Northera (droxidopa)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial requests: 3 months Continuation requests: 1 year

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

^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

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

I. Individual is 18 years of age or older; **AND**
II. Documentation is provided that 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. Documentation is provided that individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to one prior symptomatic NOH pharmacologic therapy (which may include midodrine or fludrocortisone [AHFS]).

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

I. Documentation is provided that the member has experienced a positive clinical response with Northera (droxidopa) use (e.g., sustained decrease in dizziness)

Requests for **brand** Northera must also meet the following criteria, in addition to the above Prior Authorization criteria:

I. Documentation is provided that individual has failed an adequate trial of one chemically equivalent generic droxidopa agent. Medication samples/coupons/discount cards are excluded from consideration as a trial.;
   AND

A. Documentation is provided that generic droxidopa had inadequate response; **OR**
B. Documentation is provided that generic droxidopa caused adverse outcome; **OR**
C. Documentation is provided that the individual has a genuine allergic reaction to an inactive ingredient in generic agent. Allergic reaction(s) must be clearly documented in the individual's medical record.

Notes:

1. 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.
2. Per label, effectiveness for use beyond 2 weeks of treatment has not been established and continued effectiveness should be assessed periodically.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. 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: January 26, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. 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: http://link.springer.com/article/10.1007%2Fs00415-016-8375-x.
6. Metzler M, Duerr S, Granata R et al. Neurogenic orthostatic hypotension: pathophysiology, evaluation, and management. *J Neurol*. 2013; 260(9):2212-2219. Available from: http://link.springer.com/article/10.1007/s00415-012-6736-7.