| **Methylnaltrexone (Relistor®)** | **Place of Service**<br>**Home Health Administration**<br>**Self Administration**<br>May be covered under the pharmacy benefit<br><br>**HCPC**: J2212 per 0.1mg |
|---|---|

**Conditions listed in policy (*see criteria for details*)**

- Opioid-induced constipation in patients with advanced illness
- Opioid-induced constipation in patients with chronic non-cancer pain

**AHFS therapeutic class:** GI Drugs, Miscellaneous

**Mechanism of action:** Methylnaltrexone is a peripherally-acting opioid receptor antagonist.

## (1) Special Instructions and pertinent Information

**If member is enrolled in hospice,** methylnaltrexone should be covered under the hospice benefit.
**If member is not enrolled in hospice and has a Prescription Benefit,** please refer cases to Pharmacy Services for prior authorization.

**If member is not enrolled in hospice and is covered under the Medical Benefit,** please submit clinical information for prior authorization review via fax. **Please include medical rationale why medication cannot be home self-administered.**

## (2) Prior Authorization/Medical Review is required for the following condition(s)

**All requests for Relistor® (methylnaltrexone) must be sent for clinical review and receive authorization prior to drug administration or claim payment.**

**Opioid-induced constipation**

- Diagnosis is opioid-induced constipation, AND
- Patient is receiving palliative (end of life) care or in hospice

**Covered Doses**
Up to 0.15mg/kg SC injection per day

**Coverage Period**
Cover yearly

**ICD-10:**
K59.00

**Opioid-induced constipation in chronic non-cancer pain**

- History of constipation due to opioid use for chronic non-cancer pain AND
- Patient is at least 18 years of age, AND
- Inadequate response or intolerable side effect to two laxative agents, including a hyperosmotic agent, AND
- ***Effective July 31, 2018***: Inadequate response, intolerable side effect, or contraindication to Movantik

**Covered Doses**
Up to 12mg SC injection per day

**Coverage Period**
**Initial:** 3 months
**Reauthorization:** 3 months based on initial or continued response and continued need for treatment (e.g. patient remains on opioid treatment)

**ICD-10:**
K59.00

**(3) The following condition(s) DO NOT require Prior Authorization/Preservice**
**All requests for Relistor® (methylnaltrexone) must be sent for clinical review and receive authorization prior to drug administration or claim payment.**

**(4) This Medication is NOT medically necessary for the following condition(s)**
Blue Shield's research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21):

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication**.**

Please refer to the Provider Manual and User Guide for more information.

**(5) Additional Information**

How supplied:

- 12mg/0.6ml vial
- 8mg/0.4ml syringes
- 12mg/0.6ml syringes

| Weight | Dose | SC Injection Volume |
|---|---|---|
| **< 38 kg** | 0.15 mg/kg | [Pt weight(kg) x 0.0075] and round up to nearest 0.1 ml |
| **38 kg to < 62 kg** | 8 mg | 0.4 mL (1 vial) |
| **62 kg to 114 kg** | 12 mg | 0.6 mL (1 vial) |
| **> 114 kg** | 0.15 mg/kg | [Pt weight(kg) x 0.0075] and round up to nearest 0.1 ml |

## (6) References


- Relistor® package insert. Salix Pharmaceuticals, Inc. 2017.
- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.thomsonhc.com
  1. Up to Date, Cancer Pain Management with opioids: Prevention and management of side effects. Portenoy R, et al. May 23, 2016.
  2. Hernon CM, Jackson KC, and Hallin PA. Management of opioid-Induced gastrointestinal effects in patients receiving palliative care. Pharmacotherapy 2002; 22(2):240-250.
  3. Kumar L et al. Opioid0induced constipation: Pathophysiology, clinical consequences, and management. Gastroenterology Research and Practice 2014; article ID 141737. Available at: http://www.hindawi.com/journals/grp/2014/141737/


## (7) Policy Update

Date of last revision: 2Q2018
Date of next review: 3Q2018
Changes from previous policy version:

- Section (2): Opioid-induced constipation (OIC) in chronic non-cancer pain –
  - Removed requirement for an inadequate response, intolerable side effect, or contraindication to Amitiza. Removed criteria requirements of less than 3 bowel movements per week, and that obstructive etiology for constipation is ruled out.
  - Added requirement Effective July 31, 2018: Inadequate response, intolerable side effect, or contraindication to Movantik.
    *Rationale: More cost-effective alternative available*

*BSC Drug Coverage Criteria to Determine Medical Necessity*
*Reviewed by P&T Committee*