Original Effective Date: 07/01/2018
Current Effective Date: 02/25/2023
Last P&T Approval/Version: 01/25/2023
Next Review Due By: 01/2024
Policy Number: C13402-A

Northera (droxidopa)

PRODUCTS AFFECTED

Northera (droxidopa), droxidopa

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Symptomatic neurogenic orthostatic hypotension (NOH)

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review.

A. NEUROGENIC ORTHOSTATIC HYPOTENSION (NOH)
1. Prescriber attests the member has been diagnosed with symptomatic NOH due to primary autonomic failure (Parkinson’s disease [PD], multiple system atrophy [MSA], pure autonomic failure [PAF]), dopamine beta-hydroxylase deficiency, or nondiabetic autonomic neuropathy AND
2. Prescriber attests the member 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

3. Documentation member has tried midodrine AND one of the following other medications: fludrocortisone, desmopressin, dihydroergotamine, indomethacin, pyridostigmine, erythropoietin OR member has a labeled contraindication or serious side effects to ALL of the following: midodrine, fludrocortisone, desmopressin, dihydroergotamine, indomethacin, pyridostigmine, and erythropoietin

CONTINUATION OF THERAPY:

A. NEUROGENIC ORTHOSTATIC HYPOTENSION (NOH)

1. Documentation of recent re-assessment and medical necessity for the use beyond 2 weeks of treatment [DOCUMENTATION REQUIRED]
AND
2. Prescriber attests to improvement in the symptoms of neurogenic orthostatic hypotension, such as decreased dizziness, decreased lightheadedness, decreased fainting
AND
3. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

DURATION OF APPROVAL:

Initial: 2 weeks (14 days), Continuation of therapy: 2 weeks (14 days)
Per label, effectiveness for use beyond 2 weeks of treatment has not been established and continued effectiveness should be assessed periodically.

PRESCRIBER REQUIREMENTS:

Prescribed by, or in consultation with, a board-certified cardiologist, neurologist, or nephrologist. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

18 years of age or older

QUANTITY:

Quantity limit: Maximum dose of 600 mg three times daily (maximum total daily dose of 1,800mg)

PLACE OF ADMINISTRATION:

The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Oral

DRUG CLASS:

Neurogenic Orthostatic Hypotension (NOH) - Agents

FDA-APPROVED USES:

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

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:

NON-PHARMACOLOGIC MEASURES FOR TREATMENT OF OH *Discontinuation of medications that may cause or exacerbate OH*
Alpha blockers (e.g., terazosin)
Antidepressants (e.g., SSRIs, trazodone, MAOIs, tricyclic antidepressants)
Antihypertensive drugs (e.g., sympathetic blockers)
Antiparkinsonism drugs (e.g., levodopa, pramipexole, ropinirole)
Antipsychotic drugs (e.g., olanzapine, risperidone)
Beta-blocker drugs (e.g., propranolol)
Diuretics (e.g., hydrochlorothiazide, furosemide)
Skeletal muscle relaxants (e.g., tizanidine)
Narcotic analgesics (e.g., morphine)
Phosphodiesterase inhibitors (e.g., sildenafil, tadalafil)
Sedatives/hynotics (e.g., temazepam)
Vasodilators (e.g., hydralazine, nitroglycerin, calcium channel blockers)

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
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], 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 inpatients with NOH. Supine BP should be measured prior to initiating Northera and after dose increases

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Northera (droxidopa) are considered experimental/investigational and therefore, will follow Molina’s Off- Label policy. Contraindications to Northera (droxidopa) include: history of hypersensitivity to the drug or its ingredients.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Northera CAPS 100MG, Northera CAPS 200MG, Northera CAPS 300MG, droxidopa 100mg, droxidopa 200mg, droxidopa 300mg

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Diagnosis Required Medical Information Continuation of Therapy Prescriber Requirements Quantity Contraindications/Exclusions/Discontinuation References	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file