PRIOR AUTHORIZATION POLICY

POLICY: Hyperlipidemia – Omega-3 Fatty Acid Products
- Lovaza® (omega-3-acid ethyl esters capsules – GlaxoSmithKline, generic)
- Vascepa® (icosapent ethyl capsules – Amarin, generic)

REVIEW DATE: 01/25/2023

OVERVIEW

Lovaza, a combination of ethyl esters of omega-3 fatty acids (mainly eicosapentaenoic acid [EPA] and docosahexaenoic acid [DHA]) and Vascepa, an ethyl ester of EPA, are indicated for **hypertriglyceridemia** (severe, triglyceride [TG] levels ≥ 500 mg/dL), to reduce TG levels as an adjunct to diet in adults.[1,2]

Vascepa is also indicated to **reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina** requiring hospitalization in adults with elevated TG levels (≥ 150 mg/dL) and either established cardiovascular (CV) disease or diabetes mellitus with two or more additional risk factors for CV disease, as an adjunct to maximally tolerated statin therapy.[2,3]

Lovaza and Vascepa have been studied in patients with TG levels ≥ 200 mg/dL and < 500 mg/dL in patients who had persistently high TGs despite treatment with statin therapy and proper dietary modifications.[4,5] In these short-term trials lasting 6 to 12 weeks in duration, the addition of omega-3 fatty acid therapy led to further reductions in TG levels.

Guidelines/Scientific Statements

Several guidelines are available that discuss the management of elevated TG values and have incorporated omega-3 fatty acid products.[6-11] Highlights from a few guidelines are below.

- The American College of Cardiology Expert Consensus Decision Pathway on the Management of Atherosclerotic Cardiovascular Disease (ASCVD) Risk Reduction in Patients with Persistent Hypertriglyceridemia (2021) recommends Vascepa in a variety of clinical scenarios in patients with persistent fasting hypertriglyceridemia (150 to 499 mg/dL).[6] Also, Lovaza and Vascepa are recommended in several circumstances in which patients have very elevated TG levels (≥ 500 mg/dL).
- The American Diabetes Association Standards of Care (2023) state that Vascepa should be considered for patients with ASCVD or other CV risk factors on a statin with controlled low-density lipoprotein cholesterol levels but with elevated TG levels (135 to 499 mg/dL) to reduce CV risk.[10]
- The National Lipid Association (NLA) published a scientific statement regarding Vascepa (2019).[11] Based on the REDUCE-IT trial, the NLA position is that for patients ≥ 45 years of age with clinical ASCVD, or ≥ 50 years of age with diabetes mellitus requiring medication plus at least one additional risk factor, with fasting TG levels of 135 to 499 mg/dL on high-intensity or maximally tolerated statin therapy (with or without ezetimibe), treatment with Vascepa is recommended for ASCVD risk reduction (Class I evidence rating).

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of omega-3 fatty acid products (Lovaza and Vascepa [both brand and generic]). All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

I. Coverage of **Vascepa** (brand and generic) is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Cardiovascular Risk Reduction in a Patient with Elevated Triglycerides.** Approve Vascepa (brand or generic) for 1 year if the patient meets all of the following criteria (A, B, and C):
   - **A)** Patient meets one of the following (i or ii):
     - **i.** Patient has established cardiovascular disease; OR
       Note: Examples of cardiovascular disease include a previous myocardial infarction; a history of an acute coronary syndrome event; angina (stable or unstable); past history of stroke or transient ischemic attack; peripheral arterial disease; or the patient has undergone a coronary or other arterial revascularization procedure in the past (e.g., coronary artery bypass graft, percutaneous coronary intervention, angioplasty, coronary stent procedure); OR
     - **ii.** Patient meets both of the following (a and b):
       - **a)** Patient has diabetes; AND
       - **b)** According to the prescriber, has at least two additional risk factors for cardiovascular disease.
         Note: Examples of risk factors for cardiovascular disease include hypertension; low high-density lipoprotein cholesterol levels (e.g., ≤ 40 mg/dL); renal dysfunction (creatinine clearance < 60 mL/min); family of premature coronary disease; presence of albuminuria; current cigarette smoking; familial hypercholesterolemia; and increased weight (body mass index greater than 25 kg/m^2); AND
   - **B)** Prior to initiation of therapy, the patient has a fasting baseline triglyceride level ≥ 150 mg/dL; AND
   - **C)** Patient meets one of the following criteria (i or ii):
     - **i.** Patient is receiving statin therapy; OR
     - **ii.** According to the prescriber the patient cannot tolerate statin therapy.

II. Coverage of **Lovaza** and **Vascepa** (both brand and generic) is recommended in those who meet one of the following criteria:

FDA-Approved Indication

1. **Hypertriglyceridemia with Triglyceride Levels ≥ 500 mg/dL.** Approve Lovaza or Vascepa (both brand or generic) for 1 year if the patient meets the following criteria (A and B):
   - **A)** Prior to initiation of therapy, the patient has a fasting baseline triglyceride level ≥ 500 mg/dL; AND
   - **B)** Patient has tried, or is currently receiving, one of the following products: niacin (immediate-release or extended-release), a fibrate, or a statin.
     Note: Examples of fibrates include gemfibrozil, fenofibrate, and fenofibric acid. Examples of statins include atorvastatin, rosuvastatin, simvastatin, pravastatin, lovastatin, fluvastatin, and

Livalo (pitavastatin tablets). Also, a patient who requests Vascepa may potentially be reviewed under the criteria for Cardiovascular Risk Reduction in a Patient with Elevated Triglycerides.

Other Uses with Supportive Evidence

2. **Hypertriglyceridemia with Triglyceride Levels of 150 mg/dL to < 500 mg/dL.** Approve Lovaza or Vascepa (both brand or generic) for 1 year if the patient meets the following criteria (A and B):
   A) Prior to initiation of therapy, the patient has a fasting baseline triglyceride level of 150 mg/dL to < 500 mg/dL; AND
   B) Patient has tried, or is currently receiving, one of the following products: niacin (immediate-release or extended-release), a fibrate, or a statin.
   Note: Examples of fibrates include gemfibrozil, fenofibrate, and fenofibric acid. Examples of statins include atorvastatin, rosuvastatin, simvastatin, pravastatin, lovastatin, fluvastatin, and Livalo (pitavastatin tablets). Also, a patient who requests Vascepa may potentially be reviewed under the criteria for Cardiovascular Risk Reduction in Patients with Elevated Triglycerides.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Lovaza and Vascepa (both brand and generic) is not recommended in the following situations:

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

REFERENCES

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11. Orringer CE, Jacobson TA, Maki KC. National Lipid Association Scientific Statement on the use of icosapent ethyl in statin-treated patients with elevated triglycerides and high or very-high ASCVD risk. *J Clin Lipidol*. 2019;13(6):860-872.