PRIOR AUTHORIZATION POLICY

POLICY: Droxidopa Prior Authorization Policy
- Northera® (droxidopa capsules – Lundbeck, generic)

REVIEW DATE: 11/12/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Droxidopa, a norepinephrine-type product, is indicated for the treatment of orthostatic dizziness, lightheadedness, or the "feeling that one is about to black out" in adults with symptomatic **neurogenic orthostatic hypotension (NOH)** caused by primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy.[1]

Disease Overview

Orthostatic hypotension (OH) is a sustained reduction in systolic blood pressure (SBP) of at least 20 mmHg or diastolic blood pressure (DBP) of 10 mmHg within 3 minutes of standing or head-up tilt to at least 60° on a tilt table.[2] OH may be symptomatic or asymptomatic, with only symptomatic OH requiring treatment. NOH is a specific subset of this condition, in which OH is due to inadequate release of norepinephrine from sympathetic vasomotor neurons leading to vasoconstrictor

failure. NOH is a rare, chronic and often debilitating condition that is associated with Parkinson's disease, multiple system atrophy, and pure autonomic failure, and with peripheral neuropathies and ganglionopathies that affect the autonomic nerves.[2-4] Symptoms of NOH include dizziness, lightheadedness, blurred vision, fatigue, and fainting upon standing up. These symptoms can adversely affect patients' quality of life and ability to conduct activities of daily living that involve standing or walking. Treatment of symptomatic NOH is aimed at increasing standing systolic blood pressure into the range of compensatory cerebrovascular autoregulation (approximately 50 to 150 mmHg).[5] Unapproved pharmacologic agents include fludrocortisone, dihydroergotamine (oral), indomethacin (oral or intravenous), pyridostigmine, and atomoxetine.[2-4] Midodrine, an alpha$_1$-agonist, is the only other medication approved with a similar indication (treatment of symptomatic orthostatic hypotension) to droxidopa.[6]

Guidelines

Consensus panel recommendations initiated by the American Autonomic Society and the National Parkinson Foundation for the screening, diagnosis, and treatment of NOH and associated supine hypertension were published in 2017.[7] Once a patient is diagnosed with NOH, the goals of treatment should be to reduce the burden of symptoms (especially falls), prolong standing time, and restore independence in activities of daily living. The recommendations propose a four-step treatment algorithm for NOH: assessing and adjusting preexisting medications that may be causing or exacerbating NOH, utilizing non-pharmacologic approaches (e.g., blood volume repletion, increased salt intake, physical conditioning, compression garments, elevating the head of the bed), implementing single-agent pharmacologic treatment, and with great caution, combining pharmacologic treatments. Recommended treatments include midodrine, droxidopa, fludrocortisone, and pyridostigmine. The initial choice of NOH treatments should be individualized and should consider severity, comorbid disease (especially cardiac or renal failure), and treatment goals. Based on the experience of the consensus panel, the recommendation is to titrate to maximum tolerable dose of a single medication and then, if symptomatic benefit is not obtained, consider switching to a different medication or adding a second agent and titrate from its lowest starting dose.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of droxidopa. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with droxidopa as well as the monitoring required for adverse events and long-term efficacy, approval requires droxidopa to be prescribed by or in consultation with a physician who specializes in the condition being treated.

- **Northera® (droxidopa capsules – Lundbeck, generic)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Neurogenic Orthostatic Hypotension.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has been diagnosed with symptomatic neurogenic orthostatic hypotension due to primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy; AND
   - **C)** Patient has tried two other medications for the treatment of neurogenic orthostatic hypotension; AND
     Note: Examples of other medications for the treatment of neurogenic orthostatic hypotension include atomoxetine, dihydroergotamine, fludrocortisone, indomethacin, midodrine, and pyridostigmine.
   - **D)** Patient has initiated non-pharmacological measures; AND
     Note: Examples of non-pharmacological measures include but are not limited to elevation of the head of the bed, orthostatic compression garments, and appropriate physical training.
   - **E)** The medication has been prescribed by or in consultation with a cardiologist or a neurologist.

CONDITIONS NOT COVERED

- **Northera® (droxidopa capsules – Lundbeck, generic)**

is(are) considered not medically necessary for ANY other use(s); criteria will be updated as new published data are available.

REFERENCES

1. Northera® [prescribing information]. Deerfield, IL: Lundbeck; July 2019.
2. Ju W and Sinn Dong. Diagnosis and management of neurogenic orthostatic hypotension. *Ann Clin Neurophysiology.* 2023;25(2):66-77.
3. Wieling W, Kaufmann H, Claydon et al. Diagnosis and treatment of orthostatic hypotension. *Lancet Neurol*. 2022;21(8):735-746.
4. Peixoto AJ. Evaluation and management of orthostatic hypotension: Limited data, limitless opportunity. *Cleve Clin J Med*. 2022;89(1):36-45.
5. Cipolla MJ. The cerebral circulation. San Rafael (CA): Morgan & Claypool Life Sciences; 2009. Available at: http://www.ncbi.nlm.nih.gov/books/NBK53081/. Accessed on December 8, 2024
6. ProAmatine® tablets [prescribing information]. Lexington, MA: Shire; January 2017.
7. 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(8):1567-1582.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	12/13/2023

Annual Revision	Policy name changed from Northera Prior Authorization Policy to Droxidopa Prior Authorization Policy. The generic droxidopa was added, where relevant throughout the policy.	12/11/2024
Annual Revision	**Neurogenic Orthostatic Hypotension:** Moved examples of non-pharmacological measures to a Note.	11/12/2025