UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Relistor

Program	Prior Authorization
Medication	Relistor (methylnaltrexone bromide)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Rhode Island, South Carolina, Pennsylvania- CHIP
Issue Date	12/2010
Pharmacy and Therapeutics Approval Date	7/2020
Effective Date	9/2020

1. Background:

Relistor (methylnaltrexone bromide) is an opioid antagonist 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 over-the-counter (OTC) laxative therapy and Movantik (naloxegol) before providing coverage for Relistor (methylnaltrexone bromide).

2. Coverage Criteria:

A. <u>Relistor Injection</u>

1. **<u>Initial Authorization</u>**

a. **Relistor injection** will be approved based on documentation (e.g. chart notes) demonstrating **<u>one</u>** 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. **Both** of the following:
- History of failure, contraindication or intolerance to an OTC laxative (document name and date tried).
- History of failure, contraindication or intolerance to Movantik

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

(a) Diagnosis of opioid induced constipation with chronic, non-cancer pain

-OR-

(b) 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) **Both** of the following:

(a) History of failure, contraindication or intolerance to an OTC laxative (document name and date tried)

-AND-

(b) History of failure, contraindication or intolerance to Movantik

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

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.

4. References:

1. Relistor [package insert]. Bridgewater, NJ: Salix Pharmaceuticals, Inc.; November 2018.

Change Control	
Date	Change
12/2010	New drug policy
12/2011	Annual Review
12/2012	Annual Review
3/2015	Split Opioid-Induced Constipation criteria into palliative and chronic non-cancer pain treatment sections. Opioid-Induced Constipation, Initial therapy changes: • Removed example list of advanced illnesses and replaced with new requirement clarifying diagnosis "Adult patients with advanced illness with a life expectancy of less than 6 months" per labeled indication • Simplified language "patient has opioid induced constipation due to palliative opioid therapy" to "Confirmed diagnosis of opioid-induced constipation" • Clarified first line drug therapy requirement to state osmotic laxative with examples Created new criteria for Methadone-Induced Constipation.
9/2015	For Opioid-Induced Constipation (chronic non-cancer pain) section, added requirement that there must be a history of failure, contraindication, or intolerance to Movantik. Added stimulant laxative as another option to try/fail prior to approval of Relistor as per the recommendation of the Pharmacy and Therapeutics Committee: • Revised criterion now allows approval if patient has a history of failure, contraindication, or intolerance to a stimulant or osmotic laxative Changed "palliative care" header to "cancer pain, other advanced illnesses" to highlight the differences between this indication and that of chronic non-cancer pain.
11/2016	Updated clinical criteria to align with Employer & Individual's policy. Updated policy template.
12/2016	Added coverage information for Relistor tablets.
3/2017	Changed initial authorization duration from 6 months to 12 months

11/2017	Updated background section and criteria with enhanced indication for opioid inducted constipation. Updated references.
11/2018	Annual review. Updated references.
7/2019	Annual review. Updated background and references.
7/2020	Annual review. Added Additional Clinical Rules and updated references.