

Specialty Guideline Management

droxidopa-Northera

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
|------------|--------------|
| Northera | droxidopa |

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications^{1,2}

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 (droxidopa) should be assessed periodically.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review: blood pressure measurements demonstrating a persistent, consistent decrease in systolic blood pressure (SBP) of at least 20 mmHg or decrease in diastolic blood pressure (DBP) of at least 10 mmHg within 3 minutes of standing or head-up tilt test.

Coverage Criteria

Neurogenic orthostatic hypotension¹⁻³

Authorization of 3 months may be granted for treatment of neurogenic orthostatic hypotension when both of the following criteria are met:

- Member has a persistent, consistent decrease in SBP of at least 20 mmHg or decrease in DBP of at least 10 mmHg within 3 minutes of standing or head-up tilt test.
- Member has neurogenic orthostatic hypotension due to any of the following diagnoses:
 - Primary autonomic failure due to Parkinson's disease, multiple system atrophy, or pure autonomic failure
 - Dopamine beta hydroxylase deficiency
 - Non-diabetic autonomic neuropathy

Continuation of Therapy

Neurogenic orthostatic hypotension^{1,2,4}

Authorization of 12 months may be granted for treatment of neurogenic orthostatic hypotension when both of the following criteria are met:

- Member has experienced a sustained decrease in symptoms of neurogenic orthostatic hypotension (e.g., dizziness, lightheadedness, "feeling that you are about to black out")
- Member has neurogenic orthostatic hypotension due to any of the following diagnoses:
 - Primary autonomic failure due to Parkinson's disease, multiple system atrophy, or pure autonomic failure
 - Dopamine beta hydroxylase deficiency
 - Non-diabetic autonomic neuropathy

References

1. Northera [package insert]. Deerfield, IL: Lundbeck Inc.; July 2019.
2. Droxidopa [package insert]. Parsippany, NJ: Ascend Laboratories, LLC; November 2021.
3. 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;264:1567-1582.
4. Isaacson S, Shill HA, Vernino, S, et al. Safety and durability of effect with long-term, open-label droxidopa treatment in patients with symptomatic neurogenic orthostatic hypotension (NOH303). *J Parkinsons Dis*. 2016;6:751-759.