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Coverage Policy Number IP0051

Omega-3 Fatty Acid Products

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Related Coverage Resources

INSTRUCTIONS FOR USE

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Overview

This policy supports medical necessity review for the Omega-3 Fatty Acid Product, icosapent ethyl (Vascepa®).

Medical Necessity Criteria

Icosapent ethyl (Vascepa) is considered medically necessary when **ONE** of the following is met (1 or 2):

1. **Cardiovascular Risk Reduction in Individuals with Elevated Triglycerides.** Individual meets **ALL** of the following criteria (A, B, C and D):
 - A. 18 years of age or older
 - B. Individual meets **ONE** of the following (i or ii):
 - i. Established cardiovascular disease
[for example: previous myocardial infarction (MI); a history of an acute coronary syndrome (ACS) event; angina (stable or unstable); past history of stroke or transient ischemic attack (TIA); peripheral arterial disease (PAD); or has undergone a coronary or other arterial revascularization procedure in the past (e.g., coronary artery bypass graft

- [CABG], percutaneous coronary intervention [PCI], angioplasty, coronary stent procedure)]
 - ii. Diabetes mellitus and 2 or more additional risk factors for cardiovascular disease [for example: hypertension; age greater than or equal to 50 years of age; low high-density lipoprotein cholesterol (HDL-C) levels (for example, less than or equal to 40 mg/dL); renal dysfunction (creatinine clearance less than 60 mL/min); family history of premature coronary disease; presence of albuminuria; smoker (or recently quit); familial hypercholesterolemia; and increased weight (body mass index greater than 25 kg/m²)]
 - C. Prior to initiation of icosapent ethyl (Vascepa), the individual's fasting triglyceride level is greater than or equal to 150 mg/dL
 - D. Use is adjunctive to maximally tolerated statin therapy unless contraindicated per FDA label or intolerant
2. **Hypertriglyceridemia in Individuals with Triglyceride (TG) Levels greater than or equal to 150 mg/dL.** Individual meets **ALL** of the following criteria (A, B and C):
- A. 18 years of age or older
 - B. Prior to initiation of icosapent ethyl (Vascepa), the individual's fasting triglyceride level is greater than or equal to 150 mg/dL
 - C. Individual has tried, or is currently receiving, **ONE** of the following:
 - i. Fibrate (fenofibrate, fenofibric acid, gemfibrozil)
 - ii. Niacin (immediate or extended-release)
 - iii. Statin (for example, atorvastatin, rosuvastatin, simvastatin, pravastatin, lovastatin, fluvastatin)

Note: An individual who requests icosapent ethyl (Vascepa) may potentially be reviewed under the criteria for Cardiovascular Risk Reduction in Individuals with Elevated Triglycerides.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Note: Receipt of sample product does not satisfy any criteria requirements for coverage.

Reauthorization Criteria

Icosapent ethyl (Vascepa), is considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration is up to 12 months.

Reauthorization approval duration is up to 12 months.

Conditions Not Covered

Icosapent ethyl (Vascepa) is considered experimental, investigational or unproven for **ANY** other use.

Background

OVERVIEW

Vascepa is an ethyl ester of eicosapentaenoic acid (EPA) 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
 - established cardiovascular disease or
 - diabetes mellitus and 2 or more additional risk factors for cardiovascular disease.
- as an adjunct to diet to reduce TG levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.

Vascepa has 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.^{3,4} 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.⁵⁻¹⁰ Highlights from a few guidelines are below.

- The American Diabetes Association Standards of Care regarding CV disease and risk management (2021) state that Vascepa should be considered for patients with diabetes and atherosclerotic cardiovascular disease (ASCVD) or other cardiac 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.⁹
- The National Lipid Association (NLA) published a scientific statement regarding Vascepa (2019).¹⁰ 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).

References

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