

Non-Preferred Brand Alternatives Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date
04-01-2025

Date of Origin

OBJECTIVE

The intent of the Non-Preferred Brand PAQL is to promote the use of lower cost, clinically appropriate, formulary alternatives over high-cost, non-preferred brand agents. Target agents will be approved when the patient has experienced an inadequate response to optimized therapy of the lower cost alternatives; the patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the lower cost alternative(s) that is not expected to occur with the requested agent; or the prescriber has provided documentation and the pharmacist has reviewed and approved the patient's needs for the requested agent over the lower cost alternative(s). Program is applicable to the HIM drug lists only.

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Emverm		100 MG	M ; N ; O	N		
Ryclora		2 MG/5ML	M ; N ; O	N		
Dipentum		250 MG	M ; N ; O	N		
Neupro		1 MG/24HR	M ; N ; O	N		
Neupro		2 MG/24HR	M ; N ; O	N		
Neupro		3 MG/24HR	M ; N ; O	N		
Neupro		4 MG/24HR	M ; N ; O	N		
Neupro		6 MG/24HR	M ; N ; O	N		
Neupro		8 MG/24HR	M ; N ; O	N		
Pradaxa		75 MG	M ; N ; O	O ; Y		
Pradaxa		110 MG	M ; N ; O	O ; Y		
Pradaxa		150 MG	M ; N ; O	O ; Y		
Lastacaft		0.25 %	M ; N ; O	N		
Zerviate		0.24 %	M ; N ; O	N		
Alocril		2 %	M ; N ; O	N		
Ciprofloxacin/fluocinolone ; Otovel		0.3-0.025 %	M ; N ; O	M		
Cortisporin-tc		3.3-3-10-0.5 MG/ML	M ; N ; O	N		
Rectiv		0.4 %	M ; N ; O	O ; Y		
Mirvaso		0.33 %	M ; N ; O	O ; Y		
Altabax		1 %	M ; N ; O	N		
Santyl		250 UNIT/GM	M ; N ; O	N		
Crotan		10 %	M ; N ; O	N		

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
Pradaxa	Dabigatran Etexilate Mesylate Cap 110 MG (Etexilate Base Eq)	110 MG	120	Capsules	30	DAYS			
Pradaxa	Dabigatran Etexilate Mesylate Cap 150 MG (Etexilate Base Eq)	150 MG	60	Capsules	30	DAYS			
Pradaxa	Dabigatran Etexilate Mesylate Cap 75 MG (Etexilate Base Eq)	75 MG	60	Capsules	30	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Alocril		2 %	HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025
Altabax		1 %	HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025
Ciprofloxacin/fluocinolone ; Otovel		0.3-0.025 %	HIM Annual 2025 ; HIM Quarterly 2025 ; NM HIM Annual 2025
Cortisporin-tc		3.3-3-10-0.5 MG/ML	HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025
Crotan		10 %	HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025
Dipentum		250 MG	HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025
Emverm		100 MG	HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025
Lastacraft		0.25 %	HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025
Mirvaso		0.33 %	HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Annual 2024 ; NM HIM Annual 2025
Neupro		2 MG/24HR	HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025
Neupro		4 MG/24HR	HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025
Neupro		8 MG/24HR	HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025
Neupro		1 MG/24HR	HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025
Neupro		6 MG/24HR	HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025
Neupro		3 MG/24HR	HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025
Pradaxa		110 MG	HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025
Pradaxa		75 MG	HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025
Pradaxa		150 MG	HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025
Rectiv		0.4 %	HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025
Ryclora		2 MG/5ML	HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025
Santyl		250 UNIT/GM	HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Zerviate		0.24 %	HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Pradaxa	Dabigatran Etexilate Mesylate Cap 110 MG (Etexilate Base Eq)	110 MG	HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025
Pradaxa	Dabigatran Etexilate Mesylate Cap 150 MG (Etexilate Base Eq)	150 MG	HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025
Pradaxa	Dabigatran Etexilate Mesylate Cap 75 MG (Etexilate Base Eq)	75 MG	HIM Annual 2024 ; HIM Annual 2025 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; NM HIM Annual 2024 ; NM HIM Annual 2025

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"> The requested drug is a target in Non-Preferred Brand Alternatives PA with a reject message of "Try pref alternatives first..." AND The requested agent is FDA-approved for the patient's diagnosis AND ONE of the following: <ol style="list-style-type: none"> There are NO formulary alternatives in Tiers 1 through 3 that are FDA-approved for the patient's diagnosis OR There are NO formulary alternatives that can be prescribed in a dose to fit the patient's needs OR 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 BOTH of the following are met: <ol style="list-style-type: none"> ONE of the following: <ol style="list-style-type: none"> 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 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 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 The generic of the requested brand is on formulary AND ONE of the following: <ol style="list-style-type: none"> The patient has tried and had an inadequate response to the generic [chart notes are required] OR

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	<ol style="list-style-type: none"> 2. The generic was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] OR 3. The patient has an intolerance, or hypersensitivity to the generic that is not expected to happen with the requested agent [chart notes are required] OR 4. The patient has an FDA labeled contraindication to the generic that is not expected to happen with the requested agent [chart notes are required] OR 5. The generic 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 6. The generic is not in the best interest of the patient based on medical necessity [chart notes are required] OR 7. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as the generic 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>F. There is only ONE formulary alternative to the requested brand, and it is NOT the generic equivalent AND ONE of the following:</p> <ol style="list-style-type: none"> 1. The patient has tried and had an inadequate response to the formulary alternative [chart notes are required] OR 2. The formulary alternative was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] OR 3. The patient has an intolerance, or hypersensitivity to the formulary alternative [chart notes are required] OR 4. The patient has an FDA labeled contraindication to the formulary alternative [chart notes are required] OR 5. The formulary alternative 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 6. The formulary alternative is not in the best interest of the patient based on medical necessity [chart notes are required] OR 7. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as the formulary alternative 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>G. There is NOT a generic equivalent to the requested brand AND there are TWO or more formulary alternatives to the requested brand AND ONE of the following:</p> <ol style="list-style-type: none"> 1. The patient has tried and had an inadequate response to TWO formulary alternatives [chart notes are required] OR 2. TWO formulary alternatives were discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] OR 3. The patient has an intolerance, or hypersensitivity to TWO formulary alternatives [chart notes are required] OR 4. The patient has an FDA labeled contraindication to ALL formulary alternatives [chart notes are required] OR 5. TWO formulary alternatives are 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

Module	Clinical Criteria for Approval
	<p>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> <ol style="list-style-type: none"> 6. TWO formulary alternatives are not in the best interest of the patient based on medical necessity [chart notes are required] OR 7. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as TWO formulary alternatives 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>Length of approval: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p>The requested agent will also be approved when the following are met:</p> <ol style="list-style-type: none"> 1. The member resides in Ohio AND 2. The plan is Fully Insured or HIM Shop (SG) AND BOTH of the following <ol style="list-style-type: none"> 1. The patient does NOT have any FDA labeled contraindications to the requested agent AND 2. 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: 12 months</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 AND 2. The requested drug is a target in Non-Preferred Brand Alternatives PA with a reject message of "Try pref alternatives first..." AND

Module	Clinical Criteria for Approval
	<p>3. The requested agent is FDA-approved for the patient's diagnosis</p> <p>Length of approval: 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: <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 C. BOTH of the following: <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: 12 months</p>