

SPECIALTY GUIDELINE MANAGEMENT

NORTHERA (droxidopa)

POLICY

I. 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

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 should be assessed periodically.

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

Neurogenic orthostatic hypotension

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

1. 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.
2. Member has neurogenic orthostatic hypotension due to **ONE** of the following diagnoses:
 - a. Primary autonomic failure due to Parkinson's disease, multiple system atrophy, and pure autonomic failure, OR
 - b. Dopamine beta hydroxylase deficiency, OR
 - c. Non-diabetic autonomic neuropathy

III. CONTINUATION OF THERAPY

Neurogenic orthostatic hypotension

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

1. Member has experienced a sustained decrease in dizziness
3. Member has neurogenic orthostatic hypotension due to **ONE** of the following diagnoses:
 - a. Primary autonomic failure due to Parkinson's disease, multiple system atrophy, and pure autonomic failure, OR
 - b. Dopamine beta hydroxylase deficiency, OR
 - c. Non-diabetic autonomic neuropathy

IV. REFERENCES

Northera SGM P2017a.docx

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1. Northera [package insert]. Deerfield, IL: Lundbeck inc.; August 2014.