

PHARMACY POLICY STATEMENT Kentucky 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 <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

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](http://clinicaltrials.gov/ct2/show/NCT01186770).
2. ClinicalTrials.gov. Identifier NCT01004393. Methylnaltrexone for opioid-induced constipation in cancer patients. Available: [clinicaltrials.gov/ct2/show/NCT01004393](http://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](http://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: 07/01/2019

Revised date: 05/20/2019