Effective Date **1/1/2024**
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Coverage Policy Number **IP0051**

Omega-3 Fatty Acid Products

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

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

Additional criteria that support the review for medical necessity exceptions of non-covered products are located in the Non-Covered Product Table by the respective plan type and drug list where applicable.

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

Medical Necessity Criteria

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

1. **Cardiovascular Risk Reduction in Individuals with Elevated Triglycerides.** Individual meets **ALL** of the following criteria:
    A. 18 years of age or older
    B. Documentation of **ONE** of the following:

i. Established cardiovascular disease
ii. Diabetes mellitus and 2 or more additional risk factors for cardiovascular disease

C. Prior to initiation of icosapent ethyl (Vascepa), documentation of fasting triglyceride level is greater than or equal to 150 mg/dL
D. Documentation that use is adjunctive to maximally tolerated statin therapy unless contraindicated or intolerant

2. **Hypertriglyceridemia with Triglyceride (TG) Levels greater than or equal to 150 mg/dL.** Individual meets **ALL** of the following criteria:
   A. 18 years of age or older
   B. Prior to initiation of icosapent ethyl (Vascepa), documentation of fasting triglyceride level greater than or equal to 150 mg/dL
   C. Documented failure, contraindication, or intolerance to **ONE** of the following:
      i. Fibrate
      ii. Niacin
      iii. Statin

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

Individual and Family Plan Non-Covered Products and Covered Alternatives:

Non-Covered Product	Criteria:
Vascepa (icosapent ethyl) 500 mg capsule	Documentation of trial of **icosapent ethyl 500 mg capsule** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction
Vascepa (icosapent ethyl) 1,000 mg capsule	Documentation of trial of **icosapent ethyl 1,000 mg capsule** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction

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.

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

Any other use is considered experimental, investigational, or unproven.

Background

OVERVIEW
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.[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.[1,2]

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 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).[5] 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.[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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