



Vascepa Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date
10-15-2025

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
Vascepa	icosapent ethyl cap	0.5 GM ; 1 GM	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
Vascepa	Icosapent Ethyl Cap 0.5 GM	0.5 GM	240	Capsules	30	DAYS			
Vascepa	Icosapent Ethyl Cap 1 GM	1 GM	120	Capsules	30	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Vascepa	icosapent ethyl cap	0.5 GM ; 1 GM	Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Vascepa	Icosapent Ethyl Cap 0.5 GM	0.5 GM	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; 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
Vascepa	Icosapent Ethyl Cap 1 GM	1 GM	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; 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

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 severe hypertriglyceridemia (fasting triglyceride level of greater than or equal to 500 mg/dL) OR B. The patient is using the requested agent to reduce the risk of myocardial infarction, stroke, coronary revascularization, or unstable angina requiring hospitalization AND ALL of the following: <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The patient is taking a maximally tolerated statin OR B. The patient is statin intolerant defined as experiencing ONE of the following: <ol style="list-style-type: none"> 1. Statin-related rhabdomyolysis OR 2. Statin-related skeletal muscle symptoms (e.g., myopathy, myalgia) OR 3. Statin-related elevated hepatic transaminase OR C. The patient has a hypersensitivity to at least ONE statin OR D. The patient has an FDA labeled contraindication to ALL statins <p>AND</p>

Module	Clinical Criteria for Approval
	<p>2. The patient has a fasting triglyceride level of greater than or equal to 135 mg/dL AND</p> <p>3. The patient has ONE of the following:</p> <ul style="list-style-type: none"> A. Diabetes mellitus AND TWO or more additional risk factors for cardiovascular disease OR B. Established cardiovascular disease (CVD) AND has ONE of the following: <ul style="list-style-type: none"> 1. Acute coronary syndrome OR 2. History of myocardial infarction OR 3. Stable or unstable angina OR 4. Coronary or other arterial revascularization OR 5. Stroke OR 6. Transient ischemic attack OR 7. Peripheral arterial disease, including aortic aneurysm, presumed to be of atherosclerotic origin OR C. The patient has another FDA labeled indication for the requested agent and route of administration OR D. The patient has another indication that is supported in compendia for the requested agent and route of administration AND <p>2. If the patient has an FDA labeled indication, then ONE of the following:</p> <ul style="list-style-type: none"> A. The patient's age is within FDA labeling for the requested indication for the requested agent OR B. There is support for using the requested agent for the patient's age for the requested indication AND <p>3. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p>Compendia Allowed: AHFS, or DrugDex 1, 2A, or 2B level of evidence</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> <p>The requested agent will also be approved when ONE of the following is met:</p> <ul style="list-style-type: none"> 1. The request is for a BCBS NM Fully Insured or NM HIM member and ALL of the following: <ul 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: <ul 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: <ul 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: <ul 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

Module	Clinical Criteria for Approval
	<p>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> <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> <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. The patient has had clinical benefit with the requested agent AND 3. The patient does NOT have any FDA labeled contraindications to the requested agent <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: <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:

Module	Clinical Criteria for Approval
	<ol style="list-style-type: none"><li data-bbox="472 180 1386 239">1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication AND<li data-bbox="472 239 1305 298">2. There is support for therapy with a higher dose for the requested indication <p data-bbox="233 331 636 365">Length of Approval: 12 months</p>