DROXIDOPA

Generic	Brand	HICL	GCN	Exception/Other
DROXIDOPA	NORTHERA	40936		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a documented diagnosis of Neurogenic Orthostatic Hypotension (NOH) caused by primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy and meets the following criteria?
   - Patient is 18 years or older
   - Prescription was initiated by or given in consultation with a neurologist or cardiologist
   - Previous trial of or contraindication to midodrine **OR** fludrocortisone

   If yes, continue to #2.
   If no, do not approve
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the prescriber performed baseline blood pressure readings while the patient is sitting and also within minutes of standing from a supine (lying face up) position?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a documented decrease of at least 20mmHg in systolic blood pressure or 10mmHg diastolic blood pressure within 3 minutes after standing from a sitting position?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

4. Does the patient have persistent symptoms of neurogenic orthostatic hypotension, which include dizziness, lightheadedness, and the feeling of 'blacking out'?

   If yes, **approve for 1 month by HICL for #180 capsules per 30 days.**
   APPROVAL TEXT: Renewal requires a diagnosis of Neurogenic Orthostatic Hypotension (NOH) and that the patient meets **ALL** of the following criteria while on therapy with Northera:
   - Patient has demonstrated improvement in severity from baseline symptoms of dizziness, lightheadedness, feeling faint, or feeling like the patient may black out
   - Patient had an increase in systolic blood pressure from baseline of at least 10mmHg upon standing from a supine (laying face up) position

   If no, do not approve.
   DENIAL TEXT: The guideline for **DROXIDOPA (Northera)** requires a diagnosis of Neurogenic Orthostatic Hypotension and is at least 18 years of age or older. The following criteria must also be met.
   - Patient has a documented diagnosis of Neurogenic Orthostatic Hypotension caused by primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy
   - Previous trial of or contraindication to midodrine **OR** fludrocortisone
   - Prescription was initiated by or given in consultation with a neurologist or cardiologist
   - Patient has persistent symptoms of neurogenic orthostatic hypotension which includes dizziness, lightheadedness, and the feeling of 'blacking out'
   - Prescriber performed baseline blood pressure reading while the patient is sitting and also within 3 minutes of standing from a supine (lying face up) position
   - Patient has a documented decrease of at least 20 mmHg in systolic blood pressure or 10 mmHg diastolic blood pressure within 3 minutes after standing from a sitting position

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GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Neurogenic Orthostatic Hypotension (NOH) and meets **ALL** of the following criteria?
   - Patient has demonstrated improvement in severity from baseline symptoms of dizziness, lightheadedness, feeling faint, or feeling like the patient may black out
   - Patient had an increase in systolic blood pressure from baseline of at least 10mmHg upon standing from a supine (laying face up) position

   If yes, **approve for 3 months by HICL for #180 capsules per 30 days.**
   If no, do not approve.
   DENIAL TEXT: The guideline for **DROXIDOPA (NORTHERA)** renewal requires a diagnosis of Neurogenic Orthostatic Hypotension (NOH) and that the patient meets **ALL** of the following criteria while on therapy with Northera:
   - Patient has demonstrated improvement in severity from baseline symptoms of dizziness, lightheadedness, feeling faint, or feeling like the patient may black out
   - Patient had an increase in systolic blood pressure from baseline of at least 10mmHg upon standing from a supine (laying face up) position

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RATIONALE

Promote clinically appropriate utilization of Northera (droxidopa) based on its FDA approved indication and dosing.

Northera is indicated for the treatment neurogenic orthostatic hypotension (NOH) that is associated with Parkinson's disease (PD), multiple system atrophy, and pure autonomic failure. People with NOH are severely limited in their ability to perform routine daily activities that require walking or standing. Northera is a synthetic amino acid precursor of norepinephrine, which increases blood pressure by inducing peripheral arterial and venous vasoconstriction.

Orthostatic hypotension is diagnosed when within two to five minues of quiet standing (after a five-minute period of supine rest), one or both of the following is present:
- At least a 20 mmHg fall in systolic pressure
- At least a 10 mmhg fall in diastolic pressure

Northera has a boxed warning regarding the risk of increased blood pressure while lying down (supine hypertension). The most common adverse events seen in clinical trials were headache, dizziness, nausea, hypertension, and fatigue.

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DROXIDOPA

RATIONALE (CONTINUED)

In the clinical trials referenced in the Northera prescribing information, a 'responder' to treatment had to demonstrate improvement on the OHSA item #1 score by at least 1 point, as well as an increase in systolic blood pressure of at least 10 mmHg post-standing, during the open-label dose titration period.

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

DOSE
The recommended starting dose of Northera is 100mg orally three times a day, upon arising in the morning, at midday, and in the late afternoon at least 3 hours prior to bedtime (to reduce the potential for supine hypertension during sleep). Northera may be administered with or without food.

Titrate to symptomatic response, in increments of 100mg three times daily every 24-48 hours up to a maximum dose of 600mg three times daily (maximum total daily dose of 1800mg).

FDA APPROVED INDICATIONS
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.

Northera received orphan-product designation from the FDA.

REFERENCES

- Northera [Prescribing Information]. Charlotte, NC, Chelsea Therapeutics, Aug 2014.
- Low PA, Singer W. Update on Management of Neurogenic Orthostatic Hypotension. Lancet Neurol. May 2008; 7(5):451-458.
- Hauser, Robert, Cameron Szakacs, and Horacio Kaufmann. "Integrated Efficacy and Safety Analyses of Droxidopa for Symptomatic Neurogenic Orthostatic Hypotension (P1. 284)." Neurology 84.14 Supplement (2015): P1-284.
- Kaufmann, Horacio, et al. "Droxidopa for neurogenic orthostatic hypotension A randomized, placebo-controlled, phase 3 trial." Neurology 83.4 (2014): 328-335.
- Kaufmann, Horacio, et al. "Treatment of Neurogenic Orthostatic Hypotension with Droxidopa: Results from a Multi-Center, Double-Blind, Randomized, Placebo-Controlled, Parallel Group, Induction DesignStudy (PL02. 001)." Neurology 78.Meeting Abstracts 1 (2012): PL02-001.
- Freeman, Roy et al. “Consensus statement on the definition of orthostatic hypotension, neurally mediated syncope and the postural tachycardia syndrome.” Clin Auton Res Clinical autonomic research , 2011, Vol.21(2), p.69-72

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DROXIDOPA

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/16
Created: 9/14
Client Approval: 06/16
P&T Approval: 11/14