



Northera Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date
11-01-2025

Date of Origin

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Northera	droxidopa cap	100 MG ; 200 MG ; 300 MG	M ; N ; O ; Y	O ; Y		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Northera	Droxidopa Cap 100 MG	100 MG	450	Capsules	30	DAYS			
Northera	Droxidopa Cap 200 MG	200 MG	180	Capsules	30	DAYS			
Northera	Droxidopa Cap 300 MG	300 MG	180	Capsules	30	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Northera	droxidopa cap	100 MG ; 200 MG ; 300 MG	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ;

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Northera	Droxidopa Cap 100 MG	100 MG	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Northera	Droxidopa Cap 200 MG	200 MG	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Northera	Droxidopa Cap 300 MG	300 MG	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p>Initial Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The patient has a diagnosis of neurogenic orthostatic hypotension (nOH) AND ALL of the following: <ol style="list-style-type: none"> 1. The prescriber has performed baseline (prior to therapy with the requested agent) blood pressure readings while the patient is sitting or supine (laying face up) AND also within 3 minutes of standing from a supine position AND 2. The patient has a decrease of at least 20 mmHg in systolic blood pressure or 10 mmHg diastolic blood pressure within three minutes after standing AND 3. The patient has persistent and consistent symptoms of neurogenic orthostatic hypotension (nOH) caused by ONE of the following: <ol style="list-style-type: none"> A. Primary autonomic failure (Parkinson's disease [PD], multiple system atrophy, or pure autonomic failure) OR B. Dopamine beta-hydroxylase deficiency OR C. Non-diabetic autonomic neuropathy AND 4. The prescriber has assessed the severity of the patient's baseline (prior to therapy with the requested agent) symptoms of dizziness, lightheadedness, feeling faint, or feeling like the patient may black out AND 5. The prescriber has assessed and adjusted, if applicable, any medications known to exacerbate orthostatic hypotension (e.g., diuretics, vasodilators, beta-blockers) AND 6. ONE of the following: <ol style="list-style-type: none"> A. BOTH of the following: <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The prescriber has stated that the patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat the cancer OR B. The prescriber has submitted documentation that the patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat an associated condition related to stage four advanced metastatic cancer [chart notes are required] AND 2. The use of the requested agent is consistent with best practices for the treatment of stage four advanced, metastatic cancer, or an associated condition; supported by peer-reviewed, evidence-based literature; and approved by the United States Food and Drug Administration OR

Module	Clinical Criteria for Approval				
	<p>B. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR</p> <p>C. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes are required] OR</p> <p>D. The patient has tried and had an inadequate response to midodrine [chart notes are required] OR</p> <p>E. Midodrine was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] OR</p> <p>F. The patient has an intolerance, or hypersensitivity to midodrine [chart notes are required] OR</p> <p>G. The patient has an FDA labeled contraindication to midodrine [chart notes are required] OR</p> <p>H. Midodrine is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient’s adherence of care; OR worsen a comorbid condition; OR decrease the patient’s ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes are required] OR</p> <p>I. Midodrine is not in the best interest of the patient based on medical necessity [chart notes are required] OR</p> <p>J. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as midodrine and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] OR</p> <p>B. The patient has another FDA labeled indication for the requested agent and route of administration AND</p> <p>2. If the patient has an FDA labeled indication, then ONE of the following:</p> <p>A. The patient’s age is within FDA labeling for the requested indication for the requested agent OR</p> <p>B. There is support for using the requested agent for the patient’s age for the requested indication AND</p> <p>3. If the request is for one of the following brand agents with an available generic equivalent (listed below), then ONE of the following:</p> <table border="1" data-bbox="527 1323 1122 1396"> <thead> <tr> <th data-bbox="527 1323 824 1356">Brand</th> <th data-bbox="824 1323 1122 1356">Generic Equivalent</th> </tr> </thead> <tbody> <tr> <td data-bbox="527 1356 824 1396">Northera</td> <td data-bbox="824 1356 1122 1396">droxidopa</td> </tr> </tbody> </table> <p>A. BOTH of the following:</p> <p>1. ONE of the following:</p> <p>A. The prescriber has stated that the patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat the cancer OR</p> <p>B. The prescriber has submitted documentation that the patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat an associated condition related to stage four advanced metastatic cancer [chart notes are required] AND</p> <p>2. The use of the requested agent is consistent with best practices for the treatment of stage four advanced, metastatic cancer, or an associated condition; supported by peer-reviewed, evidence-based literature; and approved by the United States Food and Drug Administration OR</p> <p>B. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR</p> <p>C. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes are required] OR</p>	Brand	Generic Equivalent	Northera	droxidopa
Brand	Generic Equivalent				
Northera	droxidopa				

Module	Clinical Criteria for Approval
	<p>D. The patient has tried and had an inadequate response to the generic equivalent [chart notes are required] OR</p> <p>E. The generic equivalent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] OR</p> <p>F. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent [chart notes are required] OR</p> <p>G. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent [chart notes are required] OR</p> <p>H. The generic equivalent is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient's adherence of care; OR worsen a comorbid condition; OR decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes are required] OR</p> <p>I. The generic equivalent is not in the best interest of the patient based on medical necessity [chart notes are required] OR</p> <p>J. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as the generic equivalent and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] OR</p> <p>K. There is support for the use of the requested brand agent over the generic equivalent AND</p> <p>4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND</p> <p>5. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months BCBSIL and BCBSMT: 12 months BCBSNM: 3 months ALL other plans: 1 month</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p>Renewal Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: Patients not previously approved for the requested agent will require initial evaluation review] AND 2. ONE of the following: <ol style="list-style-type: none"> A. The patient has a diagnosis of neurogenic orthostatic hypotension (nOH) AND BOTH of the following: <ol style="list-style-type: none"> 1. The patient has had improvement in severity from baseline symptoms (prior to therapy with the requested agent) of dizziness, lightheadedness, feeling faint, or feeling like the patient may black out [chart notes are required] AND 2. The patient had an increase in systolic blood pressure from baseline (prior to therapy with the requested agent) of at least 10 mmHg upon standing from a supine (laying face up) position OR B. BOTH of the following: <ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent AND 2. The patient has had clinical benefit with the requested agent AND

Module **Clinical Criteria for Approval**

3. If the request is for one of the following brand agents with an available generic equivalent (listed below), then ONE of the following:

Brand	Generic Equivalent
Northera	droxidopa

- A. BOTH of the following:
 - 1. ONE of the following:
 - A. The prescriber has stated that the patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat the cancer **OR**
 - B. The prescriber has submitted documentation that the patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat an associated condition related to stage four advanced metastatic cancer [chart notes are required] **AND**
 - 2. The use of the requested agent is consistent with best practices for the treatment of stage four advanced, metastatic cancer, or an associated condition; supported by peer-reviewed, evidence-based literature; and approved by the United States Food and Drug Administration **OR**
- B. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member **OR**
- C. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes are required] **OR**
- D. The patient has tried and had an inadequate response to the generic equivalent [chart notes are required] **OR**
- E. The generic equivalent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] **OR**
- F. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent [chart notes are required] **OR**
- G. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent [chart notes are required] **OR**
- H. The generic equivalent is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; **OR** cause a significant barrier to the patient’s adherence of care; **OR** worsen a comorbid condition; **OR** decrease the patient’s ability to achieve or maintain reasonable functional ability in performing daily activities; **OR** cause an adverse reaction or cause physical or mental harm [chart notes are required] **OR**
- I. The generic equivalent is not in the best interest of the patient based on medical necessity [chart notes are required] **OR**
- J. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as the generic equivalent and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] **OR**
- K. There is support for the use of the requested brand agent over the generic equivalent **AND**
- 4. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., cardiologist, neurologist) or the prescriber has consulted with a specialist in the area of the patient’s diagnosis **AND**
- 5. The patient does NOT have any FDA labeled contraindications to the requested agent

Length of Approval:

BCBSOK: 36 months
 BCBSIL and BCBSMT: 12 months
 ALL other plans: 3 months

NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

Module	Clinical Criteria for Approval
	<p>The requested agent will also be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The request is for a BCBS NM Fully Insured or NM HIM member and ALL of the following: <ol style="list-style-type: none"> A. The patient does NOT have any FDA labeled contraindications to the requested agent AND B. The requested indication is a rare disease AND C. ONE of the following: <ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 2. ALL of the following: <ol style="list-style-type: none"> A. The member resides in Ohio AND B. The plan is Fully Insured or HIM Shop (SG) AND C. The patient does NOT have any FDA labeled contraindications to the requested agent AND D. ONE of the following: <ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 3. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] <p>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p>Oncology compendia allowed: NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria</p>

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p>Quantity limit for the Target Agent(s) will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the program quantity limit OR 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: <ol style="list-style-type: none"> A. BOTH of the following: <ol style="list-style-type: none"> 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication AND 2. There is support for therapy with a higher dose for the requested indication OR B. BOTH of the following:

Module	Clinical Criteria for Approval
	<ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication AND 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit OR <p>c. BOTH of the following:</p> <ol style="list-style-type: none"> 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication AND 2. There is support for therapy with a higher dose for the requested indication <p>Length of Approval:</p> <p>BCBSIL: 12 months</p> <p>All other plans: Initial: 1 month ; Renewal: 3 months</p>