MEDICAL MUTUAL®

Drug Policy

Policy:	**Northera (droxidopa capsules)** **Prior Approval Criteria**	**Annual Review Date:** **03/20/2024** **Last Revised Date:** **03/20/2024**

OVERVIEW

Northera, a norepinephrine-type product, is indicated for the treatment of orthostatic dizziness, lightheadedness or the "feeling that one is 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 [MSA], and pure autonomic failure [PAF]), dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy. The effectiveness beyond 2 weeks of treatment has not been established. The effectiveness of Northera should be evaluated periodically. The mechanism of action of Northera is unknown. Northera is a synthetic amino acid analog that is metabolized to norepinephrine by dopa-decarboxylase, which is found throughout the body. Northera is thought to exert its effects through norepinephrine, which increases blood pressure (BP) by inducing peripheral arterial and venous vasoconstriction. Northera has a Boxed Warning regarding supine hypertension. Northera may cause or exacerbate supine hypertension in patients with nOH. Supine BP should be measured prior to initiating Northera and after dose increases.

POLICY STATEMENT

This policy involves the use of Northera. Prior authorization is recommended for pharmacy benefit coverage of Northera. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Northera as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Northera be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Northera is recommended in those who meet the following criteria:

Food and Drug Administration (FDA)-Approved Indications

1. **Neurogenic Orthostatic Hypotension (nOH).**
   Criteria. *Approve for 1 month if the patient meets the following criteria (a, b, c, d, and e):*

a) Patient is ≥ 18 years of age; AND
b) Patient has been diagnosed with symptomatic nOH due to primary autonomic failure (Parkinson's disease [PD], multiple system atrophy [MSA], and pure autonomic failure [PAF]), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy; AND
c) Northera has been prescribed by or in consultation with a cardiologist or a neurologist; AND
d) Patient meets ONE of the following conditions (i or ii):
  i. Patient has tried midodrine and one of the following other medications (e.g., fludrocortisone, desmopressin, dihydroergotamine, indomethacin, pyridostigmine, erythropoietin); OR
  ii. Patient has a contraindication or intolerance to all of the medications listed above; AND
e) Patient has initiated non-pharmacological measures including but not limited to elevation of the head of the bed, orthostatic compression garments, and appropriate physical training; AND
f) If the request is for brand Northera, the patient has tried generic droxidopa AND the brand is being requested due to formulation differences in inactive ingredients [documentation required]

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 month (30 days)
B) *Extended Approval:* 1 month (30 days)

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

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