

5.40.004

Section:	Prescription Drugs	Effective Date:	April 1, 2024
Subsection:	Cardiovascular Agents	Original Policy Date:	October 24, 2014
Subject:	Northera	Page:	1 of 5

Last Review Date: March 8, 2024

Northera

Description

Northera (**droxidopa**)

Preferred product: generic droxidopa

Background

Northera (droxidopa) is indicated for the treatment of neurogenic orthostatic hypotension (NOH). NOH is a rare, chronic and often debilitating drop in blood pressure upon standing that is associated with Parkinson's disease, multiple-system atrophy, and pure autonomic failure. Symptoms of NOH include dizziness, lightheadedness, blurred vision, fatigue and fainting when a person stands (1).

Regulatory Status

FDA-approved indication: Northera is indicated for the treatment of orthostatic dizziness, lightheadedness, or the "feeling that you are about to black out" in adult patients with symptomatic neurogenic orthostatic hypotension caused by primary autonomic failure (Parkinson's disease, 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 demonstrated. The continued effectiveness of Northera should be assessed periodically (1).

Northera has a boxed warning to alert health care professionals and patients about the risk of increased blood pressure while lying down (supine hypertension), a common problem that affects people with primary autonomic failure and can cause stroke. It is essential that patients be reminded that they must sleep with their head and upper body elevated. Supine blood

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pressure should be monitored prior to and during treatment and more frequently when increasing doses (1).

Northera may exacerbate existing ischemic heart disease, arrhythmias, and congestive heart failure. Careful consideration should be given to this potential risk prior to initiating therapy in patients with these conditions (1).

Safety and effectiveness of Northera in pediatric patients have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Northera may be considered **medically necessary** if the conditions indicated below are met.

Northera may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Neurogenic orthostatic hypotension caused by **ONE** of the following:

1. Primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure)
2. Dopamine beta-hydroxylase (DBH) deficiency
3. Non-diabetic autonomic neuropathy (NDAN)

AND ALL of the following:

1. Patient will be monitored for supine hypertension prior to and during treatment

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2. **Brand Northera ONLY:** Patient **MUST** have tried the preferred product (generic Northera: droxidopa) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

Prior-Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Neurogenic orthostatic hypotension

AND ALL of the following:

1. The patient has experienced a sustained decrease in dizziness and an increase in systolic blood pressure within 3 minutes of standing
2. Patient will be monitored for supine hypertension during treatment
3. **Brand Northera ONLY:** Patient **MUST** have tried the preferred product (generic Northera: droxidopa) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 3 months

Prior - Approval *Renewal* Limits

Duration 6 months

Rationale

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Summary

Northera is indicated for the treatment of orthostatic dizziness, lightheadedness, or the “feeling that you are about to black out” in adult patients with symptomatic neurogenic orthostatic hypotension caused by primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, and nondiabetic autonomic neuropathy. Effectiveness beyond 2 weeks of treatment has not been demonstrated. The continued effectiveness of Northera should be assessed periodically. Northera has a boxed warning to alert health care professionals and patients about the risk of increased blood pressure while lying down (supine hypertension), a common problem that affects people with primary autonomic failure and can cause stroke. Safety and effectiveness of Northera in pediatric patients have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Northera while maintaining optimal therapeutic outcomes.

References

1. Northera [package Insert]. Deerfield, IL: Lundbeck NA Ltd.; July 2019.

Policy History

Date	Action
November 2014	Addition to PA
December 2014	Annual editorial review and reference update.
December 2015	Annual editorial review
December 2016	Annual editorial review Age added to renewal requirements Policy number change from 5.16.04 to 5.40.04
September 2017	Annual editorial review and reference update Change renewal duration from 3 months to 6
September 2018	Annual review
September 2019	Annual review
September 2020	Annual review and reference update
September 2021	Annual review
December 2021	Annual review. Added requirement brand Northera has to t/f the preferred product droxidopa
September 2022	Annual review
March 2023	Annual review
December 2023	Annual review
March 2024	Annual review

Keywords

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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.