Clinical Policy Title:	droxidopa
Policy Number:	RxA.420
Drug(s) Applied:	Northera®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2021
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 orally three tiems daily during the day Titrate to symptomatic response, in increments of 100 mg orally three times daily every 24-48 hours up to a maximum dose of 600 mg orally three times daily.	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. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

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

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
midodrine	10 mg orally three times daily at 3- to 4-hour intervals (during daytime hours)	30 mg/day
fludrocortisone	0.1 to 0.2 mg orally once daily	0.2 mg/day

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

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 light-headedness, 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 June 03, 2021.
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 June 03, 2021.
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 June 03, 2021.
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 June 03, 2021.

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
Policy was reviewed: 1. Statement about provider sample ''The provision of provider samples does not guarantee coverage…" was added to Clinical Policy. 2. Therapeutic Alternatives verbiage was rephrased to "Below are suggested therapeutic alternatives based on clinical guidance..".	06/03/2021	09/14/2021

3. Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only". 4. References were reviewed and updated.		