RELISTOR®
methylnaltrexone bromide
Tablets & Subcutaneous Injection

RELISTOR Medical Exceptions and Patient Support Services Guide

Help provide patients with a clear path to their treatment for opioid-induced constipation (OIC)[1]

Please note this information is provided for your background education and is not intended to serve as guidance for specific coding, billing, and claims submissions. Decisions on which codes best describe the services provided must be made by individual providers based on specific payer guidance and requirements.

Salix cannot guarantee payment of any claim and providers should contact third-party payers for specific information on their coding, coverage, and payment policies as needed.

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.

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

About RELISTOR

Medical information

INDICATIONS[1]

- RELISTOR® (methylnaltrexone bromide) is an opioid antagonist. RELISTOR tablets and RELISTOR injection are indicated for the treatment of 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

DOSING[1]

For OIC in adult patients with chronic non-cancer pain:

- RELISTOR tablets: The recommended dosage is 450 mg once daily in the morning
- RELISTOR injection: The recommended dosage is 12 mg subcutaneously once daily

For OIC in adult patients with advanced illness:

- The pre-filled syringe is only for patients who require a RELISTOR injection dose of 8 mg or 12 mg. Use the vial for patients who require other doses of RELISTOR injection
- RELISTOR injection: See Table 1 in the full Prescribing Information for the recommended weight-based dosing; administer one dose every other day, as needed, but no more frequently than one dose in a 24-hour period

Please refer to the full Prescribing Information for dose adjustments in patients with renal or hepatic impairment.

RELISTOR prescription considerations

When it is time to prescribe RELISTOR for your patients with OIC, the following *ICD-10-CM* code could be considered*

K59.03	**Drug-induced constipation**

ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; OIC, opioid-induced constipation.

*The *ICD-10-CM* code and 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.

IMPORTANT SAFETY INFORMATION (*continued*)

- 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.

RELISTOR® methylnaltrexone bromide Tablets & Subcutaneous Injection

Information/Document Checklist

Patients' health plans may request additional information before approving coverage for RELISTOR. In your efforts to secure coverage for individual patients, you may need to provide one or more supporting letters. For your reference, we've provided template reimbursement letters on pages 4-7 as well as the following checklist to help you generate accurate payer correspondence to support your RELISTOR patients.

CHECKLIST

Patient information

- ☐ Patient name
- ☐ Date of birth
- ☐ Insurance carrier
- ☐ Insurance ID
- ☐ Insurance group number
- ☐ Case ID number (if applicable)

Clinical rationale

- ☐ Adult patient with chronic non-cancer pain diagnosed with OIC, which RELISTOR is indicated to treat
- ☐ Severity of patient's condition
- ☐ Summary of OTC laxatives and prescription therapies previously taken, including
  - Duration of and response to each treatment
  - Rationale for discontinuation
  - Recent symptoms
- ☐ Other medications taken, including
  - Duration of and response to each treatment
  - Rationale for discontinuation
  - Recent symptoms
- ☐ Clinical rationale for RELISTOR treatment, including clinical trial data supporting FDA approval, administration, and dosage information

Additional documentation

- ☐ RELISTOR full Prescribing Information
- ☐ Clinical notes/medical records
- ☐ FDA approval information
- ☐ Relevant peer-reviewed articles

OIC, opioid-induced constipation; OTC, over-the-counter.

If you have any questions about appeals or medical exceptions, you can request additional support from a RELISTOR Field Reimbursement Manager. Simply complete the form at **relistorhcp.com/reimbursement-support**

IMPORTANT SAFETY INFORMATION (*continued*)

- If severe or persistent diarrhea occurs during treatment, advise patients to discontinue therapy with RELISTOR and consult their healthcare provider.

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

RELISTOR® methylnaltrexone bromide Tablets & Subcutaneous Injection

Medical Necessity

If the payer's medical policy includes a prior authorization for the patient to be treated with RELISTOR, you can submit a Letter of Medical Necessity. This template letter is not meant to be used as a form letter. You should customize this letter to reflect the unique background and diagnosis of a particular patient as well as the special requirements of the particular payer involved. The provider is responsible for ensuring the medical necessity of the treatment. Be sure to print on office letterhead before sending for review.

Date: <Insert Date>
Payer Name: <Insert Payer Name>
Payer Address: <Insert Plan Address> **Payer Fax Number:** <Insert Plan Fax Number>
Attn: <Appeals Department>

To Whom It May Concern:

I am writing on behalf of my patient <Insert Patient Name> to provide additional information supporting medical necessity for the treatment with RELISTOR® (methylnaltrexone bromide). Within this letter I am providing my patient's medical history, diagnosis, a description of their previous drug treatment and a summary of their proposed treatment plan. I have also provided my clinically based rationale supporting the medical necessity of RELISTOR® (methylnaltrexone bromide) for my patient.

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 requires a prior authorization prior to treatment

Medication:

☐ **Relistor Tablets**: 450 mg methylnaltrexone bromide (3 x 150mg tablets) daily.

Relistor Injection:

☐ 8 mg/0.4 mL methylnaltrexone bromide in single-dose pre-filled syringe.

☐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.

☐ K59.03 ☐ _____

Drug History: (for treatment of the condition(s) requiring the requested drug)

Previous Drug Tried	Dates of Drug Trials	Results of previous drug trials

CLINICAL RATIONALE FOR MEDICAL NECESSITY

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

_____
_____
_____

☐ **Patient is stable on current drug(s); 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 information provided, I believe that RELISTOR® (methylnaltrexone bromide) is medically necessary for my patient. Please find attached the additional documents that support my clinical decision. If you need additional information for a timely approval, please contact me at <Insert Phone Number>

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)_____

IMPORTANT!
You must include your patient's medical history and diagnosis.

In order to substantiate your request for RELISTOR coverage, you should include any supporting documents that will assist the health plan in making a decision.

Be specific in this section so the health plan can make informed and timely decisions.

It is important to be clear as to why RELISTOR is the appropriate method of treatment for your patient.

It is highly recommended you include the details to support your clinical decision.

Find this template at relistorhcp.com/savings-and-resources#practice_resources

IMPORTANT SAFETY INFORMATION (*continued*)

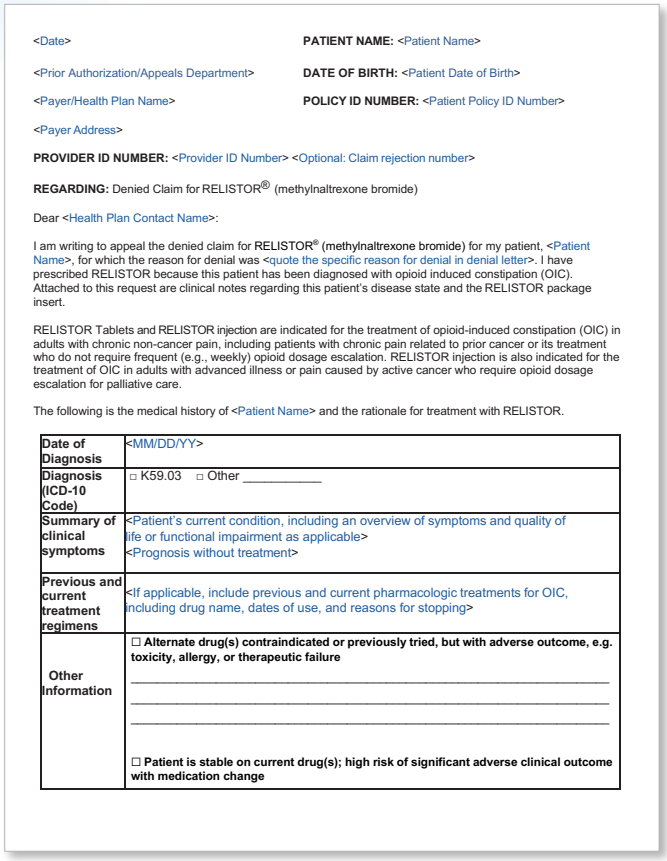
- Symptoms consistent with opioid withdrawal, including hyperhidrosis, chills, diarrhea, abdominal pain, anxiety, and yawning have occurred in patients treated with RELISTOR. Patients having disruptions to the blood-brain barrier may be at increased risk for opioid withdrawal and/or reduced analgesia 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.

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

RELISTOR® methylnaltrexone bromide Tablets & Subcutaneous Injection

Appeal Letter

If you have received a health plan's denial of RELISTOR and would like to appeal the denial, you can submit a Letter of Appeal: Prior Authorization and Claim Denial. This template letter is not meant to be used as a form letter. You should customize this letter to reflect the unique background and diagnosis of a particular patient as well as the special requirements of the particular payer involved. The provider is responsible for ensuring the medical necessity of the treatment. Be sure to print on office letterhead before sending for review.



<Date>

PATIENT NAME: <Patient Name>

<Prior Authorization/Appeals Department>

DATE OF BIRTH: <Patient Date of Birth>

<Payer/Health Plan Name>

POLICY ID NUMBER: <Patient Policy ID Number>

<Payer Address>

PROVIDER ID NUMBER: <Provider ID Number> <Optional: Claim rejection number>

REGARDING: Denied Claim for RELISTOR® (methylnaltrexone bromide)

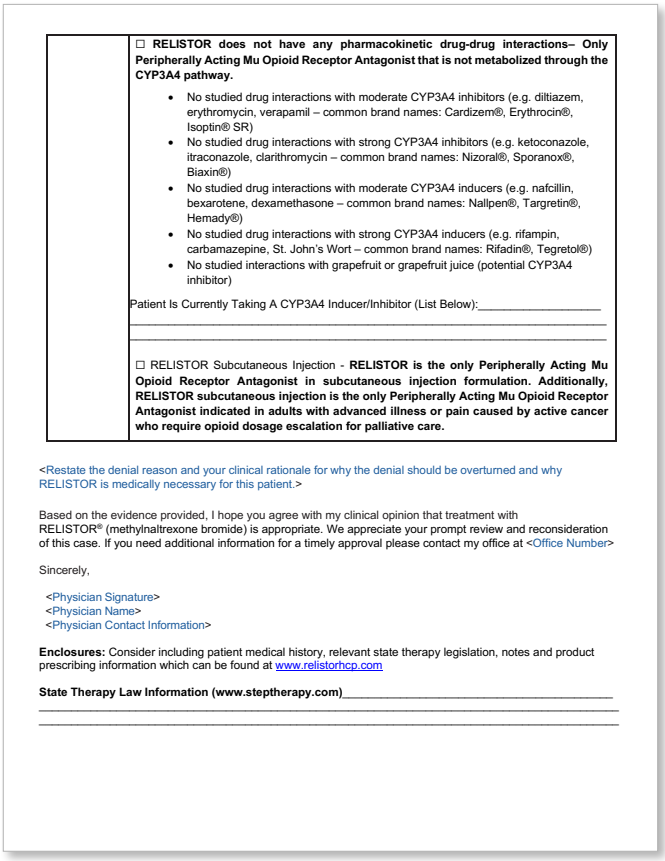
Dear <Health Plan Contact Name>:

I am writing to appeal the denied claim for **RELISTOR® (methylnaltrexone bromide)** for my patient, <Patient Name>, for which the reason for denial was <quote the specific reason for denial in denial letter>. I have prescribed RELISTOR because this patient has been diagnosed with opioid induced constipation (OIC). Attached to this request are clinical notes regarding this patient's disease state and the RELISTOR package insert.

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.

The following is the medical history of <Patient Name> and the rationale for treatment with RELISTOR.

Date of Diagnosis	<MM/DD/YY>
Diagnosis (ICD-10 Code)	□ K59.03 □ Other _____
Summary of clinical symptoms	<Patient's current condition, including an overview of symptoms and quality of life or functional impairment as applicable> <Prognosis without treatment>
Previous and current treatment regimens	<If applicable, include previous and current pharmacologic treatments for OIC, including drug name, dates of use, and reasons for stopping>
Other Information	☐ **Alternate drug(s) contraindicated or previously tried, but with adverse outcome, e.g. toxicity, allergy, or therapeutic failure** _____ _____ _____ ☐ **Patient is stable on current drug(s); 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. Additionally, 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.**

<Restate the denial reason and your clinical rationale for why the denial should be overturned and why RELISTOR is medically necessary for this patient.>

Based on the evidence provided, I hope you agree with my clinical opinion that treatment with RELISTOR® (methylnaltrexone bromide) is appropriate. We appreciate your prompt review and reconsideration of this case. If you need additional information for a timely approval please contact my office at <Office Number>

Sincerely,

<Physician Signature>
<Physician Name>
<Physician Contact Information>

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)_____
_____
_____

It is important to include a detailed description of the denial, as including specific information may reduce the appeal process timeline and mitigate additional requests for information.

A detailed patient history can support the rationale for the insurance plan to cover RELISTOR. The patient history should describe information such as the severity of your patient's condition, previous treatments, and the patient's failure on prior treatments.

It is important to be clear as to why RELISTOR is the appropriate method of treatment for your patient.

It is highly recommended you include the details to support your clinical decision.

Find this template at relistorhcp.com/savings-and-resources#practice_resources

IMPORTANT SAFETY INFORMATION (*continued*)

- 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.

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

RELISTOR® methylnaltrexone bromide Tablets & Subcutaneous Injection

Medical Exception

If RELISTOR is not available on the payer's medical policy, you may want to submit a Letter of Medical Exception. This template letter is not meant to be used as a form letter. You should customize this letter to reflect the unique background and diagnosis of a particular patient as well as the special requirements of the particular payer involved. The provider is responsible for ensuring the medical necessity of the treatment. Be sure to print on office letterhead before sending for review.

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:

☐ **Relistor Tablets**: 450 mg methylnaltrexone bromide (3 x 150mg tablets) daily.

Relistor Injection:

☐ 8 mg/0.4 mL methylnaltrexone bromide in single-dose pre-filled syringe.

☐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.

☐ K59.03 ☐ _____

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)_____

Be sure to describe the coverage restriction in detail.

In this section, include any previous treatment the patient has received so the insurance company does not request a treatment that may not be appropriate for your patient.

Be specific in this section so the health plan can make informed and timely decisions.

It is important to be clear as to why RELISTOR is the appropriate method of treatment for your patient.

It is highly recommended you include the details to support your clinical decision.

Find this template at relistorhcp.com/savings-and-resources#practice_resources

IMPORTANT SAFETY INFORMATION (*continued*)

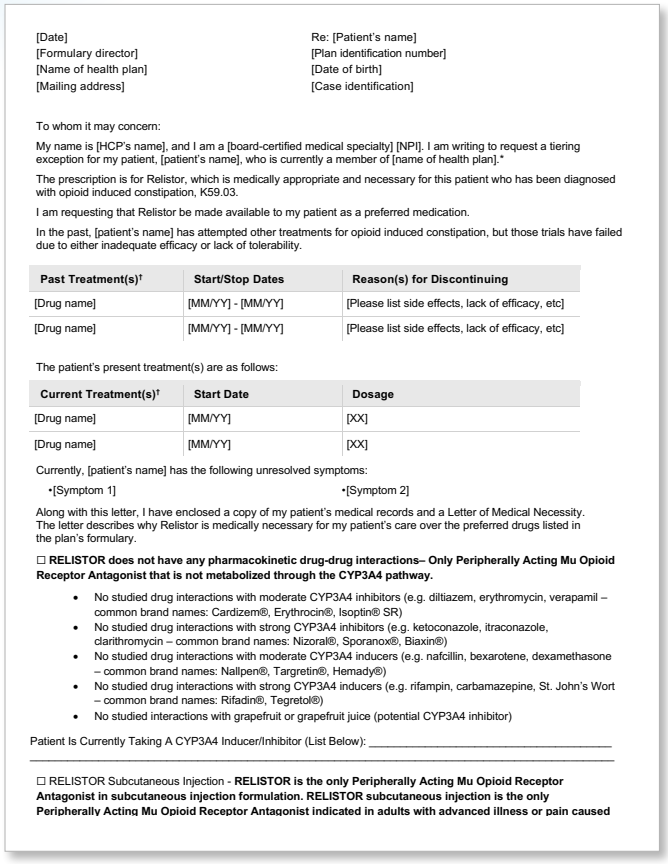
- A dosage reduction of RELISTOR tablets and RELISTOR injection is recommended in patients with moderate and severe renal impairment (creatinine clearance less than 60 mL/minute as estimated by Cockcroft-Gault). No dosage adjustment of RELISTOR tablets or RELISTOR injection is needed in patients with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

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

RELISTOR® methylnaltrexone bromide Tablets & Subcutaneous Injection

Tiered Exception

If you need to request a payer's medical policy to cover RELISTOR at a lower copay when necessary for the patient, if allowed by plan, you can submit a Tiered Exception Letter. This template letter is not meant to be used as a form letter. You should customize this letter to reflect the unique background and diagnosis of a particular patient as well as the special requirements of the particular payer involved. The provider is responsible for ensuring the medical necessity of the treatment. Be sure to print on office letterhead before sending for review.



[Date]
[Formulary director]
[Name of health plan]
[Mailing address]

Re: [Patient's name]
[Plan identification number]
[Date of birth]
[Case identification]

To whom it may concern:

My name is [HCP's name], and I am a [board-certified medical specialty] [NPI]. I am writing to request a tiering exception for my patient, [patient's name], who is currently a member of [name of health plan].*

The prescription is for Relistor, which is medically appropriate and necessary for this patient who has been diagnosed with opioid induced constipation, K59.03.

I am requesting that Relistor be made available to my patient as a preferred medication.

In the past, [patient's name] has attempted other treatments for opioid induced constipation, but those trials have failed due to either inadequate efficacy or lack of tolerability.

Past Treatment(s)†	Start/Stop Dates	Reason(s) for Discontinuing
[Drug name]	[MM/YY] - [MM/YY]	[Please list side effects, lack of efficacy, etc]
[Drug name]	[MM/YY] - [MM/YY]	[Please list side effects, lack of efficacy, etc]

The patient's present treatment(s) are as follows:

Current Treatment(s)†	Start Date	Dosage
[Drug name]	[MM/YY]	[XX]
[Drug name]	[MM/YY]	[XX]

Currently, [patient's name] has the following unresolved symptoms:

•[Symptom 1] •[Symptom 2]

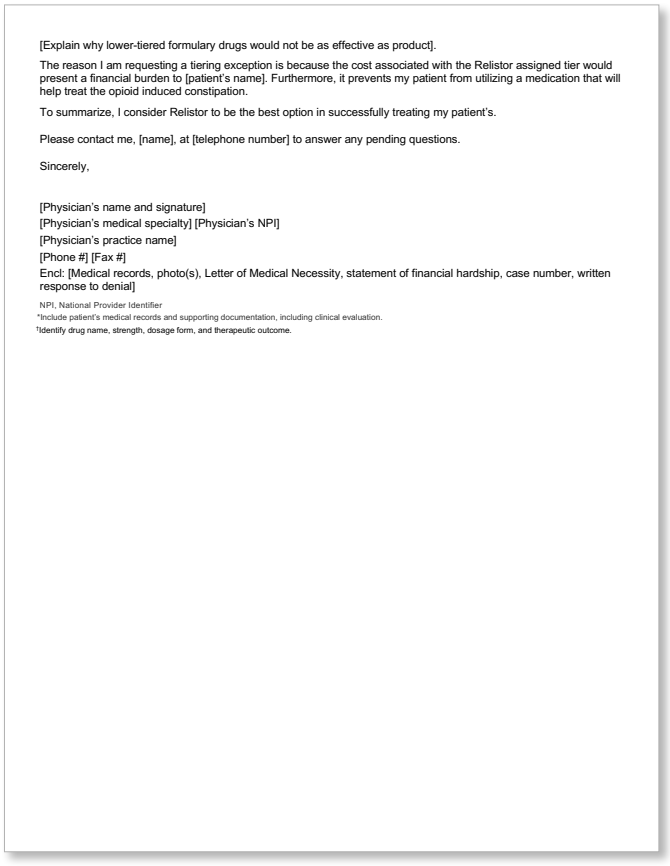
Along with this letter, I have enclosed a copy of my patient's medical records and a Letter of Medical Necessity. The letter describes why Relistor is medically necessary for my patient's care over the preferred drugs listed in the plan's formulary.

☐ **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**



[Explain why lower-tiered formulary drugs would not be as effective as product].

The reason I am requesting a tiering exception is because the cost associated with the Relistor assigned tier would present a financial burden to [patient's name]. Furthermore, it prevents my patient from utilizing a medication that will help treat the opioid induced constipation.

To summarize, I consider Relistor to be the best option in successfully treating my patient's.

Please contact me, [name], at [telephone number] to answer any pending questions.

Sincerely,

[Physician's name and signature]
[Physician's medical specialty] [Physician's NPI]
[Physician's practice name]
[Phone #] [Fax #]
Encl: [Medical records, photo(s), Letter of Medical Necessity, statement of financial hardship, case number, written response to denial]

NPI, National Provider Identifier
*Include patient's medical records and supporting documentation, including clinical evaluation.
†Identify drug name, strength, dosage form, and therapeutic outcome.

Be explicit regarding patient's previous and current treatment regimens.

It is important to be clear as to why RELISTOR is the appropriate method of treatment for your patient.

Be specific in this section so the health plan can make informed and timely decisions.

Find this template at relistorhcp.com/savings-and-resources#practice_resources

IMPORTANT SAFETY INFORMATION (*continued*)

- In the clinical studies, the most common adverse reactions were:

OIC in adult patients with chronic non-cancer pain

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

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.

RELISTOR® methylnaltrexone bromide Tablets & Subcutaneous Injection

More Access and Support Resources for You and Your Patients

The RELISTOR Patient Savings Program

$0 For RELISTOR tablets and subcutaneous injection, many eligible commercially insured patients may pay as little as $0 with our copay card*

*Eligibility Criteria, Terms and Conditions: Patient is not eligible if he/she participates in or seeks reimbursement or submits a claim for reimbursement to any federal or state healthcare program with prescription drug coverage, or where prohibited by law. Patient must be enrolled in, and must seek reimbursement from or submit a claim for reimbursement to, a commercial insurance plan. Offer excludes full cash-paying patients. Maximum benefits and other restrictions apply. Visit relistorhcp.copaysavingsprogram.com for full eligibility criteria, terms and conditions.

CoverMyMeds can help with prior authorization (PA)

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Looking for further assistance? Connect with your Field Reimbursement Manager at **relistorhcp.com/reimbursement-support**

REFERENCE: 1. RELISTOR [prescribing information]. Bridgewater, NJ: Salix Pharmaceuticals.

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.

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

Salix Pharmaceuticals

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RELISTOR® methylnaltrexone bromide Tablets & Subcutaneous Injection