Relistor (methylnaltrexone bromide)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Relistor tablets and Relistor injection are 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 injection is indicated for the treatment of opioid-induced constipation (OIC) in adult patients with advanced illness or pain caused by active cancer who require opioid dosage escalation for palliative care.

POLICY

Exclusions

Coverage will not be provided for patients with known or suspected mechanical gastrointestinal obstruction or is at an increased risk of recurrent obstruction due to the potential for gastrointestinal perforation.

Criteria for Approval

I. Relistor injection may be considered **medically necessary** when the following criteria are met:
   - Relistor is being prescribed for opioid-induced constipation in an adult patient with advanced illness or pain caused by active cancer who require opioid escalation for palliative care

   OR

- Relistor is being prescribed for opioid-induced constipation in an adult patient 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
  - The patient is unable to tolerate oral medications
    OR
  - The patient experienced an inadequate treatment response or intolerance to Movantik at optimal therapeutic dosages
    OR
  - The patient has a documented clinical reason such as expected adverse reaction or contraindication that prevents them from trying Movantik

Approval will be for **4 months**

II. Relistor tablets may be considered **medically necessary** when the following criteria are met:
- Relistor is being prescribed for opioid-induced constipation in an adult patient 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
  - The patient experienced an inadequate treatment response or intolerance to Movantik at optimal therapeutic dosages
    OR
  - The patient has a documented clinical reason such as expected adverse reaction or contraindication that prevents them from trying Movantik

Approval will be for **4 months**

Dosing and Administration
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits
- Relistor 8mg/0.4mL & 12mg/0.6mL = 30 injections per 30 days

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.
- Code(s), if applicable

REFERENCES

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- Clemens KE and Klaschik E. Management of Constipation in Palliative Care Patients. Therapeutics and Clinical Risk Management 2010;6:77–82.
- Swegle M and Logemann C. Management of Common Opioid-Induced Adverse Effects. Am Fam Physician 2006;74:1347-1354.

- Nelson AD and Camilleri M. Opioid-induced constipation: advances and clinical guidance. Ther Adv Chronic Dis 2016;7(2):121-134.
- Waldemar S and Becker G. Methylnaltrexone for opioid-induced constipation: review and meta-analysis for objective plus subjective efficacy and safety outcomes. Therapeutics and Clinical Risk Management 2016;12:401-412.
- Webster LR, Michna E, Khan A, et al. Long-term safety and efficacy of subcutaneous methylnaltrexone in patients with opioid-induced constipation and chronic noncancer pain: a phase 3, open-label trial. Pain Medicine 2017;18:1496-1504.

*Some content reprinted from CVSHealth

POLICY HISTORY

Policy #: 05.01.108
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