PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**OMEGA-3 FATTY ACIDS**
BRAND NAME (generic)	**LOVAZA (omega-3-acid ethyl esters)** **VASCEPA (icosapent ethyl)**

Status: CVS Caremark Criteria
Type: Initial Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Lovaza

Lovaza (omega-3-acid ethyl esters capsules) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (greater than or equal to 500 mg/dL) hypertriglyceridemia.

Usage Considerations: Patients should be placed on an appropriate lipid-lowering diet before receiving Lovaza and should continue this diet during treatment with Lovaza.

Laboratory studies should be done to ascertain that the lipid levels are consistently abnormal before instituting therapy with Lovaza. Every attempt should be made to control serum lipids with appropriate diet, exercise, weight loss in obese patients, and control of any medical problems such as diabetes mellitus and hypothyroidism that are contributing to the lipid abnormalities. Medications known to exacerbate hypertriglyceridemia (such as beta blockers, thiazides, estrogens) should be discontinued or changed, if possible, prior to consideration of TG-lowering drug therapy.

Limitations of Use

The effect of Lovaza on the risk for pancreatitis has not been determined.

The effect of Lovaza on cardiovascular mortality and morbidity has not been determined.

Vascepa

Vascepa (icosapent ethyl) is indicated:

- 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
  - o established cardiovascular disease or
  - o 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.

Limitations of Use:

The effect of Vascepa on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient will be on an appropriate lipid-lowering diet and exercise regimen during treatment with the requested drug

AND

- The requested drug is being prescribed to reduce triglyceride (TG) levels in a patient with severe (greater than or equal to 500 mg/dL at baseline) hypertriglyceridemia **AND**
    - The request is NOT for continuation of therapy

    OR
    - The request is for continuation of therapy **AND**
        - The patient has achieved or maintained a reduction in triglyceride (TG) levels from baseline

OR

- The request is for Vascepa **AND**
    - The requested drug is being prescribed to reduce the risk of myocardial infarction, stroke, coronary revascularization, or unstable angina requiring hospitalization in an adult patient with elevated triglyceride (TG) levels (greater than or equal to 150 mg/dL at baseline) **AND**
        - Vascepa is being prescribed as an adjunct to maximally tolerated statin therapy

        AND
        - The patient has established cardiovascular disease

        OR
        - The patient has diabetes mellitus and two or more additional risk factors for cardiovascular disease

REFERENCES

1. Lovaza [package insert]. Wixom, MI: Woodward Pharma Services LLC; February 2021.
2. Vascepa [package insert]. Bridgewater, NJ: Amarin Pharma Inc.; September 2021.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, Ohio: UpToDate, Inc.; 2022; Accessed October 14, 2022.
4. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com/. Accessed October 14, 2022.
5. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol. *Circulation.* 2019;139:e1082-1143.
6. Jacobson TA, Ito MK, Maki KC et. al. National Lipid Association Recommendations for Patient-Centered Management of Dyslipidemia: Part 1 – Full Report. Journal of Clinical Lipidology 2015;9:129-169.