

Pharmacy Policy

Droxidopa (Northera®)

Policy Number: 9.604

Version Number: 2

Version Effective Date: 3/1/2022

Product Applicability <input type="checkbox"/> All Plan+ Products	
Well Sense Health Plan <input type="checkbox"/> New Hampshire Medicaid	Boston Medical Center HealthNet Plan <input type="checkbox"/> MassHealth <input checked="" type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct <input type="checkbox"/> Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Policy Summary

The Plan will authorize coverage of Northera® when appropriate criteria are met.

Policy

Products Affected:

- **droxidopa (Northera)**

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	None

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Required Medical Information	<ol style="list-style-type: none"> 1. Diagnosis of symptomatic neurogenic orthostatic hypotension (nOH); AND 2. nOH is being caused by one of the following diagnoses: <ol style="list-style-type: none"> a. Primary autonomic failure (i.e., Parkinson’s disease, multiple system atrophy, or pure autonomic failure) b. Dopamine beta-hydroxylase deficiency c. Non-diabetic autoimmune neuropathy; AND 3. Member has been unsuccessful with at least one of the following non-pharmacologic interventions: <ol style="list-style-type: none"> a. Discontinuation of drugs that can cause orthostatic hypotension b. Raising the head of the bed 10 to 20 degrees c. Wearing compression stockings d. Performing physical maneuvers to improve venous return e. Increasing salt and water intake (if appropriate) f. Avoiding factors that may cause symptoms (e.g., overexertion in the hot weather, standing or sitting up too quickly); AND 4. An inadequate response, intolerance, or contraindication to a trial of midodrine AND fludrocortisone
Age Restriction	18 years of age or older.
Prescriber Restriction	Prescribed by or in consultation with a cardiologist or neurologist.
Coverage Duration	Initial: 3 months Reauthorization: 6 months
Other criteria	Reauthorization: <ol style="list-style-type: none"> 1. Initial criteria has been met; AND 2. The neurogenic orthostatic hypotension has stabilized without adverse effects from Northera®.

Clinical Background Information and References

1. Northera® (droxidopa) prescribing information. Lundbeck. Deerfield, IL 60015. August 2014.
2. Freeman R, Wieling W, Axelrod FB, Benditt DG, Benarroch E, Biaggioni I, et al. Consensus statement on the definition of orthostatic hypotension, neutrally mediated syncope and the postural tachycardia syndrome. *Clin Auton Res.* 2011;21:69-72.
3. Biaggioni I, Freeman R, Mathias CJ, Low P, Hewitt LA, Kaufmann H. Randomized withdrawal study of patients with symptomatic neurogenic orthostatic hypotension responsive to droxidopa. *Circulation.* 2015;65:101-107.
4. Kaufmann H, Kaplan NM. Treatment of orthostatic and postprandial hypotension. UpToDate. Last updated Sep 22, 2014. Accessed Apr 2015.

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Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date	Approved by
12/1/2020	9.054 Northera Policy retired, new policy created	1/1/2021	P&T Committee
11/11/2021	Annual review: Updated policy name to Droxidopa to reflect generic availability, removed documentation requirement, updated reauthorization criteria.	3/1/2022	P&T Committee

Next Review Date

11/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over

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these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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