

Initial Prior Authorization

Relistor

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Relistor	methylnaltrexone bromide

Indications

FDA-approved Indications

Opioid-Induced Constipation in Adult Patients with Chronic Non-Cancer Pain

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.

Opioid-Induced Constipation in Adult Patients with Advanced Illness

Relistor injection is indicated for the treatment of OIC in adult patients with advanced illness or pain caused by active cancer who require opioid dosage escalation for palliative care.

Coverage Criteria

Opioid-Induced Constipation (Advanced Pain/Active Cancer)

Authorization may be granted when the requested drug is being prescribed for opioid-induced constipation in an adult patient with advanced illness or pain caused by active cancer who requires opioid dosage escalation for palliative care and the following criteria is met:

- The request is for Relistor injection.

Opioid-Induced Constipation (Chronic Pain)

Authorization may be granted when the drug is being prescribed for opioid-induced constipation in an adult patient with chronic non-cancer pain, including chronic pain related to prior cancer or its treatment, who does NOT require frequent (e.g., weekly) opioid dosage escalation when ONE of the following criteria is met:

- The patient is unable to tolerate oral medications and the following criteria is met:
 - The request is for Relistor injection.
- The request is for Relistor injection and ALL of the following criteria are met:
 - The patient meets ONE of the following:
 - The patient has experienced an inadequate treatment response to ANY of the following: lubiprostone (Amitiza), naloxegol (Movantik), naldemedine (Symproic).
 - The patient has experienced an intolerance to ANY of the following: lubiprostone (Amitiza), naloxegol (Movantik), naldemedine (Symproic).
 - The patient has a contraindication that would prohibit a trial of ALL of the following: lubiprostone (Amitiza), naloxegol (Movantik), naldemedine (Symproic).
 - The patient meets ONE of the following:
 - The patient has experienced an inadequate treatment response to Relistor tablets.
 - The patient has experienced an intolerance to Relistor tablets.
- The request is for Relistor tablets and ONE of the following criteria is met:
 - The patient has experienced an inadequate treatment response to ANY of the following: lubiprostone (Amitiza), naloxegol (Movantik), naldemedine (Symproic).
 - The patient has experienced an intolerance to ANY of the following: lubiprostone (Amitiza), naloxegol (Movantik), naldemedine (Symproic).
 - The patient has a contraindication that would prohibit a trial of ALL of the following: lubiprostone (Amitiza), naloxegol (Movantik), naldemedine (Symproic).

Duration of Approval(DOA)

- 5138-A: DOA: 4 months

References

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3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 09/10/2024).
4. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Adult Cancer Pain. Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/pain.pdf. Accessed September 10, 2024.
5. Clemens KE, Klaschik E. Managing opioid-induced constipation in advanced illness: focus on methylnaltrexone bromide. *Ther Clin Risk Manag*. 2010;6:77-82.
6. Nelson AD, Camilleri M. Opioid-induced constipation: advances and clinical guidance. *Ther Adv Chronic Dis*. 2016;7(2):121-134.
7. Siemens W, Becker G. Methylnaltrexone for opioid-induced constipation: review and meta-analysis for objective plus subjective efficacy and safety outcomes. *Ther Clin Risk Manag*. 2016;12:401-412.
8. 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 Med*. 2017;18(8):1496-1504.
9. Crockett SD, Greer KB, Heidelbaugh JJ, et al. American Gastroenterological Association Institute Guideline on the Medical Management of Opioid-Induced Constipation. *Gastroenterology*. 2019;156(1):218-226.