Clinical Policy: Droxidopa (Northera™)
Reference Number: NH.PMN.17
Effective Date: 08/2016
Last Review Date: 12/2017
Line of Business: Medicaid

Coding Implications
Revision Log

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

- 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 (including 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. Neurogenic Orthostatic Hypotension (NOH) (must meet all)**:**

1. Diagnosis of symptomatic neurogenic orthostatic hypotension caused by one of the following (a, b, or c):
   a. Primary autonomic failure (Parkinson's disease, multiple system atrophy, or pure autonomic failure);
   b. Dopamine beta-hydroxylase deficiency;
   c. Non-diabetic autonomic neuropathy;
2. Failure of midodrine or fludrocortisone at maximum indicated doses, unless member experiences clinically significant adverse effects or has contraindication(s) to midodrine and fludrocortisone;
3. Request does not exceed 1800 mg/day and health plan approved daily quantity limit.

Approval duration: 14 days

B. Other diagnoses/indications – Refer to CP.PHAR.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

II. Continued Therapy

A. Neurogenic Orthostatic Hypotension (NOH) (must meet all)**:**

1. Previously received medication via Centene benefit or member has previously met initial approval criteria;
2. Request does not exceed 1800 mg/day and health plan approved daily quantity limit.

Approval duration: 3 months

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy; or
2. Refer to CP.PMN.53 if requested indication is NOT listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

Approval duration: 3 months

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.PMN.53 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation Key

NOH: Neurogenic orthostatic hypotension

V. Dosage and Administration

The starting dose is 100 mg three times during the day. Titrate by 100 mg three times daily, up to a maximum dose of 600 mg three times daily.

VI. Product Availability

Capsules: 100 mg, 200 mg, and 300 mg

VII. References

1. Northera Prescribing Information. Deerfield, IL: Lundbeck; October 2016. Available at: https://www.northera.com. Accessed October 2016.

2. Vijayan J, Sharma VK. Neurogenic orthostatic hypotension - management update and role of droxidopa. Ther Clin Risk Manag. 2015 Jun 8;11:915-23.

Reviews, Revisions, and Approvals	Date	Approval Date
Policy created.	04/16	08/16
Converted to integrated template; Removed requirement of a medication being prescribed by or in consultation with a specialist; Added required conditions of autonomic failure, dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy; Added maximum dose of 1800mg/day. Changed continued treatment duration of approval to 3 months. Removed continued criteria limiting 14 days per 365 day cycle.	10/16	11/16

Reviews, Revisions, and Approvals	Date	Approval Date
Annual Review, No Changes	12/17	12/17

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 discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers,

members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.