Pharmacy Policy

Northera®
Policy Number: 9.054
Version Number: 3.0
Version Effective Date: 09/07/2017

Product Applicability

☑ All Plan+ Products

<table>
<thead>
<tr>
<th>Well Sense Health Plan</th>
<th>Boston Medical Center HealthNet Plan</th>
</tr>
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<tbody>
<tr>
<td>☑ New Hampshire Medicaid</td>
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<tr>
<td>☑ NH Health Protection Program</td>
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<tr>
<td>☑ MassHealth</td>
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<tr>
<td>☑ Qualified Health Plans/ConnectorCare/Employer Choice Direct</td>
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<td>☑ Senior Care Options</td>
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Note: Disclaimer and audit information is located at the end of this document.

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

Description of Item or Service
Orthostatic hypotension (OH) is defined as a sustained decrease of at least 20 mmHg in systolic blood pressure or 10 mmHg in diastolic blood pressure within three minutes of head-up tilt or standing. OH is more commonly seen in patients with hypertension, particularly in patients whose hypertension is uncontrolled. Patients may experience dizziness, lightheadedness, syncope, visual disturbances, and other problems that potentially have a large impact on those activities of daily living that require standing or walking. OH can be symptomatic of acute or chronic volume depletion.

Several non-pharmacologic measures should be considered when treating patients presenting with OH. Specific examples are listed in table 1.

Table 1 – Non-pharmacologic Measures for Treatment of OH
<table>
<thead>
<tr>
<th>Non-pharmacologic Measures for Treatment of OH</th>
<th>Examples</th>
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</table>
| Discontinuation of medications that may cause or exacerbate OH | - Alpha blockers (e.g., terazosin)  
- Antidepressants (e.g., SSRIs, trazodone, MAOIs, tricyclic antidepressants)  
- Antihypertensive drugs (e.g., sympathetic blockers)  
- Antiparkinsonism drugs (e.g., levodopa, pramipexole, ropinirole)  
- Antipsychotic drugs (e.g., olanzapine, risperidone)  
- Beta-blocker drugs (e.g., propranolol)  
- Diuretics (e.g., hydrochlorothiazide, furosemide)  
- Skeletal muscle relaxants (e.g., tizanidine)  
- Narcotic analgesics (e.g., morphine)  
- Phosphodiesterase inhibitors (e.g., sildenafil, tadalafil)  
- Sedatives/hypnotics (e.g., temazepam)  
- Vasodilators (e.g., hydralazine, nitroglycerin, calcium channel blockers) |
| Lifestyle modifications | - Arising slowly in stages  
- Avoiding straining/coughing/walking in hot weather  
- Maintaining hydration  
- Avoiding overheating  
- Raising the head of the bed 10 to 20 degrees  
- Using custom-fitted elastic stockings  
- Modifying meals (if symptoms appear to be associated with eating) |
| Physical maneuvers | - Tensing the legs by crossing them while actively standing on both legs |
| Increased salt and water intake | - Eating high-sodium containing foods  
- Taking salt tablets  
**Strategy may not be appropriate for every patient** |
| Meal modification | - Avoiding large meals  
- Ingesting meals low in carbohydrates  
- Minimizing alcohol intake  
- Drinking water with meals  
- Avoiding activities or sudden standing immediately after eating |

When non-pharmacologic measures do not sufficiently prevent symptoms of OH, pharmacologic interventions should be considered. Most widely used agents for treatment of OH are fludrocortisone and midodrine.

Northera® (droxidopa) is a synthetic amino acid analogue precursor to norepinephrine that is indicated for the treatment of orthostatic dizziness, lightheadedness, or the “feeling that you are about to black out” in adult patients with symptomatic neurogenic orthostatic hypotension (NOH) caused by primary autonomic failure (i.e., Parkinson’s disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy.

Northera® was studied in three clinical trials. The first trial was a randomized, placebo-controlled, parallel group study that evaluated Northera® in patients with nOH associated with Parkinson disease, multiple system atrophy, and primary autonomic failure. Patients were titrated to the maximum tolerated dose of 100 to 600

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mg three times daily for seven days. There was a no significant change from baseline for the composite score of the Orthostatic Hypotension Questionnaire (OHQ) compared with placebo. However, Northera® resulted in significant difference in the secondary end points of mean change in standing systolic blood pressure from baseline and absolute mean change in dizziness at week 1. A second study evaluated Northera® in 225 patients with symptomatic nOH associated with Parkinson’s disease. Northera® treatment resulted in a significant improvement in the score for dizziness/light-headedness/feeling faint/feeling like might black out. Northera® also resulted in a significant absolute mean change in dizziness at week 1, although this effect was not observed beyond week 1.

The third trial was a randomized, open-label, parallel group study extension study that evaluated patients who were already receiving Northera® from previous studies. Patients received their Northera® titrated dose for three months, then entered a 2-week withdrawal phase prior to enrolling in the study. Changes in standing DBP and SBP were not clinically significant.

Northera® is dosed 100 mg three times daily initially, and is titrated in increments of 100 mg three times daily every 24 to 48 hours to a maximum daily dose of 1800 mg. The effectiveness of Northera® beyond two weeks of treatment has not been established.

**Policy**

The Plan may authorize coverage of Northera® for members meeting the following clinical criteria

**Prior Authorization**

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

**Initial Criteria (Duration of Approval – 3 months)**

Documentation of the following:

1. Must be 18 years of age or older; **AND**
2. Northera® is being prescribed by or in consultation with a cardiologist or neurologist; **AND**
3. Diagnosis of symptomatic neurogenic orthostatic hypotension (nOH); **AND**
4. nOH is being caused by one of the following diagnoses:
   a. Primary autonomic failure (i.e., Parkinson’s disease, multiple system atrophy, or pure autonomic failure)
   b. Dopamine beta-hydroxylase deficiency
   c. Non-diabetic autoimmune neuropathy; **AND**
5. Documentation that at least **one** of the following non-pharmacologic interventions has been tried but has not been successful:
   a. Discontinuation of drugs that can cause orthostatic hypotension
   b. Raising the head of the bed 10 to 20 degrees
   c. Wearing compression stockings

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Northera®

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6. An inadequate response, intolerance, or contraindication to a trial of midodrine **AND** fludrocortisone

Re-authorization *(Duration of approval – 6 months)*

Documentation of the following:

1. The neurogenic orthostatic hypotension has stabilized without adverse effects from Northera®

*Quantity Limitations Apply – See Appendix A*

**Limitations**

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

- When the above criteria are not met.

**Clinical Background Information and References**


**Appendix A – Quantity Limitations for Northera®**

<table>
<thead>
<tr>
<th>Medication Name</th>
<th>Maximum Quantity</th>
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<tbody>
<tr>
<td>Northera® 100 mg capsule</td>
<td>3 capsules/day</td>
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<tr>
<td>Northera® 200 mg capsule</td>
<td>6 capsules/day</td>
</tr>
<tr>
<td>Northera® 300 mg capsule</td>
<td>6 capsules/day</td>
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**Original Approval Date** | **Original Effective Date** | **Policy Owner** | **Approved by** |
<table>
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<tbody>
<tr>
<td>05/14/2015</td>
<td>09/01/2015 (BMCHP) and 10/01/2015 (Well Sense)</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>
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<th>Review Date</th>
<th>Summary of Revisions</th>
<th>Revision Effective Date</th>
<th>Approved by</th>
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<tr>
<td>05/12/2016</td>
<td>P&amp;T Annual Review, added neurologist to specialist prescribers.</td>
<td>09/15/2016</td>
<td>P&amp;T Committee NH DHHS</td>
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<tr>
<td>05/11/2017</td>
<td>P&amp;T Annual Review, added age requirement in criteria.</td>
<td>09/05/2017</td>
<td>P&amp;T Committee</td>
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### Next Review Date

05/10/2018

### Other Applicable Policies

- 9.002 Mandatory Generic Substitution Policy
- 9.015 Quantity Limitation Policy

### 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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