Original Effective Date: 07/01/2018
Current Effective Date: 03/27/2026
Last P&T Approval/Version: 01/28/2026
Next Review Due By: 01/2027
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. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

Drug and Biologic Coverage Criteria

A. NEUROGENIC ORTHOSTATIC HYPOTENSION (NOH)

1. Documented diagnosis of symptomatic neurogenic orthostatic hypotension (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 and older

QUANTITY:

Maximum 600 mg three times daily

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:
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.

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:
Northera has a Black Box Warning for supine hypertension. Monitor supine blood pressure prior to and during treatment and more frequently when increasing doses. Elevating the head of the bed lessens the risk of supine hypertension, and blood pressure should be measured in this position. If supine hypertension cannot be managed by elevation of the head of the bed, reduce or discontinue Northera.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Northera CAPS 100MG, 200MG, 300MG
Droxidopa CAPS 100MG, 200MG, 300MG

REFERENCES

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: References	Q1 2026
REVISION- Notable revisions: References	Q1 2025
REVISION- Notable revisions: Required Medical Information Quantity Background Other Special Considerations Available Dosage Forms References	Q1 2024
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