Pharmacy Policy Bulletin: J-0489 Northera (droxidopa) – Commercial and Healthcare Reform	
Number: J-0489	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** 1. Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0489-012	**Original Date:** 09/03/2014
Effective Date: 10/08/2025	**Review Date:** 09/17/2025

Drugs Product(s):	• Northera (droxidopa)
FDA-Approved Indication(s):	• 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 (e.g., Parkinson's disease [PD], multiple system atrophy, or pure autonomic failure), dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy.

Background:	• The exact mechanism of action of Northera in the treatment of neurogenic orthostatic hypotension is unknown. Northera is a synthetic amino acid analog that is directly metabolized to norepinephrine by dopa-decarboxylase, which is extensively distributed throughout the body. It is believed that the pharmacological effects of Northera are through norepinephrine and not through the parent molecule or other metabolites. Norepinephrine increases blood pressure by inducing peripheral arterial and venous vasoconstriction.
	• Clinical studies of Northera ranged from 1 week to 3 months. Patients entering the studies were required to have a decrease of at least 20 mmHg or 10 mmHg in systolic or diastolic blood pressure, respectively, within 3 minutes after standing, as well as symptoms associated with nOH.
	• According to the 2017 American College of Cardiology/American Heart Association/Heart Rhythm Society guidelines for the evaluation and management of patients with syncope, appropriate treatment for nOH begins with acute water ingestion (Class I recommendation), with other pharmacologic therapy options for certain patients including midodrine, fludrocortisone, and/or Northera. All three of these agents have the same Class IIa recommendation.
	• Prescribing Considerations:
	  ○ Effectiveness beyond 2 weeks of treatment has not been established. The continued effectiveness of Northera should be assessed periodically.
	  ○ Northera has a black box warning for supine hypertension.

	○ Northera is dosed three times a day: morning, midday, and late afternoon (at least 3 hours before bedtime). This dosing must be followed to reduce the potential for supine hypertension during sleep. ○ Supine blood pressure should be monitored prior to and during treatment and more frequently when increasing doses. If supine hypertension cannot be managed by elevation of the head of the bed, the Northera dose should be reduced or discontinued.

Approval Criteria

I. Initial Authorization (ICD-10: I95.1, G90, R55)

When a benefit, coverage of Northera (droxidopa) may be approved when all of the following criteria are met **(A. through E.)**:

A. The member is 18 years of age or older.

B. The member has a diagnosis of neurogenic orthostatic hypotension (nOH) substantiated by both of the following **(1. and 2.)**:

1. The member meets one (1) of the following criteria **(a. or b.)**:

a. Documentation of a decrease of at least 20 mmHg in systolic blood pressure within 3 minutes of standing.

b. Documentation of a decrease of at least 10 mmHg in diastolic blood pressure within 3 minutes of standing.

2. The member has at least one (1) of the following symptoms of nOH upon standing **(a. through d.)**:

a. Dizziness

b. Lightheadedness

c. Feeling faint

d. Feeling likely to black out

C. The cause of nOH is one (1) of the following **(1., 2., or 3.)**:

1. Primary autonomic failure (for example, PD, multiple system atrophy, or pure autonomic failure)

2. Dopamine beta-hydroxylase deficiency

3. Non-diabetic autonomic neuropathy

D. The member has experienced therapeutic failure or intolerance to one (1) of the following plan-preferred products, or contraindication to all **(1. or 2.)**:

1. midodrine

2. fludrocortisone

E. If the request is for brand Northera, the member has experienced therapeutic failure or intolerance to generic droxidopa.

II. Reauthorization

When a benefit, reauthorization of Northera (droxidopa) may be approved when all of the following criteria are met **(A. and B.)**:

A. The member meets one (1) of the following criteria **(1. or 2.)**:

1. The member has experienced an increase in systolic or diastolic blood pressure upon standing from baseline.

2. The member has experienced a decrease from baseline in at least one (1) of the following symptoms of nOH upon standing **(a. through d.)**:

a. Dizziness

b. Lightheadedness

c. Feeling faint

d. Feeling likely to black out

B. If the request is for brand Northera, the member has experienced therapeutic failure or intolerance to generic droxidopa.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

Initial Authorization

- Commercial and HCR Plans: If approved, up to a 4 week authorization may be granted.

Reauthorization

- Commercial and HCR Plans: If approved, up to a 3 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Northera [package insert]. Deerfield, IL: Lundbeck; February 2017.
2. Freeman R, Abuzinadah A, Gibbons C, et al. Orthostatic Hypotension. *JACC*. 2018;72(11):1294-1309.
3. Shen W-K, Sheldon RS, Benditt DG, et al. 2017 ACC/AHA/HRS guideline for the evaluation and management of patients with syncope: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *Circulation*. 2017;136(5).