <62 kg: 8 mg
62 kg to 114 kg: 12 mg
>114 kg: 0.15 mg/kg

Symproic:

OIC: 0.2 mg once daily

Trulance:

CIC and IBS-C: 3mg once daily

Maximum Quantity Limits –

Amitiza, lubiprostone, lsbrela: #60 per 30 days

Linzess, Motegrity, Movantik, Relistor (tablets), Symproic, Trulance: #30 per 30 days

PLACE OF ADMINISTRATION:

The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

The recommendation is that injectable medications in this policy will be for pharmacy or medical benefit coverage and the subcutaneous injectable products administered in a place of service that is a non- hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Oral, Subcutaneous

DRUG CLASS:

Gastrointestinal Chloride Channel Activators, CIC Agents - Guanylate Cyclase-C (GC-C) Agonists, IBS Agent - Guanylate Cyclase-C (GC-C) Agonists, IBS Agent - Sodium/Hydrogen Exchanger 3 (NHE3) Inhibitor, 5-HT4 Receptor Agonists, Peripheral Opioid Receptor Antagonists

FDA-APPROVED USES:

Amitiza (lubiprostone) is indicated for chronic idiopathic constipation (CIC) in adults, 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, and irritable bowel syndrome with constipation (IBS-C) in women ≥ 18 years old

Limitations of use: Effectiveness of Amitiza in the treatment of OIC in patients taking diphenylheptane opioids (e.g., methadone) has not been established

lsbrela (tenapanor) is indicated for treatment of irritable bowel syndrome with constipation (IBS-C) in adults

Linzess (linaclotide) is indicated in adults for treatment of irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation (CIC), and functional constipation (FC) in pediatric patients 6 to 17 years of age

Motegrity (prucalopride) is indicated for the treatment of chronic idiopathic constipation (CIC) in adults

Movantik (naloxegol) is indicated for the 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

Relistor (methylalnaltrexone) tablets and injection are indicated for the treatment of opioid-induced constipation (OIC) in adults with chronic non-cancer pain, including patients with chronic pain related to

Molina Healthcare, Inc. confidential and proprietary © 2024

This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.

Drug and Biologic Coverage Criteria

prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation
Relistor (methylnaltrexone) injection is indicated for the treatment of OIC in adults with advanced illness or pain caused by active cancer who require opioid dosage escalation for palliative care

Symproic (naldemedine) is indicated for the 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

Trulance (plecanatide) is indicated in adults for treatment of chronic idiopathic constipation (CIC) and irritable bowel syndrome with constipation (IBS-C)

COMPENDIAL APPROVED OFF-LABELED USES:

Irritable bowel syndrome with constipation in males (Amitiza)

APPENDIX

APPENDIX:

Rome IV Diagnostic Criteria for Constipation

Must include two or more of the following criteria for diagnosis:

*Criteria should be fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis

- Straining during at least 25% of defecations
- Sensation of anorectal obstruction/blockage for at least 25% of defecations
- Lumpy or hard stools in at least 25% of defecations
- Manual maneuvers to facilitate at least 25% of defecations (e.g., digital evacuation, support of the pelvic floor)
- Sensation of incomplete evacuation for at least 25% of defecations
- Fewer than three spontaneous bowel movements per week
- Loose stools are rarely present without the use of laxatives

Rome IV Diagnostic Criteria for IBS-C

Must include two or more of the following criteria for diagnosis:

*Criteria should be fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis

- Recurrent abdominal pain on average at least 1 day/week in the last 3 months related to defecation
- Associated with a change in the frequency of stool
- Associated with a change in the form (appearance) of stool

IBS with predominant constipation (IBS-C):

- >25% of bowel movements with Bristol stool types 1 or 2
- <25% of bowel movements with Bristol stool types 6 or 7
- Patient reports that abnormal bowel movements are usually constipation

Rome IV Diagnostic Criteria for OIC

Loose stools are rarely present without the use of laxatives and must include two or more of the following criteria for diagnosis:

- Straining during more than 25% of defecations
- Lumpy or hard stools (Bristol Stool Form Scale 1-2) more than 25% of defecations
- Sensation of incomplete evacuation more than 25% of defecations
- Sensation of anorectal obstruction/blockage more than 25% of defecations
- Manual maneuvers to facilitate more than 25% of defecations (e.g., digital evacuation, support of the pelvic floor)
- Fewer than three SBM per week

Rome IV Diagnostic Criteria for Functional Constipation in a Child/Adolescent

Must include two or more of the following criteria for diagnosis:

*Criteria should be fulfilled at least once per week for a minimum of 1 month with insufficient criteria for a diagnosis of IBS

- Two or fewer defecations in the toilet per week in a child of a developmental age of at least 4 years
- At least one episode of fecal incontinence per week
- History of retentive posturing or excessive volitional stool retention
- History of painful or hard bowel movements
- Presence of a large fecal mass in the rectum
- History of large diameter stools which can obstruct the toilet
- After appropriate evaluation, the symptoms cannot be fully explained by another medical condition

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Irritable Bowel Syndrome with Constipation is a chronic functional gastrointestinal (GI) disorder that arises from an abnormal functioning of the GI tract, not from structural or biochemical abnormalities and it is characterized by chronic abdominal pain, bloating and altered appearance or frequency of bowel movements. First-line treatment consists of lifestyle modifications such as dietary modification (increasing fiber and fluid intake, gluten and lactose avoidance) and physical activity. Patients are then recommended to try various over-the-counter stool softeners, bulking agents, or stimulants. If treatment failure persists, then pro-secretory agents (i.e., lsbrela, Linzess, Amitiza, Trulance) can be initiated.

Chronic idiopathic constipation (CIC), defined as constipation in which the underlying cause is unknown, is a common and debilitating disease. First-line treatment consists of lifestyle modifications such as increasing fiber and fluid intake and exercise. Patients are then recommended to try various over-the-counter stool softeners, bulking agents, or stimulants. If treatment failure persists, then pro-secretory agents (i.e., Linzess, Amitiza, Trulance, Motegrity) can be initiated.

Opioid-induced bowel dysfunction refers to the set of gastrointestinal adverse effects associated with opioid therapy, including constipation. Constipation is by far the most common and debilitating gastrointestinal effect of opioids, and some degree of constipation is near universal in patients taking opioid medications. The term opioid-induced constipation refers simply to constipation that is a result of opioid therapy. In addition to the Rome IV diagnostic criteria, a consensus definition of OIC is “a change when initiating opioid therapy from baseline bowel habits that is characterized by any of the following: reduced bowel movement frequency, development or worsening of straining to pass bowel movements, a sense of incomplete rectal evacuation, or harder stool frequency.” The AGA recommends use of laxatives, including stool softeners, osmotic laxatives, lubricants, and stimulant laxatives, as first-line treatment agents. In patients with laxative refractory OIC, the AGA recommends naldemedine, naloxegol, and methylnaltrexone (i.e., Symproic, Movantik, Relistor). The AGA makes no recommendation for the use of lubiprostone (i.e., Amitiza) due to evidence gap.

Functional constipation is a common condition experienced by children and adolescents in which patients have infrequent bowel movements with hard stools that can be difficult or painful to pass. There is no known underlying organic cause and there are typically multiple contributing factors. The efficacy of Linzess for the treatment of functional constipation in pediatric patients 6 to 17 years of age was established in a 12-week double-blind, placebo-controlled, randomized, multicenter clinical trial (NCT04026113) and supported by efficacy data from adequate and well-controlled trials in adults with chronic idiopathic constipation (constipation that persists and isn't connected to an underlying illness). For enrollment in the pediatric clinical trial, Rome III diagnostic criteria for functional constipation were modified to require that patients have less than three spontaneous bowel movements (SBMs) per week

Drug and Biologic Coverage Criteria

(defined as a BM that occurred in the absence of laxative, enema, or suppository use on the calendar day of or before the BM) and one or more of the following criteria at least once per week for at least two months before the screening visit:

- History of stool withholding or excessive voluntary stool retention
- History of painful or hard bowel movements (BMs)
- History of large diameter stools that may obstruct the toilet
- Presence of a large fecal mass in the rectum
- At least one episode of fecal incontinence per week

The primary efficacy endpoint was a 12-week change from baseline in SBM frequency rate. Patients who received Linzess experienced a greater improvement in the average number of SBMs per week than patients who received placebo. SBM frequency improved during week one and was maintained throughout the remainder of the 12-week treatment period. The most common adverse reaction reported in pediatric patients 6 to 17 years of age with functional constipation is diarrhea.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of the products affected are considered experimental/investigational and therefore, will follow Molina's Off- Label policy.

Contraindications to Amitiza (lubiprostone), lubiprostone include: Patients with known or suspected mechanical gastrointestinal obstruction

Contraindications to Ibsrela (tenapanor) include: Pediatric patients less than 6 years of age, and patients with known or suspected mechanical gastrointestinal obstruction

Contraindications to Linzess (linaclotide) include: Patients with known or suspected mechanical gastrointestinal obstruction, patients less than 2 years of age

Contraindications to Motegrity (prucalopride) include: hypersensitivity to Motegrity, Intestinal perforation or obstruction due to structural or functional disorder of the gut wall, obstructive ileus, severe inflammatory conditions of the intestinal tract such as Crohn's disease, ulcerative colitis, and toxic megacolon/megarectum

Contraindications to Movantik (naloxegol) include: Patients with known or suspected gastrointestinal obstruction and at risk of recurrent obstruction, concomitant use with strong CYP3A4 inhibitors (e.g., clarithromycin, ketoconazole), and known serious or severe hypersensitivity reaction to Movantik or any of its excipients.

Contraindications to Relistor (methylnaltrexone) include: Patients with known or suspected mechanical gastrointestinal obstruction and at increased risk of recurrent obstruction

Contraindications to Symproic (naldemedine) include: Patients with known or suspected gastrointestinal obstruction or at increased risk of recurrent obstruction, and patients with a history of a hypersensitivity reaction to naldemedine

Contraindications to Trulance (plecanatide) include: Patients less than 6 years of age due to the risk of serious dehydration, and patients with known or suspected mechanical gastrointestinal obstruction

OTHER SPECIAL CONSIDERATIONS:

Motegrity (prucalopride) has a warning for suicidal ideation and behavior and recommends patients be monitored for suicidal ideation and behavior as well as self-injurious ideation and new-onset or worsening of depression. Patients should discontinue Motegrity immediately and contact their healthcare provider if they experience any unusual changes in mood or behavior, or they experience emerging suicidal thoughts or behaviors.

Ibsrela (tenapanor) has a black box warning for risk of serious dehydration in pediatric patients.

Drug and Biologic Coverage Criteria

Trulance (plecanatide) has a black box warning for risk of serious dehydration in pediatric patients.

Linzess (linaclotide) has a black box warning for risk of serious dehydration in pediatric patients less than 2 years of age.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPSC CODE	DESCRIPTION
J2212	Injection, methylnaltrexone, 0.1 mg

AVAILABLE DOSAGE FORMS:

Amitiza CAPS 8MCG, 24MCG

Ibsrela TABS 50MG

Linzess CAPS 72MCG, 145MCG, 290MCG

Lubiprostone CAPS 8MCG, 24MCG

Motegrity TABS 1MG, 2MG

Movantik TABS 12.5MG, 25MG

Relistor SOLN 8MG/0.4ML, 12MG/0.6ML

Relistor TABS 150MG

Symproic TABS 0.2MG

Trulance TABS 3MG

REFERENCES

1. Amitiza (lubiprostone) [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals America; November 2020.
2. Ibsrela (tenapanor) [prescribing information]. Waltham, MA: Ardelyx Inc; April 2022.
3. Linzess (linaclotide) [prescribing information]. Madison, NJ: Allergan USA, Inc; June 2023.
4. Motegrity (prucalopride) [package insert]. Lexington, MA: Shire Pharmaceuticals, Inc; November 2020.
5. Movantik (naloxegol) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals; March 2023.
6. Relistor [package insert]. Raleigh, NC: Salix Pharmaceuticals. April 2020.
7. Symproic (naldemedine) [prescribing information]. Raleigh, NC: BioDelivery Sciences International, Inc; May 2020.
8. Bharucha A, Dorn S, Lembo A. 'American Gastroenterological Association medical position statement on constipation. *Gastroenterology*. 2013 Jan;144(1):211-7.
9. Bharucha AE, Pemberton JH, Locke GR. American Gastroenterological Association technical review on constipation. *Gastroenterology* 2013;144:218–238.
10. Ford AC, Moayyedi P, Lacy BE, et al; Task Force on the Management of Functional Bowel Disorders. American College of Gastroenterology monograph on the management of irritable bowel syndrome and chronic idiopathic constipation. *Am J Gastroenterol*. 2014 Aug;109 Suppl 1:S2-26.
11. American Gastroenterological Association Institute Guideline on the Medical Management of Opioid-Induced Constipation. Crockett SD, Greer KB, Heidelbaugh JJ, Falck-Ytter Y, Hanson BJ, Sultan S, American Gastroenterological Association Institute Clinical Guidelines Committee. *Gastroenterology*. 2019;156(1):218. Epub 2018 Oct 16.
12. Paquette IM, Varma M, Ternent C, et al. The American Society of Colon and Rectal Surgeons' Clinical

Molina Healthcare, Inc. confidential and proprietary © 2024

This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed, or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.

Drug and Biologic Coverage Criteria

- Practice Guideline for the Evaluation and Management of Constipation. *Diseases of the Colon & Rectum*. 2016;59(6):479-492. doi:10.1097/dcr.0000000000000599.
13. Weinberg DS, Smalley W, Heidelbaugh JJ, Sultan S. American Gastroenterological Association Institute Guideline on the Pharmacological Management of Irritable Bowel Syndrome. *Gastroenterology*. 2014;147(5):1146-1148. doi:10.1053/j.gastro.2014.09.001.
 14. Drossman DA, Hasler WL. Rome IV-Functional GI Disorders: Disorders of Gut- Brain Interaction. *Gastroenterology*. 2016;150(6):1257-61.
 15. Palsson OS, Whitehead WE, Van tilburg MA, et al. Rome IV Diagnostic Questionnaires and Tables for Investigators and Clinicians. *Gastroenterology* 2016.
 16. Crockett, S. D., Greer, K. B., Heidelbaugh, J. J., Falck-Ytter, Y., Hanson, B. J., & Sultan, S. (2019). American Gastroenterological Association Institute guideline on the Medical Management of opioid-induced constipation. *Gastroenterology*, 156(1), 218-226. doi:10.1053/j.gastro.2018.07.016
 17. Tabbers, M. M., DiLorenzo, C., Berger, M. Y., Faure, C., Langendam, M. W., Nurko, S., ... Benninga, M. A. (2014). Evaluation and Treatment of Functional Constipation in Infants and Children. *Journal of Pediatric Gastroenterology and Nutrition*, 58(2), 265–281. <https://doi.org/10.1097/mpg.0000000000000266>
 18. Chang, L., Sultan, S., Lembo, A., Verne, G. N., Smalley, W., & Heidelbaugh, J. J. (2022). AGA Clinical Practice Guideline on the Pharmacological Management of Irritable Bowel Syndrome With Constipation. *Gastroenterology*, 163(1), 118–136. <https://doi.org/10.1053/j.gastro.2022.04.016>
 19. Chang, L., Chey, W. D., Imdad, A., Almario, C. V., Bharucha, A. E., Diem, S., ... Sultan, S. (2023). American Gastroenterological Association-American College of Gastroenterology Clinical Practice Guideline: Pharmacological Management of Chronic Idiopathic Constipation. *Gastroenterology*, 164(7), 1086–1106. <https://doi.org/10.1053/j.gastro.2023.03.214>

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Products Affected Required Medical Information Continuation of Therapy Contraindications/Exclusions/Discontinuation References	Q1 2024
REVISION- Notable revisions: Required Medical Information Age Restrictions Quantity FDA-Approved Uses Appendix Background References	Q3 2023
NEW CRITERIA CREATION	Q1 2023