Pharmacy Policy

Rectiv®

Policy Number: 9.040
Version Number: 6.0
Version Effective Date: 11/14/2017

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
□ ________________________________

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

Policy Summary
The Plan will authorize coverage of Rectiv® when appropriate criteria are met.

Description of Item or Service
Rectiv® (nitroglycerin) rectal ointment 0.4% is a nitrate vasodilator FDA approved for the treatment of moderate to severe pain associated with chronic anal fissure for up to 3 weeks.

As with other nitrates, the major side effect of Rectiv® is headache. Use of Rectiv® within a few days of drugs that can increase the risk of hypotension when concurrently used with nitrates is contraindicated. Rectiv® is also contraindicated in patients with severe anemia, or increased intracranial pressure. The safety and effectiveness of Rectiv® in pediatric patients under 18 years of age have not been established.

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.
Because topical nitrates cause high incidence of headache, and are marginally superior to placebo, topical nitrates remains an alternative treatment for anal fissure.

In 2010, Standards Practice Task Force of the American Society of Colon and Rectal Surgeons (ASCRS) and in 2014, the American College of Gastroenterology (ACG) recommended non-operative treatment to be the first step in therapy. These conventional treatments include sitz baths, psyllium fiber and bulking agents with or without the addition of topical anesthetics or anti-inflammatory ointments. When these treatments fail, rectal formulation of nitroglycerin can be used. Topical calcium channel blockers (unavailable commercially in the US) may also be effective and have a lower incidence of adverse effects than topical nitrates.

**Policy**

The Plan may authorize coverage of Rectiv® for members meeting the following criteria:

**Prior Authorization** – *(Duration of Approval – Maximum of 3 weeks)*

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

1. A diagnosis of moderate to severe pain associated with chronic anal fissures; **AND**
2. Age is 18 years or older; **AND**
3. An inadequate response to at least one bulk forming laxative.

**Quantity Limitations Apply - See appendix A**

**Limitations**

The Plan will not approve coverage of Rectiv® in the following instances:

- When the above criteria are not met.

**Clinical Background Information and References**


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Rectiv®

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Appendix A – Quantity Limitations for Rectiv®

<table>
<thead>
<tr>
<th>Medication Name and Strength</th>
<th>Maximum Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rectiv®</td>
<td>30 gram/30 days</td>
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<table>
<thead>
<tr>
<th>Original Approval Date</th>
<th>Original Effective Date</th>
<th>Policy Owner</th>
<th>Approved by</th>
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<tbody>
<tr>
<td>07/01/2013</td>
<td>10/01/2013</td>
<td>Pharmacy Services</td>
<td>Pharmacy &amp; Therapeutics (P&amp;T) Committee NH DHHS</td>
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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>12/13/2013</td>
<td>Policy applied to ConnectorCare/Qualified Health Plan</td>
<td>04/01/2014</td>
<td>P&amp;T Committee</td>
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<tr>
<td>07/10/2014</td>
<td>P&amp;T annual review. No changes required.</td>
<td>11/01/2014</td>
<td>P&amp;T Committee NH DHHS</td>
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<td>07/09/2015</td>
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<td>11/04/2015</td>
<td>P&amp;T Committee</td>
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<td>11/14/2016</td>
<td>P&amp;T Committee</td>
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<td>P&amp;T annual review, No changes required</td>
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Next Review Date

07/12/2018

Other Applicable Policies

9.002 Mandatory Generic Substitution Policy
9.015 Quantity Limitation Policy
OCA 3.14 Medically Necessary Policy

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Reference to Applicable Laws and Regulations, If Any

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.

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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