Clinical Policy: Droxidopa (Northera)
Reference Number: CP.CPA.130
Effective Date: 11.16.16
Last Review Date: 11.17
Line of Business: Commercial

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Droxidopa (Northera™) is a synthetic amino acid precursor of norepinephrine.

FDA approved indication
Northera 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 (Parkinson’s disease [PD], multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Northera is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Symptomatic Neurogenic Orthostatic Hypotension (must meet all):
      1. Diagnosis of symptomatic neurogenic orthostatic hypotension;
      2. Failure of midodrine OR fludrocortisone unless member experiences clinically significant adverse effects or has contraindication(s);
      3. Dose does not exceed 1800 mg/day.
      Approval duration: Length of benefit

   B. Other diagnoses/indications
      1. Refer to CP.CPA.09 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy
   A. Symptomatic neurogenic orthostatic hypotension (must meet all):
      1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
      2. Member is responding positively to therapy;
      3. Dose does not exceed 1800 mg/day.
      Approval duration: Length of benefit

   B. Other diagnoses/indications (must meet 1 or 2):

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1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy. 
   **Approval duration: Duration of request or 12 months (whichever is less); or**
2. Refer to CP.CPA.09 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

### III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.CPA.09 or evidence of coverage documents.

### IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*

- PD: Parkinson’s Disease
- nOH: neurogenic orthostatic hypotension

*Appendix B: General Information*

- Symptoms of nOH may include lightheadedness, dizziness, visual disturbances, presyncope, and syncope in response to sudden postural change.
- Effectiveness beyond two weeks of treatment has not been established. Per package labeling for Northera, continued effectiveness of Northera should be assessed periodically.
- Includes a boxed warning for reduction or discontinuation of Northera if supine hypertension cannot be managed by elevation of the head of the bed with any increase in dose.

*Appendix C: Therapeutic Alternatives*

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>midodrine</td>
<td>10 mg PO TID At 3 to 4 hour intervals (during daytime hours)</td>
<td>30 mg per day</td>
</tr>
<tr>
<td>fludrocortisone</td>
<td>0.1 to 0.2 mg PO QD</td>
<td>0.2 mg per day</td>
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</tbody>
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*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

### V. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptomatic neurogenic orthostatic hypotension</td>
<td>100 mg PO TID</td>
<td>1800 mg PO/day</td>
</tr>
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</table>

Titrate to symptomatic response, in increments of 100 mg PO TID every 24-48 hours up to a maximum dose of 600 mg PO TID.
VI. Product Availability
Capsules: 100 mg, 200 mg, 300 mg

VII. References

Reviews, Revisions, and Approvals

<table>
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<tr>
<th>Converted to new template. Minor changes to verbiage and grammar. References updated.</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
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<tbody>
<tr>
<td>01.19.17</td>
<td>11.17</td>
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Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a
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This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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