Pharmacy Policy Bulletin

Title:	Icosapent ethyl (Vascepa®)
Policy #:	Rx.01.228

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for **icosapent ethyl (Vascepa®)** as provided under the member's prescription drug benefit.

Description:

Elevated triglyceride levels are associated with and appear to be implicated in the pathogenesis of atherosclerosis and cardiovascular disease (CVD). Atherosclerosis is the most common underlying pathology in patients with CVD. Fasting plasma triglyceride concentrations may be categorized according to the National Cholesterol Education Program (NCEP) as normal (<150 mg/dL), borderline (150–199 mg/dL), high triglyceride (HTG; 200–499 mg/dL), and severe HTG (HTG; ≥500 mg/dL). Patients with triglycerides above 500 mg/dL are also at risk of pancreatitis. Elevated plasma triglyceride concentrations contribute to increased risk of cardiovascular disease, both directly and because such elevations are associated with risk factors such as obesity, metabolic syndrome, and type 2 diabetes mellitus. Diet and lifestyle changes along with treatment or elimination of secondary causes are recommended before direct pharmacotherapy. If these changes are not possible or not effective, initiating triglyceride-lowering pharmacotherapy may be required.

Vascepa® (icosapent ethyl) is indicated:

1. As an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥ 150 mg/dL) and
    a. Established cardiovascular disease or
    b. Diabetes mellitus and 2 or more additional risk factors for cardiovascular disease.
2. As an adjunct to diet to reduce TG levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.

The mechanisms of action contributing to reduction of cardiovascular events with Vascepa® (icosapent ethyl) are not completely understood but are likely multi-factorial. Increased omega-3 fatty acid eicosapentaenoic acid (EPA) lipid composition from carotid plaque specimens and increased circulating EPA/arachidonic acid ratio have been observed following EPA treatment. EPA inhibits platelet aggregation under some ex vivo conditions. However, the direct clinical meaning of individual findings is not clear.

Policy:

Severe Hypertriglyceridemia

INITIAL CRITERIA: Icosapent ethyl (Vascepa®) is approved when ALL of the following are met:

1. Diagnosis of severe hypertriglyceridemia defined as pre-treatment triglyceride level greater than or equal to 500 mg/dl; and
2. Member is 18 years of age or older; and
3. Medication will be used adjunct to an appropriate lipid-lowering diet; and

4. Member has an inadequate response or inability to tolerate omega-3-acid ethyl esters (generic Lovaza®)

Initial authorization duration: 6 Months

REAUTHORIZATION CRITERIA: Icosapent ethyl (Vascepa®) is approved when ALL of the following are met:

1. Documentation of positive clinical response to therapy; and
2. Member continues to use the medication adjunct to an appropriate lipid-lowering diet

Reauthorization duration: 2 years

Hypertriglyceridemia—Reduction of risk of cardiovascular events

INITIAL CRITERIA Icosapent ethyl (Vascepa®) is approved when ALL of the following are met:

1. Diagnosis of hypertriglyceridemia; and
2. Member is 18 years of age or older; and
3. Member has pre-treatment triglyceride level between 150 mg/dL to 499 mg/dL; and
4. ONE of the following:
    a. Member has established cardiovascular disease; OR
    b. Both of the following:
        i. Diagnosis of diabetes mellitus; and
        ii. Member has 2 or more additional risk factors for cardiovascular disease (e.g., cigarette smoking, hypertension, creatinine clearance less than 60 ml/min, etc.); and
5. One of the following:
    a. Member has been receiving 12 consecutive weeks of statin therapy at maximally tolerated dose and will continue to receive statin therapy at maximally tolerated dose; or
    b. Inability to tolerate statin therapy

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA Icosapent ethyl (Vascepa®) is re-approved when BOTH of the following are met:

1. Documentation of positive clinical response to therapy; and
2. One of the following:
    a. Member continues to receive statin therapy at maximally tolerated dose; or
    b. Inability to tolerate statin therapy

Reauthorization duration: 2 years

Black Box Warning as shown in the drug Prescribing Information:

N/A

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company’s products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Skulas-Ray AC, Wilson PWF, Harris WS et al on behalf of the American Heart Association. Omega-3 fatty acids for the management of hypertriglyceridemia. Circulation. 2019;140. Accessed July 13, 2022.

Vascepa® (icosapent ethyl) [prescribing information]. Bridgewater, NJ: Amarin Pharma, Inc.; December 2019. Available from: https://amarincorp.com/docs/Vascepa-PI.pdf. Accessed July 13, 2022.

Yuan, G, Al-Shali, KZ, Hegele, RA. Hypertriglyceridemia: its etiology, effects and treatment. CMAJ. 2007;176:1113–1120. doi: 10.1503/cmaj.060963. Accessed July 13, 2022.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Generic	Brand
Icosapent ethyl	Vascepa®

Cross References:

Off-Label Use Rx.01.33

Policy Version Number:	4.00
P&T Approval Date:	June 09, 2022
Policy Effective Date:	October 01, 2022
Next Required Review Date:	June 09, 2023