
Title: Droxidopa (Northera®)

Policy #: Rx.01.166

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for **droxidopa (Northera®)** as provided under the member's prescription drug benefit.

Description:

Droxidopa (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 two weeks of treatment has not been demonstrated. The continued effectiveness of droxidopa should be assessed periodically.

The exact mechanism of action of droxidopa in the treatment of neurogenic orthostatic hypotension is unknown. Droxidopa is a synthetic amino acid analog that is directly metabolized to norepinephrine by dopa-decarboxylase, which is extensively distributed throughout the body. Droxidopa is believed to exert its pharmacological effects through norepinephrine and not through the parent molecule or other metabolites. Norepinephrine increases blood pressure by inducing peripheral arterial and venous vasoconstriction. Droxidopa in humans induces small and transient rises in plasma norepinephrine. Droxidopa is also known as L-dihydroxyphenylserine, or L-DOPS.

Policy:

INITIAL CRITERIA: Droxidopa (Northera®) is approved when ALL of the following are met:

1. Diagnosis of symptomatic neurogenic orthostatic hypotension; and
2. Prescribed by, or in consultation with, ONE of the following:
 - a. Cardiologist; or
 - b. Neurologist; or
 - c. Nephrologist; and
3. Age 18 years or older; and
4. Attempt has been made to manage neurogenic orthostatic hypotension through at least one non-pharmacologic intervention (e.g., use of compression stockings/abdominal binder, increasing salt/fluid intake, participation in regular exercise, discontinue or reduce hypotensive or antihypertensive medications); and
5. Inadequate response or inability to tolerate midodrine or fludrocortisone; and
6. For the Brand Northera only, inadequate response or inability to tolerate generic droxidopa

Initial authorization duration: 1 month

REAUTHORIZATION CRITERIA: Droxidopa (Northera®) is re-approved when ALL of the following are met:

1. Diagnosis of symptomatic neurogenic orthostatic hypotension; and
2. For the Brand Northera only, inadequate response or inability to tolerate generic droxidopa; and
3. Prescribed by, or in consultation with, ONE of the following:

- a. Cardiologist; or
 - b. Neurologist; or
 - c. Nephrologist; and
4. Documentation of positive clinical response to therapy (e.g., improvement in symptoms such as orthostatic dizziness, lightheadedness, etc.)

Reauthorization duration: 12 months

Black Box Warning as shown in the drug Prescribing Information:

Supine hypertension: Monitor supine blood pressure prior to and during treatment and more frequently when increasing doses. Elevating the head of the bed lessens the risk of supine hypertension, and blood pressure should be measured in this position. If supine hypertension cannot be managed by elevation of the head of the bed, reduce or discontinue Northera.

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Northera (droxidopa) [package insert]. Deerfield IL. Lundbeck Pharmaceutical LLC. July 2019. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=2179f02c-48d7-48eb-8007-5ae43d8d16bc&type=display> . Accessed July 13, 2022.

Droxidopa. Micromedex 2.0. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: <http://www.micromedexsolutions.com>. Accessed July 13, 2022.

Freeman R. Current pharmacologic treatment for orthostatic hypotension. Clinical Autonomic Research 2008; 18(1):14-18. Accessed July 13, 2022.

Freeman R. Neurogenic orthostatic hypotension. New England Journal of Medicine 2008; 358:615-624. Accessed July 13, 2022.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Generic	Brand
Droxidopa	Northera®

Cross References:

Off-Label Use Rx.01.33

Policy Version Number:	9.00
P&T Approval Date:	June 09, 2022
Policy Effective Date:	October 01, 2022
Next Required Review Date:	June 09, 2023

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.

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