Navigating Coverage

RELISTOR®
methylnaltrexone bromide
Tablets

Additional steps may be required to gain access to RELISTOR®. Use this guide to learn how to help your patients get what you prescribed.

Your RELISTOR Field Reimbursement Manager will provide education on:

- Prior authorization (PA) process
- Requirement for streamlined PA process
- How to avoid PA denials

INDICATION

- RELISTOR® (methylnaltrexone bromide) is an opioid antagonist. RELISTOR tablets are indicated for the treatment of opioid-induced constipation (OIC) in adults 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.

IMPORTANT SAFETY INFORMATION

- RELISTOR tablets are contraindicated in patients with known or suspected mechanical gastrointestinal obstruction and patients at increased risk of recurrent obstruction due to the potential for gastrointestinal perforation.
- Cases of gastrointestinal perforation have been reported in adult patients with opioid-induced constipation and advanced illness with conditions that may be associated with localized or diffuse reduction of structural integrity in the wall of the gastrointestinal tract (e.g., peptic ulcer disease, Ogilvie's syndrome, diverticular disease, infiltrative gastrointestinal tract malignancies, or peritoneal metastases). Take into account the overall risk-benefit profile when using RELISTOR in patients with these conditions or other conditions which might result in impaired integrity of the gastrointestinal tract wall (e.g., Crohn's disease). Monitor for the development of severe, persistent, or worsening abdominal pain; discontinue RELISTOR in patients who develop this symptom.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

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Prior authorization (PA)

Getting it right the first time

Start it

- Obtain PA form through health plan website, pharmacy, or CoverMyMeds
- Fill out the PA form detailing the necessity of RELISTOR
- Verify information is accurate and complete including chart documentation
- Suggested code ICD-10-CM code K59.03
- Include correct dosing of RELISTOR 450mg, three 150-mg tablets once daily[2]

Submit it

- Submit PA form to patient's insurance plan for review
- Follow up with the plan if you have not received an approval or denial in a timely manner
  - Electronic submission review may be immediate or take 2-3 days
  - Fax submission review may take 10-14 days

Monitor it

- Contact your Field Reimbursement Manager (FRM) for help with reviewing the PA outcome and next steps
- Inform the patient's pharmacy when PA is approved
- Be sure the patient has copay cards, if eligible,† and use it when filling their RELISTOR at the pharmacy

*The ICD-10-CM code and all other patient access-related information are provided for informational purposes only. It is the treating physician's responsibility to determine the proper diagnosis, treatment, and applicable ICD-10-CM code. Salix Pharmaceuticals does not guarantee coverage or reimbursement for the product.

†This offer is not valid for patients covered by Medicare, Medicaid, or any other federal or state funded healthcare program or where prohibited by law.

ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification.

IMPORTANT SAFETY INFORMATION (continued)

- If severe or persistent diarrhea occurs during treatment, advise patients to discontinue therapy with RELISTOR tablets and consult their healthcare provider.
- Symptoms consistent with opioid withdrawal, including hyperhidrosis, chills, diarrhea, abdominal pain, anxiety, and yawning have occurred in patients treated with RELISTOR tablets. Patients having disruptions to the blood-brain barrier may be at increased risk for opioid withdrawal and/or reduced analgesia and should be monitored for adequacy of analgesia and symptoms of opioid withdrawal.
- Avoid concomitant use of RELISTOR tablets with other opioid antagonists because of the potential for additive effects of opioid receptor antagonism and increased risk of opioid withdrawal.

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Common reasons for PA denial

REASON FOR DENIAL	CONSIDERATIONS FOR AVOIDING DENIAL
PA not completed or incorrect	Confirm PA, fill in missing or inaccurate documentation, check for administrative errors, and resubmit
Dosing does not match indication	Confirm dosing • RELISTOR 450 mg, three 150-mg tablets once daily (90 tablets/prescription)[2] • Please refer to full Prescribing Information for dosing adjustments
Invalid diagnosis code	Confirm ICD-10-CM code and resubmit • K59.03
Did not try and fail on a formulary alternative	Include information on why RELISTOR is necessary and appropriate for the patient
Product is a plan exclusion	Confirm coverage, as Medicare excludes certain drugs • RELISTOR is not in a Medicare-excluded category[3]

A LETTER OF MEDICAL EXCEPTION MAY BE REQUIRED. IF SO...

- Keep it concise
- Submit on practice letterhead
- Include patient name
- Include dosing: RELISTOR 450 mg, three 150-mg tablets once daily
- Specify diagnosis K59.03
- State your treatment rationale
- Include your name, signature, and date

Scan the QR code for more PA resources.

IMPORTANT SAFETY INFORMATION (continued)

- In a clinical study, the most common adverse reactions for RELISTOR tablets (≥ 2% of RELISTOR patients and at a greater incidence than placebo) in patients with chronic non-cancer pain were: abdominal pain (14%), diarrhea (5%), headache (4%), abdominal distention (4%), vomiting (3%), hyperhidrosis (3%), anxiety (2%), muscle spasms (2%), rhinorrhea (2%), and chills (2%).
- The use of RELISTOR tablets during pregnancy may precipitate opioid withdrawal in a fetus due to the immature fetal blood-brain barrier. Advise pregnant women of the potential risk to a fetus. Because of the potential for serious adverse reactions, including opioid withdrawal, in breastfed infants, advise women that breastfeeding is not recommended during treatment with RELISTOR tablets.

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Complete a PA with CoverMyMeds in 3 easy steps

- **Step 1: Create an account** with CoverMyMeds, or log into your existing account at covermymeds.com.
- **Step 2:** Shorten time to therapy by **creating a PA request** required for treatment, or complete a pharmacy-initiated request.
- **Step 3: Fill in medical details**, then click the button to electronically submit the request for plan determination.

Get signed up!

CoverMyMeds offers individual training to offices to assist with the PA submission process.

Live Chat/Request Training for a Sponsored Brand: covermymeds.com
Phone: 1-866-452-5017
Resources: go.covermymeds.com/help

covermymeds®

Scan the QR code for more PA resources.

IMPORTANT SAFETY INFORMATION (continued)

- A dosage reduction of RELISTOR tablets is recommended in patients with moderate and severe renal impairment (creatinine clearance less than 60 mL/minute as estimated by Cockcroft-Gault). No dosage adjustment of RELISTOR tablets is needed in patients with mild renal impairment.
- A dosage reduction of RELISTOR tablets is recommended in patients with moderate (Child-Pugh Class B) or severe (Child-Pugh Class C) hepatic impairment. No dosage adjustment of RELISTOR tablets is needed in patients with mild hepatic impairment (Child-Pugh Class A).

To report SUSPECTED ADVERSE REACTIONS, contact Salix Pharmaceuticals at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

REFERENCES: 1. ICD-10. Centers for Medicare & Medicaid Services. Updated October 1, 2024. Accessed February 11, 2025: https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=56632&ver=23&. **2.** RELISTOR. Prescribing Information. Salix Pharmaceuticals; 2024. **3.** Centers for Medicare and Medicaid Services. Information partners can use on: Medicare Drug Coverage under Medicare Part A, Part B, Part C, & Part D. https://www.cms. gov/outreach-and-education/outreach/partnerships/downloads/11315-p.pdf. Accessed February 11, 2025.

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