Clinical Policy: Droxidopa (Northera™)

Reference Number: PA.CP.PMN.17
Effective Date: 01/18
Last Review Date: 11/2016
Line of Business: Medicaid

Coding Implications
Revision Log

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 Pennsylvania Health and Wellness ® 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: 30days

B. Other diagnoses/indications – Refer to PA.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 Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. ;

3. Participant has seen improvement in NOH symptoms
4. Request does not exceed 1800 mg/day and health plan approved daily quantity limit.

Approval duration: 6 months

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or the Continuity of Care policy (PA.LTSS.PHAR.01) applies and documentation supports positive response to therapy; or
2. Refer to PA.CP.PMN.53 if requested indication is NOT listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

Approval duration: 6 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 – PA.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