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Policy Number: C24671-A

Constipation Agents

PRODUCTS AFFECTED

Amitiza (lubiprostone), Ibsrela (tenapanor), Linzess (linaclotide), lubiprostone, Motegrity (prucalopride), Movantik (naloxegol), prucalopride, Relistor (methylnaltrexone), Symproic (naldemedine), Trulance (plecanatide)
*Xphozah (tenapanor) – SEE XPHOZAH (TENAPANOR) MHI C27292-A

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, Functional constipation in pediatrics

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. This clinical policy will be reviewed along with state and federal requirements, the benefit being administered, and formulary preferencing. 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. 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. The Pharmacy and

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Therapeutics Committee has determined that biosimilars may be preferred.

A. FOR ALL INDICATIONS:

1. Prescriber attests the requested agent will not be used in combination with other functional gastro-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 THIS IS A 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/PDL alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s).
   MOLINA REVIEWER NOTE: For Illinois Marketplace, please see Appendix.

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

1. Documented diagnosis of IBS-C
   AND
2. 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)

C. 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,

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support of the pelvic floor)
(e) Sensation of incomplete evacuation for at least 25% of defecations
(f) Fewer than three spontaneous bowel movements per week
(g) Loose stools are rarely present without the use of laxatives
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, magnesium oxide, lactulose); OR At least one bulk- forming laxative (e.g. psyllium or methylcellulose)

D. 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

E. 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

F. 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.)
AND
3. Documentation of trial/failure (2 week trial for each agent), FDA labeled contraindication, or

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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:

None

AGE RESTRICTIONS:

Functional Constipation (Linzess only): 2 to 17 years of age
Irritable Bowel Syndrome with Constipation (IBS-C) LINZESS ONLY: 7 years of age and older
All other indications: 18 years of age and older

QUANTITY:

Amitiza, lubiprostone:
CIC and OIC: 24mcg twice daily
IBS-C: 8mcg twice daily

Ibsrela:
IBS-C: 50mg twice daily

Linzess:
IBS-C:
Adults: 290 mcg once daily
Pediatrics 7 and older: 145 mcg once daily
CIC: 145 mcg or 72 mcg once daily
FC: 72 mcg once daily

Motegrity, prucalopride:
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

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<38kg: 0.15 mg/kg
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

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 the treatment of 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.*

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

Linzess (linaclotide) is indicated for treatment of irritable bowel syndrome with constipation (IBS-C) in adults and pediatric patients 7 years of age and older, chronic idiopathic constipation (CIC) in adults, and functional constipation (FC) in pediatric patients 2 years of age and older.

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 (methylnaltrexone) 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 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

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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

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

State Specific Information State Marketplace
Illinois (Source: Illinois General Assembly)
"(215 ILCS 134/45.1) Sec. 45.1. Medical exceptions procedures required. (c) An off-formulary exception request shall not be denied if: (1) the formulary prescription drug is contraindicated; (2) the patient has tried the formulary prescription drug while under the patient's current or previous health insurance or health benefit plan and the prescribing provider submits evidence of failure or intolerance; or (3) the patient is stable on a prescription drug selected by his or her health care provider for the medical condition under consideration while on a current or previous health insurance or health benefit plan. (d) Upon the granting of an exception request, the insurer, health plan, utilization review organization, or other entity shall authorize the coverage for the drug prescribed by the enrollee's treating health care provider, to the extent the prescribed drug is a covered drug under the policy or contract up to the quantity covered. (e) Any approval of a medical exception request made pursuant to this Section shall be honored for 12 months following the date of the approval or until renewal of the plan."

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

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- <25% of bowel movements with Brisol 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., Ibsrela, 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,

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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 (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.

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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.

Contraindications/Exclusions:
Diagnosis of IBS-C should include ruling out of IBS-C organic disease (alarm symptoms), dys-synergic defecation, IBS-D or slow colonic transit. Diagnosis of any of these concurrently is an exclusion.
Diagnosis of CIC should include ruling out secondary causes of chronic constipation (e.g., drug-induced constipation, IBS-C, Inflammatory bowel disease, colorectal cancer, hypothyroidism, electrolyte imbalances). Diagnosis of any of these concurrently is an exclusion.
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.

OTHER SPECIAL CONSIDERATIONS:
Ibsrela (tenapanor) 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.
Trulance (plecanatide) has a Black Box Warning for risk of serious dehydration in pediatric patients.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS 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
Prucalopride Succinate TABS 1MG, 2MG
Relistor SOLN 12MG/0.6ML

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3. Linzess (linaclotide) capsules, for oral use [prescribing information]. Madison, NJ: Allergan USA, Inc; May 2026.
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5. Movantik (naloxegol) tablets, for oral use [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals; March 2023.
6. Relistor tablets, for oral use; injection, for subcutaneous use [prescribing information]. Raleigh, NC: Salix Pharmaceuticals; May 2024.
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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Diagnosis Age Restrictions FDA-Approved Uses References	Q3 2026
REVISION- Notable revisions: Required Medical Information Age Restrictions FDA-Approved Uses Contraindications/Exclusions/Discontinuation Available Dosage Forms References	Q1 2026
REVISION- Notable revisions: References	Q1 2025
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

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