UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 2042-16
Program	Prior Authorization/Medical Necessity
Medication	Northera® (droxidopa)*
P&T Approval Date	10/2014, 4/2015, 2/2016, 2/2017, 4/2017, 4/2018, 4/2019, 4/2020, 4/2021, 4/2022, 4/2023, 4/2024, 4/2025, 4/2026
Effective Date	7/1/2026

1. Background:

Northera (droxidopa)* 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 (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 two weeks of treatment has not been established. The continued effectiveness of Northera* should be assessed periodically.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Northera*** will be approved based on **all** of the following criteria

   a. Diagnosis of symptomatic neurogenic orthostatic hypotension (nOH) as defined by **one** of the following when an upright position is assumed or when using a head-up tilt-table testing at an angle of at least 60 degrees:

      (1) At least a 20 mm Hg fall in systolic pressure
      (2) At least a 10 mm Hg fall in diastolic pressure

      -AND-

   b. nOH caused by **one** of the following:

      (1) Primary autonomic failure (e.g., Parkinson's disease, multiple system atrophy, and pure autonomic failure)
      (2) Dopamine beta-hydroxylase deficiency
      (3) Non-diabetic autonomic neuropathy

      -AND-

   c. Diagnostic evaluation has excluded other causes associated with orthostatic hypotension (e.g., congestive heart failure, fluid restriction, malignancy)

      -AND-

   d. The patient has tried at least **two** of the following non-pharmacologic interventions:

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(1) Discontinuation of drugs which can cause orthostatic hypotension [e.g., diuretics, antihypertensive medications (primarily sympathetic blockers), anti-anginal drugs (nitrates), alpha-adrenergic antagonists, and antidepressants]
(2) Raising the head of the bed 10 to 20 degrees
(3) Compression garments to the lower extremities or abdomen
(4) Physical maneuvers to improve venous return (e.g., regular modest-intensity exercise)
(5) Increased salt and water intake, if appropriate
(6) Avoiding precipitating factors (e.g., overexertion in hot weather, arising too quickly from supine to sitting or standing)

-AND-

e. No previous diagnosis of supine hypertension

-AND-

f. Prescribed by or in consultation with **one** of the following specialists:

(1) Cardiologist
(2) Neurologist
(3) Nephrologist

-AND-

g. History of failure (after a trial of at least 30 days), contraindication or intolerance to **both** of the following medications:

(1) fludrocortisone (generic Florinef)
(2) midodrine (generic ProAmatine)

Authorization will be issued for 12 months.

B. Reauthorization

1. **Northera*** will be approved based on the following criteria:

a. Documentation of positive clinical response to Northera* therapy

-AND-

b. Physiological countermeasures for nOH continue to be employed

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

*** Multi-source brand Northera may be excluded from coverage**

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3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class
- Supply limits may be in place.

4. References:

1. Northera [package insert]. Deerfield IL: Lundbeck NA Ltd; July 2019.
2. Fedorowski, A, Ricci, F, Hamrefors, V, et. al. Orthostatic Hypotension: Management of a Complex, But Common, Medical Problem. *Circ Arrhythm Electrophysiol*. 2022; 15: 212-29.
3. Wieling, W, Kaufmann, H, Glaydon, VE, et. al. Diagnosis and treatment of orthostatic hypotension. *Lancet Neurol.* 2022; 21: 735-46.

Program	Prior Authorization/Medical Necessity – Northera*
Change Control	
Date	Change
10/2014	New program.
4/2015	Added definition of orthostatic hypotension; Separated diagnosis of NOH and the potential causes of NOH in the criteria; Modified to require 2 non-pharmacologic interventions; Modified to require a 30 day trial of the alternative medications.
2/2016	Annual review with no change to clinical intent. Updated references
7/2016	Added Indiana and West Virginia coverage information.
11/2016	Administrative change. Added California coverage information.
2/2017	Administrative change. Updated references.
4/2017	Removed medical record requirement. State mandate reference language updated.
4/2018	Annual review. Updated references.
4/2019	Annual review with administrative changes. Added statement regarding use of automated processes and updated references.
4/2020	Annual review. Updated references.
4/2021	Annual review. Noted that multi-source brand may be excluded from coverage.
4/2022	Annual review. Updated references.
4/2023	Annual review. No changes.
4/2024	Annual review. Increased authorization periods to 12 month and updated references.
4/2025	Annual review. Brands of Florinef and ProAmatine are no longer available – updated to list generic only.
4/2026	Annual review. No changes.

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