

## PRIOR AUTHORIZATION POLICY

**POLICY:** Northera Prior Authorization Policy

- Northera® (droxidopa capsules – Lundbeck)

**REVIEW DATE:** 12/13/2023

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### OVERVIEW

Northera, a norepinephrine-type product, is indicated for the treatment of orthostatic dizziness, lightheadedness, or the “feeling that one is about to black out” in adults with symptomatic **neurogenic orthostatic hypotension (NOH)** caused by primary autonomic failure (Parkinson’s disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy.<sup>1</sup>

### Disease Overview

Orthostatic hypotension (OH) is a sustained reduction in systolic blood pressure (SBP) of at least 20 mmHg or diastolic blood pressure (DBP) of 10 mmHg within 3 minutes of standing or head-up tilt to at least 60° on a tilt table.<sup>2</sup> OH may be symptomatic or asymptomatic, with only symptomatic OH requiring treatment. NOH is a specific subset of this condition, in which OH is due to inadequate release of norepinephrine from sympathetic vasomotor neurons leading to vasoconstrictor failure. NOH is a rare, chronic and often debilitating condition that is associated with Parkinson’s disease, multiple system atrophy, and pure autonomic failure, and with peripheral neuropathies and ganglionopathies that affect the autonomic nerves.<sup>2-4</sup> Symptoms of NOH include dizziness, lightheadedness, blurred vision, fatigue, and fainting upon standing up. These symptoms can adversely affect patients’ quality of life and ability to conduct activities of daily living that involve standing or walking. Treatment of symptomatic NOH is aimed at increasing standing systolic blood pressure into the range of compensatory cerebrovascular autoregulation (approximately 50 to 150 mmHg).<sup>5</sup> Unapproved pharmacologic agents include fludrocortisone, dihydroergotamine (oral), indomethacin (oral or intravenous), pyridostigmine, and atomoxetine.<sup>2-4,6</sup> Midodrine, an alpha<sub>1</sub>-agonist, is the only other medication approved with a similar indication (treatment of symptomatic orthostatic hypotension) to Northera.<sup>7</sup>

### Guidelines

Consensus panel recommendations initiated by the American Autonomic Society and the National Parkinson Foundation for the screening, diagnosis, and treatment of NOH and associated supine hypertension were published in 2017.<sup>8</sup> Once a patient is diagnosed with NOH, the goals of treatment should be to reduce the burden of symptoms (especially falls), prolong standing time, and restore independence in activities of daily living. The recommendations propose a four-step treatment algorithm for NOH: assessing and adjusting preexisting medications that may be causing or exacerbating NOH, utilizing non-pharmacologic approaches (e.g., blood volume repletion, increased salt intake, physical conditioning, compression garments, elevating the head of the bed), implementing single-agent pharmacologic treatment, and with great caution, combining pharmacologic treatments. Recommended treatments include midodrine, Northera, fludrocortisone, and pyridostigmine. The initial choice of NOH treatments should be individualized and should consider severity, comorbid disease (especially cardiac or renal failure), and treatment goals. Based on the experience of the consensus panel, the recommendation is to titrate to maximum tolerable dose of a single medication and then, if symptomatic benefit is not obtained, consider switching to a different medication or adding a second agent and titrate from its lowest starting dose.

### POLICY STATEMENT

12/13/2023

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Prior Authorization is recommended for prescription benefit coverage of Northera. Because of the specialized skills required for evaluation and diagnosis of patients treated with Northera as well as the monitoring required for adverse events and long-term efficacy, approval requires Northera to be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals are provided for the duration noted below.

**Automation:** None.

## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Northera is recommended in those who meet the following criteria:

### FDA-Approved Indication

- 1. Neurogenic Orthostatic Hypotension.** Approve for 1 year if the patient meets the following (A, B, C, D, and E):
  - A)** Patient is  $\geq 18$  years of age; AND
  - B)** Patient has been diagnosed with symptomatic neurogenic orthostatic hypotension due to primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy; AND
  - C)** Patient has tried two other medications; AND  
Note: Examples of other medications include atomoxetine, dihydroergotamine, fludrocortisone, indomethacin, midodrine, and pyridostigmine.
  - D)** Patient has initiated non-pharmacological measures including but not limited to elevation of the head of the bed, orthostatic compression garments, and appropriate physical training; AND
  - E)** The medication has been prescribed by or in consultation with a cardiologist or a neurologist.

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Northera is not recommended in the following situations:

- 1.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

## REFERENCES

1. Northera® [prescribing information]. Deerfield, IL: Lundbeck; July 2019.
2. Freeman R, Wieling W, Axelrod FB, et al. Consensus statement on the definition of orthostatic hypotension, neurally mediated syncope and the postural tachycardia syndrome. *Clin Auton Res.* 2011;21(2):69-72
3. Wieling W, Kaufmann H, Claydon et al. Diagnosis and treatment of orthostatic hypotension. *Lancet Neurol.* 2022;21(8):735-746.
4. Peixoto AJ. Evaluation and management of orthostatic hypotension: Limited data, limitless opportunity. *Cleve Clin J Med.* 2022;89(1):36-45.
5. Cipolla MJ. The cerebral circulation. San Rafael (CA): Morgan & Claypool Life Sciences; 2009. Available at: <http://www.ncbi.nlm.nih.gov/books/NBK53081/>. Accessed on December 8, 2023.
6. Merative Micromedex®. © 2023 Merative. Available at: <https://www.micromedexsolutions.com>. Accessed on December 8, 2023. Search terms: dihydroergotamine and indomethacin.
7. ProAmatine® tablets [prescribing information]. Lexington, MA: Shire; January 2017.
8. Gibbons CH, Schmidt P, Biaggioni I, et al. The recommendations of a consensus panel for the screening, diagnosis, and treatment of neurogenic orthostatic hypotension and associated supine hypertension. *J Neurol.* 2017;264(8):1567-1582.

