Pharmacy Policy

Relistor®, Movantik™

Policy Number: 9.118
Version Number: 10.0
Version Effective Date: 03/01/2016

Product Applicability

- All Plan* Products

Well Sense Health Plan
- New Hampshire Medicaid
- NH Health Protection Program

Boston Medical Center HealthNet Plan
- MassHealth
- Qualified Health Plans/ConnectorCare/Employer Choice Direct
- Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Policy Summary

The Plan will authorize coverage of Relistor® or Movantik™ when appropriate criteria are met.

Description of Item or Service

Opioid therapy is a well-established cause of drug-induced constipation, especially for patients receiving chronic palliative therapy for advanced illnesses, such as cancer. Opioids bind to mu (μ) receptors throughout the body. Mu-receptor binding in intestinal cells impedes intestinal peristalsis, causing constipation. Stool softeners, stimulant laxatives, and osmotic laxatives are most commonly used for treatment of opioid-induced constipation.

Relistor® (methylnaltrexone bromide) is a mu-receptor antagonist, blocking opioid binding at intestinal cells and allowing peristalsis and laxation. It is indicated for the treatment of opioid-induced constipation in patients with chronic non-cancer pain as well as in patients with advanced illness who are receiving palliative care and have not had a sufficient response to laxative therapy. Relistor® was shown to be effective for the

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treatment of opioid-induced constipation in patients with chronic non-cancer pain who had been taking opioids for at least four weeks. Relistor® does not appreciably pass the blood-brain-barrier, and thus has no effect upon analgesia. Most patients receiving Relistor® therapy experience laxation 30 minutes to several hours after injection. Common side effects include abdominal pain, flatulence, nausea, dizziness, and diarrhea. Therapy with Relistor® should be discontinued if the patient experiences vomiting, nausea, severe diarrhea, or severe abdominal pain. Relistor® is administered as a subcutaneous injection. The usual dosing schedule for chronic non-cancer pain is 12 mg once daily. The dosing schedule for advanced illness requiring palliative care is one dose every other day as needed. Relistor® should not be dosed more frequently than one dose in a 24-hour period.

Relistor® is contraindicated in patients with known or suspected gastrointestinal perforation, as well as in patients at increased risk for recurrent obstruction. Some patients using Relistor® have experienced symptoms consistent with opioid withdrawal (e.g., hyperhidrosis, chills, diarrhea, abdominal pain, anxiety, yawning). Use of Relistor® beyond four months has not been studied in the advanced illness population. Prior to starting methlnaltrexone for the treatment of opioid-induced constipation in chronic non-cancer pain, patients should discontinue all maintenance laxative therapy; laxatives can be used as needed if there is a suboptimal response after three days of therapy.

Movantik™ (naloxegol) is a pegylated derivative of naloxone indicated for the treatment of opioid-induced constipation in adult patients with chronic non-cancer pain. Unlike Relistor®, Movantik™ is administered orally. The initial dose of Movantik™ in patients with normal renal function is 25 mg once daily in the morning on an empty stomach, at least one hour before or two hours after the first meal of the day. If a patient is not able to tolerate the 25 mg dose, then the dose should be reduced to 12.5 mg once daily. Maintenance laxatives should be discontinued prior to initiating Movantik™. Laxatives may be used as needed if there is a suboptimal response after three days of treatment with Movantik™. The most common adverse effects seen with Movantik™ include abdominal pain, diarrhea, nausea, flatulence, vomiting, headache, hyperhidrosis, and back pain.

Movantik™ is contraindicated when coadministered with strong CYP3A4 inhibitors (e.g., clarithromycin, ketoconazole). Coadministration can cause opioid withdrawal symptoms (hyperhidrosis, chills, diarrhea, abdominal pain, anxiety, irritability, and yawning).

Policy

The Plan may authorize coverage of Relistor® and Movantik™ for treatment of specific conditions when the following criteria are met:

**Prior Authorization – (Duration of Approval – Maximum of 4 months)**

A prior authorization request will be required for all prescriptions for Relistor® and Movantik™. These requests will be approved when the following criteria are met:

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<table>
<thead>
<tr>
<th>Medication</th>
<th>Approval Criteria</th>
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</table>
| Relistor®  | Documentation of the following:  
1. A diagnosis of an advanced illness* requiring *palliative therapy* with opioids (diagnosis and specific opiate therapy must be documented); **OR**  
Member has chronic non-cancer pain** AND has been taking an opioid analgesic for at least 4 weeks immediately prior to request (as evidenced by pharmacy claims); **AND**
2. A diagnosis of opioid-induced constipation; **AND**
3. An inadequate response or intolerance to a trial of at least one agent from within each of the following laxative agents:  
   - Fiber laxative (e.g., psyllium, methylcellulose, calcium polycarbophil)  
   - Stimulant laxative (e.g., bisacodyl, senna)  
   - Osmotic laxative (e.g., polyethylene glycol, magnesium citrate, milk of magnesia, lactulose, sorbitol; **AND**
4. An inadequate response, intolerance, or contraindication Movantik™ **AND**  
   Amitiza® *(only applicable for members with a diagnosis of chronic non-cancer pain)*  

*Advanced illness such as incurable cancer or end-stage life threatening disease.**

**Chronic non-cancer pain such as back pain, fibromyalgia, joint/extremity pain, rheumatoid arthritis, or neurologic/neuropathic pain** |

| Movantik™ | Documentation of the following:  
1. Member has a diagnosis of chronic non-cancer pain; **AND**
2. Member has been taking an opioid analgesic for at least 4 weeks immediately prior to the request (as evidenced by pharmacy claims); **AND**
3. An inadequate response or intolerance to at least one agent from within each of the following laxative types:  
   - Fiber laxative (e.g., psyllium, methylcellulose, calcium polycarbophil)  
   - Stimulant laxative (e.g., bisacodyl, senna)  
   - Osmotic laxative (e.g., polyethylene glycol, magnesium citrate, milk of magnesia, sorbitol, lactulose) |

*Quantity Limitations Apply – see appendix A*

**Limitations**

The Plan will not approve coverage of Relistor® or Movantik™ in the following instances:

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1. When the above criteria is not met
2. Doses exceeding once daily dosing
3. Movantik™ or Relistor® is being prescribed for constipation that is not opioid-induced

Clinical Background Information and References

2. Lexi-Comp Inc. Lexi-Drugs (comp + Specialties) Reader v. 2.4080428; 2008.

Appendix A – Quantity Limitations

<table>
<thead>
<tr>
<th>Medication Name</th>
<th>Maximum Quantity</th>
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<tbody>
<tr>
<td>Relistor®</td>
<td>2 vials/day, 8 kits/28 days</td>
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<tr>
<td>Movantik™ 12.5 mg, 25 mg tablet</td>
<td>30 tablets per 30 days</td>
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Original Approval Date | Original Effective Date | Policy Owner | Approved by
11/12/2008            | 03/12/2009              | Pharmacy Services | Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History

<table>
<thead>
<tr>
<th>Review Date</th>
<th>Summary of Revisions</th>
<th>Revision Effective Date</th>
<th>Approved by</th>
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<tbody>
<tr>
<td>03/11/2010</td>
<td>P&amp;T annual review, no changes required</td>
<td>07/01/2010</td>
<td>P&amp;T Committee</td>
</tr>
<tr>
<td>03/10/2011</td>
<td>Added Hyperemesis gravidarum as approvable indication for treatment over 7 days for 5HT₃ blocker</td>
<td>07/01/2011</td>
<td>P&amp;T Committee</td>
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<tr>
<td>07/14/2011</td>
<td>policy applied to Commercial</td>
<td>11/01/2011</td>
<td>P&amp;T Committee</td>
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<tr>
<td>11/10/2011</td>
<td>P&amp;T annual review, added definition for advanced illness, add criteria for once daily with more than 1 vial per dose.</td>
<td>03/01/2012</td>
<td>P&amp;T Committee</td>
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<tr>
<td>08/22/2012</td>
<td>Policy applied to NH Medicaid</td>
<td>12/01/2013</td>
<td>P&amp;T Committee</td>
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### Policy Revisions History

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<thead>
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<th>Date</th>
<th>Description</th>
<th>Date</th>
<th>Committee</th>
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<tbody>
<tr>
<td>11/08/2012</td>
<td>P&amp;T annual review, no changes required</td>
<td>03/01/2013</td>
<td>P&amp;T Committee</td>
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<tr>
<td>11/14/2013</td>
<td>P&amp;T annual review, no criteria changes</td>
<td>03/01/2014</td>
<td>P&amp;T Committee</td>
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<td>12/13/2013</td>
<td>Policy applied to ConnectorCare/Qualified Health Plan (QHP)</td>
<td>01/01/2014</td>
<td>P&amp;T Committee</td>
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<tr>
<td>11/13/2014</td>
<td>P&amp;T annual review, added criteria for the indication of non-cancer pain,</td>
<td>03/02/2015</td>
<td>P&amp;T Committee</td>
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<tr>
<td></td>
<td>increased quantity allowed and removed specific quantity limit override</td>
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<td>NH DHHS</td>
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<td></td>
<td>criteria</td>
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<tr>
<td>11/12/2015</td>
<td>P&amp;T annual review, added criteria and quantity limit for Movantik™; added</td>
<td>03/01/2016</td>
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<td></td>
<td>step therapy with Movantik™ and Amitiza® to Relistor® criteria for</td>
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<td>indication of chronic non-cancer pain</td>
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### Next Review Date

11/10/2016

### Other Applicable Policies

- 9.002 Mandatory Generic Substitution Program
- 9.015 Quantity Limitation Program

### Reference to Applicable Laws and Regulations, If Any

N/A

### Disclaimer Information

Medical Policies are the Plan’s guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member’s benefit document, and when appropriate, coordinates with the Member’s health care Providers to consider the individual Member’s health care needs.

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Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan’s service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member’s benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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