MEDICAL MUTUAL®

Drug Policy

Policy:	Relistor (methylnaltrexone bromide)	Annual Review Date: 05/16/2024 Last Revised Date: 05/16/2024

OVERVIEW

Relistor is a mu-opioid receptor antagonist that acts peripherally in tissues such as the GI tract, thereby decreasing the constipating effects of opioids. Relistor injection is 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 and for the treatment of OIC in adults with advanced illness or pain caused by active cancer who require opioid dosage escalation for palliative care. Relistor tablets are approved 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.

POLICY STATEMENT

This policy involves the use of Relistor. Prior authorization is recommended for pharmacy benefit coverage of Relistor. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Relistor is recommended in those who meet the following criteria:

1. **Opioid-Induced Constipation (OIC), initial therapy**
   Criteria. *Patient must meet the following criteria (A, B, C, D, E, F, and G):*
   - **A.** The patient has one of the following (i or ii):
     - **i.** Diagnosis of chronic non-cancer pain; OR
     - **ii.** Diagnosis of advanced illness and is receiving palliative care; AND
   - **B.** The patient is 18 years of age or older; AND
   - **C.** The patient has been taking opioids for 4 weeks or more; AND
   - **D.** The patient has failed on or is intolerant to at least 2 of the following with or without a stool softener in the past 3 months:
     - **i.** At least one stimulant laxative (e.g. bisacodyl); OR

ii. At least one osmotic laxative (e.g. PEG 3350); OR
iii. At least one saline laxative (e.g. magnesium citrate); AND

E. The patient is not using another opioid antagonist (e.g. naloxone); AND
F. The patient does not have a known or suspected gastrointestinal obstruction and is not at increased risk of recurrent obstruction; AND
G. The patient has failed on or is intolerant to BOTH lubiprostone AND Movantik.

2. Continuation of Therapy
Criteria. *Patient must meet the following criteria (A and B):*

A. The patient has demonstrated a beneficial response to Relistor, per the prescribing physician (e.g. increased number of bowel movements from baseline); AND
B. The patient continues to meet all criteria above for initial therapy.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 4 months for patients with advanced illness receiving palliative care
1 year for patients with chronic non-cancer pain
B) *Extended Approval:* 4 months for patients with advanced illness receiving palliative care
1 year for patients with chronic non-cancer pain

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Relistor has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

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