ALASKA MEDICAID
Prior Authorization Criteria

LOVAZA®(omega-3-acid ethyl esters),
VASCEPA®(icosapent ethyl)

FDA INDICATIONS AND USAGE[1,2]

Lovaza (omega-3-acid ethyl esters) 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 (HTG). Vascepa is an ethyl ester of eicosapentaenoic acid (EPA) 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 established cardiovascular disease or diabetes mellitus and 2 or more additional risk factors for cardiovascular disease. Vascepa is also indicated as an adjunct to diet to reduce TG levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.

APPROVAL CRITERIA[1,2,3,4]

Hypertriglyceridemia

1. Patient is 18 years of age or older **AND;**
2. The patient will be on an appropriate lipid-lowering diet and exercise regimen during treatment **AND;**
3. The patient has had prior to the start of treatment with a triglyceride lowering drug, a triglyceride level greater than or equal to 500 milligrams/deciliter **AND;**
4. The patient has tried and failed a fibrate or niacin for 30 days or provide letter of medical necessity for non-trial.

Cardiovascular risk reduction (Vascepa only)

1. Patient is 18 years of age or older **AND;**
2. The request is for Vascepa **AND;**
3. The patient will be on an appropriate lipid-lowering diet and exercise regimen during treatment **AND;**
4. 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 levels greater than 150 milligrams/deciliter **AND;**
5. Is being prescribed as an adjunct to maximally tolerated statin therapy **AND;**
6. The patient has established cardiovascular disease or the patient has diabetes mellitus and two or more additional risk factors for cardiovascular disease.

DENIAL CRITERIA[1,3]

1. Failure to meet approval criteria.

CAUTIONS[1,2]

- Use with caution in patients with known hypersensitivity to fish and/or shellfish.
- May cause more frequent recurrences of symptomatic atrial fibrillation or flutter in patients with paroxysmal or persistent atrial fibrillation, particularly within the first months of initiating therapy.
- VASCEPA was associated with an increased risk of bleeding. The incidence of bleeding was greater in patients receiving concomitant antithrombotic medications, such as aspirin, clopidogrel, or warfarin.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 12 months

QUANTITY LIMIT

- 120 capsules per 30 days

REFERENCES / FOOTNOTES:

1. Lovaza [package insert]. Research Triangle Park, NC: GlaxoSmithKline; April 2019.
2. Vascepa [package insert]. Bedminster, NJ: Arnarin Pharma Inc.; December 2019.
3. 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
4. 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.