PRIOR AUTHORIZATION CRITERIA

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

Status: CVS Caremark Criteria
Type: Initial Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Epanova

Epanova (omega-3-carboxylic acids) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥500mg/dL) hypertriglyceridemia.

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

Laboratory studies should be done to ascertain that the triglyceride levels are consistently abnormal before instituting Epanova therapy. 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 triglyceride-lowering drug therapy.

Limitations of Use

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

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

Lovaza

Lovaza (omega-3-acid ethyl esters) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥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 Lovaza therapy. 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 triglyceride-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

AND

- The patient has, or did have prior to the start of treatment with a triglyceride lowering drug, a triglyceride level greater than or equal to 500 milligrams/deciliter

OR

- Vascepa 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 150 milligrams/deciliter) **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. Epanova [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; March 2017.
2. Lovaza [package insert]. Research Triangle Park, NC: GlaxoSmithKline; April 2019.
3. Vascepa [package insert]. Bedminster, NJ: Arnarin Pharma Inc.; December 2019.
4. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed November 2019.
5. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed November 2019.
6. Grundy SM, Stone NJ, et al. 2018 ACC/AHA Guideline on the Management of Blood Cholesterol. Journal of the American College of Cardiology Nov 2018, 25709; DOI: 10.1016/j.jacc.2018.11.003
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8. Berglund L, Brunzell JD, Goldberg AC, et al, “Evaluation and Treatment of Hypertriglyceridemia: An Endocrine Society Clinical Practice Guideline,” J Clin Endocrinol Metab, September 2012, 97: 2969–2989.

