Northera

Description

Northera (droxidopa)

Background
Northera capsules (droxidopa) are 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
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 in patients 18 years of age or older with a diagnosis of neurogenic orthostatic hypotension (NOH) and if the conditions indicated below are met.

Northera is considered investigational in patients less than 18 years of age and 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 the following:
1. Patient will be monitored for supine hypertension prior to and during treatment
Section: Prescription Drugs  Effective Date: October 1, 2019
Subsection: Cardiovascular Agents  Original Policy Date: October 24, 2014
Subject: Northera  Page: 3 of 4

Prior-Approval Renewal Requirements

Age  18 years of age or older

Diagnosis

Patient must have the following:

- Neurogenic orthostatic hypotension

AND 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

Policy Guidelines

Pre-PA Allowance

None

Prior - Approval Limits

Duration  3 months

Prior - Approval Renewal Limits

Duration  6 months

Rationale

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

Policy History

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<td>November 2014</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 13, 2019 and is effective on October 1, 2019.