Market Applicability							
Market	DC	GA	КҮ	MD	NJ	NY	WA
Applicable	Х	Х	Х	Х	Х	Х	NA

# Northera (droxidopa)

Override(s)	Approval Duration
Prior Authorization	1 year
Quantity Limit	

Medications	Quantity Limit
Northera (droxidopa) 100mg^	3 capsules per day
Northera (droxidopa) 200mg, 300mg	6 capsules per day

<sup>^</sup>Titration dosing until symptomatic response or maximal daily dose has been achieved: May approve up to an additional #15 (fifteen) 100 mg capsules per day in the first 14 days (2 weeks) of therapy.

#### **APPROVAL CRITERIA**

Requests for Northera (droxidopa) may be approved if the following criteria are met:

- I. Individual is 18 years of age or older; AND
- II. Individual has a diagnosis of symptomatic neurogenic orthostatic hypotension (NOH) caused by:
  - A. Primary autonomic failure [such as but not limited to Parkinson's disease (PD), multiple system atrophy (MSA), pure autonomic failure (PAF), Dementia with Lewy Bodies (DLB)]; OR
  - B. Dopamine beta-hydroxylase deficiency; OR
  - C. Non-diabetic autonomic neuropathy;

## AND

III. Individual has had a trial and inadequate response or intolerance to one prior symptomatic NOH pharmacologic therapy (which may include midodrine or fludrocortisone [AHFS]).

## Notes:

 Northera (droxidopa) has a black box warning for 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 droxidopa.

New Program Date 09/05/2017 This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply. CRX-ALL-0413-19

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Market Applicability							
Market	DC	GA	КҮ	MD	NJ	NY	WA
Applicable	Х	Х	Х	Х	Х	Х	NA

2. Per label, effectiveness for use beyond 2 weeks of treatment has not been established and continued effectiveness should be assessed periodically.

State Specific Mandates				
State name	Date effective	Mandate details (including specific bill if applicable)		
N/A	N/A	N/A		

#### Key References:

- 1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: <u>http://www.clinicalpharmacology.com</u>. Updated periodically.
- 2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: March 8, 2019.
- 3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
- 4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
- 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 [published online ahead of print Jan 3 2017]. J Neurol. Available from: <u>http://link.springer.com/article/10.1007%2Fs00415-016-8375-x</u>. Accessed on: March 7, 2019.
- Metzler M, Duerr S, Granata R et al. Neurogenic orthostatic hypotension: pathophysiology, evaluation, and management. *J Neurol.* 2013; 260(9):2212-2219. Available from: <u>http://link.springer.com/article/10.1007/s00415-012-6736-7</u>. Accessed on: March 7, 2019.

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