

PHARMACY POLICY STATEMENT

Indiana Medicaid

DRUG NAME	Relistor (methylnaltrexone)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include stool softeners, bulk forming laxatives, osmotic laxatives, stimulant laxatives, lubricant laxatives QUANTITY LIMIT— 90 tablets per 30 days, or 30 pre-filled syringes per 30 days (15 syringes or single-dose vials in cancer/advanced illness)
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Relistor (methylnaltrexone) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

OPIOID-INDUCED CONSTIPATION (OIC)

For **initial** authorization:

1. Member is 18 years old or older, with diagnosis of OIC; AND
2. One of the following:
 - a) Member has been receiving opioids for non-cancer pain for longer than 4 weeks, and does **not** require frequent (e.g., weekly) opioid dosage escalation;
 - b) Member has diagnosis of an advanced illness or active cancer; AND
3. Medication must be prescribed by or in consultation with a gastroenterologist, oncologist, palliative care or pain management specialist; AND
4. One of the following:
 - a) Member is unable to swallow oral medications, and has a documented 4-day trial and failure of ALL of the following:
 - i) Suppository of glycerin or bisacodyl;
 - ii) Enema of sodium phosphate, glycerin, mineral oil, or docusate;
 - iii) Enema of bisacodyl; OR
 - b) Member is able to swallow oral medication, and has a documented 4-day trial and failure of ALL of the following:
 - i) A bulk forming laxative (e.g., psyllium, methylcellulose);
 - ii) An osmotic agent (e.g., polyethylene glycol, lactulose);
 - iii) A stimulant laxative (e.g., bisacodyl, sennosides);
 - iv) A stool softener (e.g., docusate);
 - v) A lubricant laxative (e.g., mineral oil);
 - vi) Amitiza (lubiprostone) (requires prior authorization);
 - vii) Symproic (naldemedine) (requires prior authorization);
 - viii) Movantik (naloxegol) (requires prior authorization); AND
5. Member does NOT have a known or suspected mechanical gastrointestinal obstruction.

6. **Dosage allowed:** For OIC in non-cancer pain: oral tablet 450 mg once daily in the morning or subcutaneous injection 12 mg once daily. For OIC in advanced illness or cancer: up to 12 mg every other day as needed subcutaneously.

Note: Relistor oral tablet is not indicated for OIC in advanced illness.

If member meets all the requirements listed above, the medication will be approved for 3 months.

For **reauthorization:**

1. Member meets all initial authorization criteria; AND
2. Member has not experienced severe or persistent diarrhea during treatment; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of constipation.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.

CareSource considers Relistor (methylnaltrexone) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
05/20/2019	New policy for Relistor created.

References:

1. ClinicalTrials.gov. Identifier NCT01186770. A study of oral methylnaltrexone (MNTX) for the treatment of opioid-induced constipation in subjects with chronic, non-malignant pain. Available: clinicaltrials.gov/ct2/show/NCT01186770.
2. ClinicalTrials.gov. Identifier NCT01004393. Methylnaltrexone for opioid-induced constipation in cancer patients. Available: clinicaltrials.gov/ct2/show/NCT01004393.
3. ClinicalTrials.gov. Identifier NCT00672477. Study evaluating subcutaneous methylnaltrexone for treatment of opioid-induced constipation in patients with advanced illness. Available: clinicaltrials.gov/ct2/show/NCT00672477.
4. Crockett SD, et al. American gastroenterological association institute guideline on the medical management of opioid-induced constipation. *Gastroenterology*. 2019 Jan 1;156(1):218-26.
5. Nee J, et al. Efficacy of treatments for opioid-Induced constipation: systematic review and meta-analysis. *Clinical Gastroenterology and Hepatology*. 2018 Oct 1;16(10):1569-84.
6. Relistor [prescribing information]. Bridgewater, NJ: Salix Pharmaceuticals Inc. 2018 Mar.

Effective date: 10/01/2019

Revised date: 05/20/2019