

Pharmacy Policy Bulletin: J-0502 Relistor (methylnaltrexone bromide) – Commercial and Healthcare Reform	
Number: J-0502	Category: Prior Authorization
Line(s) of Business: <input checked="" type="checkbox"/> Commercial <input checked="" type="checkbox"/> Healthcare Reform <input type="checkbox"/> Medicare	Benefit(s): Commercial: Prior Authorization (1.): 1. Other Managed Prior Authorization = Yes w/ Prior Authorization Healthcare Reform: Not Applicable
Region(s): <input checked="" type="checkbox"/> All <input type="checkbox"/> Delaware <input type="checkbox"/> New York <input type="checkbox"/> Pennsylvania <input type="checkbox"/> West Virginia	Additional Restriction(s): None
Version: J-0502-012	Original Date: 09/07/2016
Effective Date: 04/25/2025	Review Date: 04/09/2025

Drugs Product(s):	<ul style="list-style-type: none"> Relistor (methylnaltrexone bromide)
FDA-Approved Indication(s):	<ul style="list-style-type: none"> Relistor Tablets: <ul style="list-style-type: none"> 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 (for example weekly) opioid dosage escalation. Relistor Injection: <ul style="list-style-type: none"> Treatment of 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 (weekly., weekly) opioid dosage escalation. Treatment of OIC in adults with advanced illness or pain caused by active cancer who require opioid dosage escalation for palliative care.

Background:	<ul style="list-style-type: none"> Relistor is a therapeutic agent classified as a peripherally acting opioid antagonist, and therefore acts on the mu-opioid receptors in the gastrointestinal tract. By acting as an antagonist in the gastrointestinal tract, Relistor is effective against OIC without impacting opioid-mediated analgesic effects on the central nervous system (CNS). Constipation is a common side effect of opioids that patients do not develop tolerance to. The 2019 American Gastroenterological Association (AGA) medical management of OIC guideline recommends: <ul style="list-style-type: none"> Traditional laxatives as first-line agents (strong recommendation, moderate quality of evidence). Examples of traditional laxatives include osmotic laxatives (for example lactulose, magnesium citrate, polyethylene glycol), stimulant laxatives (for example bisacodyl, senna), stool softeners (for example docusate), and lubricant laxatives (for example mineral oil) In patients with laxative refractory OIC, Symproic (strong recommendation, high quality of evidence), Movantik (strong recommendation, moderate
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	<p>quality of evidence), or Relistor (conditional recommendation, low quality of evidence) over no treatment.</p> <ul style="list-style-type: none"> ○ The AGA makes no recommendation for the use of Amitiza (lubiprostone) or Motegrity in OIC (evidence gap). ● The Rome IV definition for OIC is the following: new or worsening symptoms of constipation when initiating, changing, or increasing opioid therapy that must include two (2) or more of the following: <ol style="list-style-type: none"> 1. Straining during more than 25% of defecations 2. Lumpy or hard stools more than 25% of defecations 3. Sensation of incomplete evacuation more than 25% of defecations 4. Sensation of anorectal obstruction/blockage more than 25% of defecations 5. Manual maneuvers to facilitate more than 25% of defecations (e.g., digital evacuation, support of the pelvic floor) 6. Fewer than 3 spontaneous bowel movements per week ● An adequate response to OIC therapy is defined as 3 or more spontaneous bowel movements (SMB) per week, with an increase of 1 or more SBM/week over baseline, for 3 or more of the first 4 weeks of the treatment period. A SBM was defined as a bowel movement without the use of a laxative for 24 hours. ● Patients receiving Relistor tablets experienced a 13% increase in response rate compared to patients receiving placebo. ● ICD-10 K59.09 code for other constipation may also be accepted if patients are on a concurrent opioid medication. ● Prescribing Information: <ul style="list-style-type: none"> ○ In adult patients with chronic non-cancer pain and OIC, patients receiving opioids for less than 4 weeks may be less responsive to Relistor. ○ Discontinue Relistor if treatment with an opioid pain medication is discontinued. ○ Relistor is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction and at increased risk of recurrent obstruction.
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Approval Criteria

I. Initial Authorization

A. Relistor Tablets

When a benefit, coverage of Relistor tablets may be approved when all of the following criteria are met (**1. through 5.**):

1. The member is 18 years of age or older.
2. The member meets one (1) of the following criteria (**a. or b.**):
 - a. The member has a diagnosis of OIC (ICD-10: K59.03) due to chronic non-cancer pain.
 - b. The member has a diagnosis of OIC (ICD-10: K59.03) due to chronic pain related to prior cancer or its treatment and does not require frequent (for example weekly) opioid dosage escalation.
3. The member has been taking opioid medications for at least one month.
4. The member has experienced therapeutic failure, contraindication, or intolerance to scheduled dosing of one (1) laxative.
5. The member has experienced therapeutic failure, contraindication, or intolerance to all of the following plan-preferred products (**a., b., and c.**):
 - a. Movantik
 - b. generic lubiprostone
 - c. Symproic

B. Relistor Subcutaneous Injection

When a benefit, coverage of Relistor subcutaneous injection may be approved when all of the following criteria are met **(1. through 5.)**:

1. The member is 18 years of age or older.
2. The member meets one (1) of the following criteria **(a., b., or c.)**:
 - a. The member has a diagnosis of OIC (ICD-10: K59.03) due to chronic non-cancer pain.
 - b. The member has a diagnosis of OIC (ICD-10: K59.03) due to chronic pain related to prior cancer or its treatment and does not require frequent (for example weekly) opioid dosage escalation.
 - c. The member has a diagnosis of OIC (ICD-10: K59.03) and advanced illness or pain caused by active cancer and requires opioid dosage escalation for palliative care.
3. The member has been taking opioid medications for at least one month.
4. The member has experienced therapeutic failure, contraindication, or intolerance to scheduled dosing of one (1) laxative.
5. The member has experienced therapeutic failure, contraindication, or intolerance to all of the following plan-preferred products **(a., b., and c.)**:
 - a. Movantik
 - b. generic lubiprostone
 - c. Symproic

II. Reauthorization

When a benefit, reauthorization of Relistor may be approved when the following criterion is met **(A.)**:

- A. The provider attests that the member has experienced positive clinical response to therapy.

- III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

- I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
- II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. American Gastroenterological Association Institute Guideline on the Medical Management of Opioid-Induced Constipation. *Gastroenterology*. 2019 Jan;156(1):218-226.
2. Relistor [package insert]. Bridgewater, NJ: Salix Pharmaceuticals, a division of Valeant Pharmaceuticals North America LLC; March 2018.

Pharmacy policies do not constitute medical advice, nor are they intended to govern physicians' prescribing or the practice of medicine. They are intended to reflect the plan's coverage and reimbursement guidelines. Coverage may vary for individual members, based on the terms of the benefit contract.

The plan retains the right to review and update its pharmacy policy at its sole discretion. These guidelines are the proprietary information of the plan. Any sale, copying or dissemination of the pharmacy policies is prohibited; however, limited copying of pharmacy policies is permitted for individual use.