Commercial/Healthcare Exchange PA Criteria

Effective: March 1, 2006

Prior Authorization: Omega 3's

Products Affected: Lovaza oral capsule, omega-3-acid ethyl esters oral capsules, Vascepa oral capsule, icosapent ethyl oral capsule

Medication Description: Reduction in the hepatic production of triglyceride-rich very low-density lipoproteins. Possible cellular mechanisms include inhibition of acyl CoA:1,2 diacylglycerol acyltransferase, increased hepatic mitochondrial and peroxisomal beta-oxidation, and a reduction in the hepatic synthesis of triglycerides. The mechanisms contributing to reduction of cardiovascular events are not completely understood but are likely multi-factorial (eg, increased eicosapentaenoic acid [EPA] composition from carotid plaques, increased circulating EPA/arachidonic acid ratio, inhibition of platelet aggregation).

Covered Uses:

1. Lovaza, omega-3-acid ethyl esters, Vascepa: Adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (greater than or equal to 500 mg per dL) hypertriglyceridemia (HTG).
2. Vascepa: 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.

Exclusion Criteria: N/A

Required Medical Information:

1. Diagnosis
2. Previous medications tried/failed
3. Current triglyceride level

Age Restrictions: 18 years of age and older

Prescriber Restrictions: N/A

Coverage Duration: 12 months

Other Criteria:

Initial:

Severe hypertriglyceridemia (Lovaza, omega-3-acid ethyl esters, Vascepa, and icosapent ethyl)

1. Patient has a diagnosis of severe (greater than or equal to 500 mg per dL) hypertriglyceridemia; **AND**
2. Patient has a documented intolerance, contraindication, or treatment failure with, a fibric acid product (e.g. gemfibrozil, fenofibrate) **OR** a prescription niacin product (e.g. Niaspan).

Disorder of cardiovascular system (Vascepa and icosapent ethyl only)

1. Patient has a diagnosis of established cardiovascular disease (CVD) or diabetes mellitus; **AND**
2. Patient has a documented triglyceride levels 150 mg/dL; **AND**
3. Patient is currently on maximally tolerated statin therapy

Continuation: Documentation showing reduction or stabilization in triglyceride levels.

References:

1. Lovaza (omega-3-acid ethyl esters) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; September 2020.
2. Vascepa (icosapent ethyl) [prescribing information]. Bedminster, NJ: Amarin Pharma Inc; December 2019.

Policy Revision History:

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	3/2016
2	Update	Moved to updated template	All	2/14/2020

3	Update	Added generic icosapent ethyl to products affected Added the following FDA labeled indication for Vascepa: 2. Vascepa: 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. Added continuation criteria: Documentation showing reduction or stabilization in triglyceride levels. Added Criteria for the following indication : Disorder of cardiovascular system *Disorder of cardiovascular system* *1. Patient has a diagnosis of established cardiovascular disease (CVD) or diabetes mellitus; AND* *2. Patient has a documented triglyceride levels 150 mg/dL; AND* *3. Patient is currently on maximally tolerated statin therapy*	Products affected	1/1/2021