Clinical Policy: Droxidopa (Northera™)

Reference Number: PA.CP.PMN.17
Effective Date: 01/18
Last Review Date: 10/30/2019

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.
- Effectiveness beyond 2 weeks of treatment has not been established. The continued effectiveness of Northera should be assessed periodically.

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 up to maximally indicated doses, unless both are contraindicated or clinically significant adverse are experienced;
3. Dose does not exceed 1,800 mg (6 capsules) per day.

Approval duration: 14days

B. Other diagnoses/indications – Refer to PA.CP.PMN.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. Member is responding positively to therapy;

3. If request is for a dose increase, new dose does not exceed 1,800 mg (6 capsules) per day.

Approval duration: 12 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: 12 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
FDA: Food and Drug Administration
NOH: Neurogenic orthostatic hypotension
PD: Parkinson's disease

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
midodrine	10 mg PO TID at 3 to 4 hour intervals (during daytime hours)	30 mg/day
fludrocortisone	0.1 to 0.2 mg PO QD	0.2 mg/day

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.

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): history of hypersensitivity to the drug or its ingredients
- Boxed warning(s): supine hypertension

Appendix D: General Information
- Symptoms of nOH may include lightheadedness, dizziness, visual disturbances, presyncope, and syncope in response to sudden postural change.
- Effectiveness of Northera beyond two weeks of treatment has not been established. Per package labeling for Northera, continued effectiveness of Northera should be assessed periodically.

- The package labeling for Northera includes a Black Box warning for reduction or discontinuation of Northera if supine hypertension cannot be managed by elevation of the head of the bed.

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; February 2017. Available at: http://www.northera.com. Accessed July 22, 2018.
2. Vijayan J, Sharma VK. Neurogenic orthostatic hypotension - management update and role of droxidopa. Ther Clin Risk Manag. 2015 Jun 8;11:915-23.
3. Jones PK, Shaw BH, Raj SR. Orthostatic hypotension: managing a difficult problem. Expert Rev Cardiovasc Ther. 2015 Nov;13(11):1263-76. doi: 10.1586/14779072.2015.1095090. Epub 2015 Oct 1.
4. Shibao C, Lipsitz LA, Biaggioni I et al. Evaluation and treatment of orthostatic hypotension. J Am Soc Hypertens. 2013 Jul-Aug;7(4):317-24. doi: 10.1016/j.jash.2013.04.006. Epub 2013 May 27.

Reviews, Revisions, and Approvals	Date	Approval Date
4Q 2018 annual review: changed Initial Approval duration from Length of Benefit to 14 days, and due to lack of evidence of effectiveness of Northera after 2 weeks of treatment; changed Continued Therapy approval duration from Length of Benefit to 12 months in order to assess for continued efficacy in light of the black box warning potential for severe supine hypertension with use of Northera; removed the requirement to wait 365 days before reauthorizing Northera even in cases where efficacy at 14 days has been demonstrated; changed Continued Therapy approval duration from 14 days to 12 months; references reviewed and updated.	07/18	
4Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	10/30 /19	