MEDICAL MUTUAL®

Drug Policy

Policy:	Omega-3 Fatty Acid Products Icosapent Ethyl (generic of Vascepa) Lovaza (omega-3 acid ethyl esters) Omega-3-acid Ethyl Esters (generic of Lovaza) Triklo (omega-3-acid ethyl esters) Vascepa (icosapent ethyl)	Annual Review Date: 03/20/2025 Last Revised Date: 03/20/2025

OVERVIEW

Lovaza and Vascepa are indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia. Vascepa is also indicated for risk reduction of myocardial infarction (MI), stroke, coronary revascularization, and unstable angina requiring hospitalization in patients with elevated triglyceride levels ≥ 150 mg/dL. Lovaza is a combination of ethyl esters of omega-3 fatty acids, principally eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). The daily dose of Lovaza is 4 g/day taken as a single 4-gram dose (four capsules) or as two 2-gram doses (two capsules given twice daily [BID]). Each 1-gram capsule of Lovaza contains at least 900 mg of ethyl esters of omega-3 fatty acids sourced from fish oils (approximately 465 mg of EPA and 375 mg of DHA). Vascepa is an ethyl ester of the omega-3 fatty acid EPA. The daily dose of Vascepa is 4 g/day taken as four 0.5 gram capsules BID with food or as two 1-gram capsules BID with food. The safety and effectiveness in pediatric patients have not been established for either of these agents. The most common adverse events (AEs) of Lovaza include dyspepsia, eructation, taste perversion, and arthralgia, while Vascepa is associated with musculoskeletal pain, peripheral edema, constipation, gout, atrial fibrillation, arthralgia and oropharyngeal pain. Both agents have it noted in their prescribing information that the effects on the risk for pancreatitis have not been determined. They are not discussed further in this document.

POLICY STATEMENT

This policy involves the use of Omega-3 Fatty Acid products. Prior authorization is recommended for pharmacy benefit coverage of Lovaza and Vascepa. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Omega-3 Fatty Acid products is recommended in those who meet the following criteria:

1. Severe Hypertriglyceridemia with Triglyceride (TG) Levels 500 mg/dL or higher (all products).

Criteria. *Patient must meet the following criteria (A, B, C, and D):*

A. The patient is 18 years of age or older; AND
B. The patient has a fasting baseline (pre-treatment) triglyceride (TG) level of ≥ 500 mg/dL; AND
C. The patient has tried, or is currently receiving ONE of the following products for at least 90 days AND has not achieved adequate efficacy according to the prescribing physician (a, b, or c):
  a. A fibrate (e.g. gemfibrozil, fenofibrate, fenofibric acid); OR
  b. A statin (e.g. atorvastatin, fluvastatin, lovastatin, pravastatin, rosuvastatin, simvastatin); OR
  c. An over-the-counter (OTC) omega-3 fatty acid product (e.g. fish oil supplements) at maximum recommended dosage; AND
D. The patient has been on and will continue an appropriate lipid-lowering diet and exercise regimen; AND
E. If brand Lovaza is requested, the patient has failed a trial of generic omega-3 acid ethyl esters for a minimum of 90 days *

2. Risk Reduction of Myocardial Infarction (MI), Stroke, Coronary Revascularization, and Unstable Angina Requiring Hospitalization in Patients with Elevated Triglyceride Levels ≥ 150 mg/dL (Vascepa and generic icosapent only)

Criteria. *Patient must meet the following criteria (A, B, C, D, and E):*

A. The patient is 18 years of age or older; AND
B. Vascepa will be used as an adjunct to maximally tolerated statin therapy; AND
C. Vascepa is being used to reduce the risk of myocardial infarction (MI), stroke, coronary revascularization, and unstable angina requiring hospitalization in patients; AND
D. The patient has a fasting baseline (pre-treatment) triglyceride (TG) level of ≥ 150 mg/dL; AND
E. The patient meets one of the following criteria (a or b):
  a. The patient has established cardiovascular disease as defined as one of the following (i, ii, iii, iv, v, vi, vii, viii, or ix):
    i. Multivessel coronary artery disease (CAD); OR
    ii. Prior MI; OR
    iii. Hospitalization for high-risk acute coronary syndrome (ACS); OR
    iv. Prior ischemic stroke; OR
    v. Symptomatic carotid artery disease with ≥50% carotid arterial stenosis; OR
    vi. Asymptomatic carotid artery disease with ≥70% carotid arterial stenosis; OR
    vii. History of carotid revascularization; OR
    viii. Ankle brachial index (ABI) < 0.9 with symptoms of intermittent claudication; OR
    ix. History of aortoiliac or peripheral arterial intervention; OR
  b. The patient has diabetes mellitus with **two** or more additional risk factors for cardiovascular disease defined below (i, ii, iii, iv, v, vi, vii, viii, or ix):
    i. The patient is a man ≥ 55 years of age OR a woman ≥ 65 years of age; OR
    ii. The patient is a cigarette smoker or has stopped smoking within the past 3 months; OR
    iii. The patient has hypertension (HTN) defined as BP ≥140 mm Hg systolic OR ≥90 mm Hg diastolic OR the patient is on antihypertensive medication; OR
    iv. The patient is a man with an HDL-C ≤ 40 mg/dL or a woman with an HDL-C ≤ 50 mg/dL; OR

v. The patient has a high-sensitivity C-reactive protein (hsCRP) level > 3.00 mg/L (0.3 mg/dL); OR
vi. The patient has renal dysfunction defined as a creatinine clearance (CrCl) between 30 and 60 mL/min; OR
vii. The patient has retinopathy; OR
viii. The patient has microalbuminuria OR macroalbuminuria; OR
ix. The patient has an ABI < 0.9 without symptoms of intermittent claudication

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Omega-3 Fatty Acid products have not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

*** Documentation Requirements:**
The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

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