RXADVANCE
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Clinical Policy Title:	droxidopa
Policy Number:	RxA.420
Drug(s) Applied:	Northera®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

Droxidopa (Northera®) is a synthetic amino acid precursor of norepinephrine.

Northera® 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 2 weeks of treatment has not been established. The continued effectiveness of Northera® should be assessed periodically.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Droxidopa (Northera®)	nOH	100 mg PO TID during the day Titrate to symptomatic response, in increments of 100 mg PO TID every 24-48 hours up to a maximum dose of 600 mg PO TID.	1,800 mg/day

Dosage Forms

- Capsules: 100 mg, 200 mg, and 300 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Neurogenic Orthostatic Hypotension (must meet all)**:**

1. Diagnosis of symptomatic nOH caused by one of the following (a, b, or c):
   a. Primary autonomic failure (PD, multiple system atrophy, or pure autonomic failure);
   b. Dopamine beta-hydroxylase deficiency;
   c. Non-diabetic autonomic neuropathy;
2. Age ≥ 18 years;
3. Failure of midodrine or fludrocortisone at up to maximally indicated doses, unless both are contraindicated or clinically significant adverse are experienced;
4. Dose does not exceed 1,800 mg (6 capsules) per day.

Approval Duration
Commercial: 14 days
Medicaid: 14 days

II. Continued Therapy Approval

A. Neurogenic Orthostatic Hypotension (must meet all)**:**

1. Member is currently receiving the medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 1,800 mg (6 capsules) per day.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
nOH: neurogenic orthostatic hypotension
PD: Parkinson's disease

APPENDIX B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
midodrine	10 mg PO TID at 3 to 4-hour intervals (during daytime hours)	30 mg/day
fludrocortisone	0.1 to 0.2 mg PO QD	0.2 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - history of hypersensitivity to the drug or its ingredients.

- Boxed Warning(s):
  - supine hypertension.

APPENDIX D: General Information

- Symptoms of nOH may include lightheadedness, dizziness, visual disturbances, presyncope, and syncope in response to sudden postural change.
- Effectiveness of Northera beyond two weeks of treatment has not been established. Per package labeling for Northera, continued effectiveness of Northera should be assessed periodically.
- The package labeling for Northera includes a Black Box warning for reduction or discontinuation of Northera if supine hypertension cannot be managed by elevation of the head of the bed.

References

1. Northera Prescribing Information. Deerfield, IL: Lundbeck; July 2019. Available at: http://www.northera.com. Accessed July 19, 2020.
2. Vijayan J, Sharma VK. Neurogenic orthostatic hypotension - management update and role of droxidopa. Ther Clin Risk Manag. 2015 Jun 8;11:915-23. Accessed July 19, 2020.
3. Jones PK, Shaw BH, Raj SR. Orthostatic hypotension: managing a difficult problem. Expert Rev Cardiovasc Ther. 2015 Nov;13(11):1263-76. doi: 10.1586/14779072.2015.1095090. Epub 2015 Oct 1. Accessed July 19, 2020.
4. Shibao C, Lipsitz LA, Biaggioni I et al. Evaluation and treatment of orthostatic hypotension. J Am Soc Hypertens. 2013 Jul-Aug;7(4):317-24. doi: 10.1016/j.jash.2013.04.006. Epub 2013 May 27. Accessed July 19, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Policy title table was updated. 2. Dosing information was updated. 3. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…". 4. References were updated.	07/19/2020	09/14/2020

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