

Date: <Insert Date>

Attn: <Department>

<Name of health plan>

<Case ID Number if available>

Payer Address: <Insert plan address(es)>

Payer Fax Number: <Insert plan fax number(s)>

To Whom It May Concern:

I understand that the <Insert plan name> has decided not to provide coverage for RELISTOR® (methylnaltrexone bromide). However, I believe that <Insert patient name> requires RELISTOR® (methylnaltrexone bromide) without restriction due to clinical and medical circumstances. Please see below for details about the medical history and treatment rationale that supports the claim for this medical exception request.

Patient Information:

Patient's Name		Date of Birth
Patient's Address		
City	State	Zip Code
Member ID #	Policy or Group #	

- I need approval for a drug that is not on the plan's list of covered drugs
- I have been using a drug that was previously included on the plan's list of covered drugs, but is being removed or was removed from this list during the plan year
- I request an exception to the requirement that my patient try another drug before I can prescribe this drug

Medication: <input type="checkbox"/> Relistor Tablets: 450 mg methylnaltrexone bromide (3 x 150mg tablets) daily. Relistor Injection: <input type="checkbox"/> 8 mg/0.4 mL methylnaltrexone bromide in single-dose pre-filled syringe. <input type="checkbox"/> 12 mg/0.6 mL methylnaltrexone bromide in a single-dose pre-filled syringe, or single-dose vial.		
Date Started:	Expected Length of Therapy:	
Diagnosis – Please list all diagnoses being treated with the requested drug and corresponding ICD-10 codes. <input type="checkbox"/> K59.03 <input type="checkbox"/> _____		
Drug History: (for treatment of the condition(s) requiring the requested drug)		
Drug Tried	Dates of Drug Trials	Results of previous drug trials

JUSTIFICATION FOR REQUEST FOR MEDICAL EXCEPTION

Alternate drug(s) contraindicated or previously tried, but with adverse outcome, e.g. toxicity, allergy, or therapeutic failure.

Patient is stable on RELISTOR; high risk of significant adverse clinical outcome with medication change.

RELISTOR does not have any pharmacokinetic drug-drug interactions– Only Peripherally Acting Mu Opioid Receptor Antagonist that is not metabolized through the CYP3A4 pathway.

- No studied drug interactions with moderate CYP3A4 inhibitors (e.g. diltiazem, erythromycin, verapamil – common brand names: Cardizem®, Erythrocin®, Isoptin® SR)
- No studied drug interactions with strong CYP3A4 inhibitors (e.g. ketoconazole, itraconazole, clarithromycin – common brand names: Nizoral®, Sporanox®, Biaxin®)
- No studied drug interactions with moderate CYP3A4 inducers (e.g. nafcillin, bexarotene, dexamethasone – common brand names: Nallpen®, Targretin®, Hemady®)
- No studied drug interactions with strong CYP3A4 inducers (e.g. rifampin, carbamazepine, St. John’s Wort – common brand names: Rifadin®, Tegretol®)
- No studied interactions with grapefruit or grapefruit juice (potential CYP3A4 inhibitor)

Patient Is Currently Taking A CYP3A4 Inducer/Inhibitor (List Below): _____

RELISTOR Subcutaneous Injection - RELISTOR is the only Peripherally Acting Mu Opioid Receptor Antagonist in subcutaneous injection formulation. RELISTOR subcutaneous injection is the only Peripherally Acting Mu Opioid Receptor Antagonist indicated in adults with advanced illness or pain caused by active cancer who require opioid dosage escalation for palliative care.

Based on the above, I hope that you agree RELISTOR® (methylnaltrexone bromide) is an appropriate choice for my patient. A timely approval would be greatly appreciated by myself and my patient.

Please contact me at <Insert phone number> if you need more information to approve this medical exception.

Sincerely

<Insert Healthcare Provider Name>

<Insert Signature>

Enclosures: Consider including patient medical history, relevant state therapy legislation, notes and product prescribing information which can be found at www.relistorhcp.com

State Therapy Law Information (www.steptherapy.com) _____

FOR THE PRESCRIBERS BACKGROUND INFORMATION:

INDICATIONS

- RELISTOR® (methylnaltrexone bromide) is an opioid antagonist. RELISTOR tablets and RELISTOR injection 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.
- RELISTOR injection is also indicated for the treatment of OIC in adults with advanced illness or pain caused by active cancer who require opioid dosage escalation for palliative care.

IMPORTANT SAFETY INFORMATION

- RELISTOR tablets and injection 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.
- If severe or persistent diarrhea occurs during treatment, advise patients to discontinue therapy with RELISTOR 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. 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 with other opioid antagonists because of the potential for additive effects of opioid receptor antagonism and increased risk of opioid withdrawal.
- The use of RELISTOR during pregnancy may precipitate opioid withdrawal in a fetus due to the immature fetal blood-brain barrier and should be used during pregnancy only if the potential benefit justifies the potential risk to the 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. In nursing mothers, a decision should be made to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.
- A dosage reduction of RELISTOR tablets and RELISTOR injection 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 or RELISTOR injection 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). No dosage adjustment of RELISTOR injection is needed for patients with mild or moderate hepatic impairment. In patients with severe hepatic impairment, monitor for methylnaltrexone-related adverse reactions and dose adjust per Prescribing Information as may be indicated.
- In the clinical studies, the most common adverse reactions were:

OIC in adult patients with chronic non-cancer pain

- RELISTOR tablets ($\geq 2\%$ of RELISTOR patients and at a greater incidence than placebo): abdominal pain (14%), diarrhea (5%), headache (4%), abdominal distention (4%), vomiting (3%), hyperhidrosis (3%), anxiety (2%), muscle spasms (2%), rhinorrhea (2%), and chills (2%).
- RELISTOR injection ($\geq 1\%$ of RELISTOR patients and at a greater incidence than placebo): abdominal pain (21%), nausea (9%), diarrhea (6%), hyperhidrosis (6%), hot flush (3%), tremor (1%), and chills (1%).

OIC in adult patients with advanced illness

- RELISTOR injection ($\geq 5\%$ of RELISTOR patients and at a greater incidence than placebo): abdominal pain (29%), flatulence (13%), nausea (12%), dizziness (7%), and diarrhea (6%).

Please see the accompanying full [Prescribing Information](#).

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