UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 2076-11
Program	Prior Authorization/Medical Necessity
Medication	Relistor (methylnaltrexone bromide)
P&T Approval Date	2/2016, 12/2016, 11/2017, 7/2018, 7/2019, 7/2020, 7/2021, 7/2022, 7/2023
Effective Date	10/1/2023; Oxford only: 10/1/2023

1. Background:

Relistor (methylnaltrexone bromide) and Symporic (naldemedine) are opioid antagonists 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 also indicated for the treatment of opioid-induced constipation in patients with advanced illness or pain caused by active cancer who require opioid dosage escalation for palliative care. Physicians and patients should periodically assess the need for continued treatment with Relistor.

This prior authorization program is intended to encourage the use of lower cost alternatives. This program requires a member to try lower-cost options before providing coverage for Relistor.

2. Coverage Criteria[a]:

A. Relistor Injection

1. **Initial Authorization**

a. **Relistor** injection will be approved based on documentation (e.g. chart notes) demonstrating **one** of the following:

1) Diagnosis of opioid induced constipation in patients with advanced illness receiving palliative care

-OR-

2) **Both** of the following

a) **ONE of the following**

i. Diagnosis of opioid induced constipation with chronic, non-cancer pain

-OR-

ii. Diagnosis of opioid induced constipation in patients with chronic pain related to prior cancer diagnosis or cancer treatment who do not require frequent (e.g., weekly) opioid dosage escalation

-AND-

b) **One** of the following:

i. The patient is not able to swallow oral medications.

-OR-

ii. History of failure, contraindication or intolerance to **BOTH** of the following:

- lubiprostone (generic Amitiza)

-AND-

- Symproic

Authorization will be issued for 12 months

2. **Reauthorization**

a. **Relistor injection** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Relistor injection therapy

Authorization will be issued for 12 months.

B. Relistor Tablets*

1. **Initial Authorization**

a. Relistor tablets will be approved based on **BOTH** of the following:

1) **ONE** of the following

i. Diagnosis of opioid induced constipation with chronic, non-cancer pain

-OR-

ii. Diagnosis of opioid induced constipation in patients with chronic pain related to prior cancer diagnosis or cancer treatment who do not require frequent (e.g., weekly) opioid dosage escalation

-AND-

2) History of failure, contraindication or intolerance to **BOTH** of the following:

a) lubiprostone (generic Amitiza)

-AND-

b) Symproic

Authorization will be issued for 12 months

2. **Reauthorization**

   a. **Relistor tablets** will be approved based on the following criterion:

      1) Documentation of positive clinical response to Relistor tablet therapy

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

*Relistor tablets are typically excluded from coverage

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.
- Notification/Prior Authorization may be in place.

4. References:

1. Amitiza [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; November 2020.
2. Relistor [package insert]. Bridgewater, NJ: Salix Pharmaceuticals, Inc.; April 2020.
3. Symproic [package insert]. Raleigh, NC: BioDelivery Sciences International. July 2021.
4. Chang, L, Sultan, S, et. al. AGA Clinical Practice Guideline on the Pharmacological Management of Irritable Bowel Syndrome with Constipation. *Gastroenterology*: 2022; 162:118-36.

Program	Prior Authorization/Medical Necessity – Relistor
Change Control	
Date	Change
2/2016	New program
7/2016	Added Indiana and West Virginia coverage information.
11/2016	Added California coverage information.
12/2016	Added coverage information for Relistor Tablets
11/2017	Annual review. Updated background section and criteria with enhanced indication for opioid inducted constipation. Updated references.
7/2018	Removed Movantik as a first line option and added Symproic. Updated references.
7/2019	Annual review. Updated background section and references.
7/2020	Annual review. Updated initial authorization and references.
7/2021	Annual review. Updated references.
7/2022	Annual review. Updated references.
7/2023	Annual review. Removed OTC laxative and added generic Amitiza as step for Relistor. Updated references.