UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Northera

Program	Prior Authorization
Medication	Northera (droxidopa)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania CHIP, Rhode Island, South Carolina
Issue Date	9/2014
Pharmacy and Therapeutics Approval Date	4/2020
Effective Date	6/2020

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. 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:
   (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) Florinef (fludrocortisone)
   (2) ProAmatine (midodrine)

Authorization will be issued for 3 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.

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; 2019.
2. Shibao C, Lipsitz LA, Biaggioni I. Evaluation and treatment of orthostatic hypotension. J Am Soc Hypertens. 2013;7(4):317-324.
3. Freeman, R, Abuzinadah, AR, Gibbons, C, et. al. Orthostatic Hypotension. *J Am Coll Cardiol.* 2018:72 (11); 1294-1309.
4. 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): 1567-82.

Program	Prior Authorization – Northera
Change Control	
Date	Change
9/18/2014	New policy
12/17/2015	Annual Review
10/2016	Updated to align with Employer & Individual criteria. Updated policy template.
2/2017	Annual review. Updated references.
3/2017	Changed reauthorization duration to 12 months
4/2017	Removed medical record requirements
4/2018	Annual Review. Updated references.
12/2019	Annual review with administrative changes.
4/2020	Updated references.