Lovaza® (omega-3 ethyl esters)
Vascepa® (icosapent ethyl)
Effective 04/01/2020

Plan	☒ MassHealth ☐ Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	**Specialty Medications** All Plans — Phone: 866-814-5506 — Fax: 866-249-6155 **Non-Specialty Medications** MassHealth — Phone: 877-433-7643 — Fax: 866-255-7569 Commercial — Phone: 800-294-5979 — Fax: 888-836-0730 Exchange — Phone: 855-582-2022 — Fax: 855-245-2134 **Medical Specialty Medications (NLX)** All Plans — Phone: 844-345-2803 — Fax: 844-851-0882		
Exceptions	N/A		

Overview
Lovaza and Vascepa are types of omega 3 fatty acids indicated as adjuncts to diet to reduce triglyceride levels in adults with severe hypertriglyceridemia. Vascepa is also indicated as an adjunct to statin therapy to reduce the risk of myocardial infarction, coronary revascularization, and unstable angina requiring hospitalization in adults with elevated triglycerides.

FDA Approved Indications
1. Treatment of severe hypertriglyceridemia (≥ 500 mg/dL)
2. Treatment of elevated triglyceride levels (≥ 150 mg/dL) despite maximally tolerated statin therapy with established cardiovascular disease or diabetes mellitus **(Vascepa only)**

Coverage Guidelines
Approval will be granted if the member meets the following drug specific criteria:

Omega-3-acid ethyl esters (Lovaza®):
Authorization may be granted for members who are currently receiving treatment for an approved indication, excluding when the product is obtained as samples or via manufacturer's patient assistance program.

OR

Authorization may be granted for members when all the following criteria are met:
1. The member has a diagnosis of severe hypertriglyceridemia (≥ 500 mg/dL)
2. The member has had a documented side effect, allergy, or treatment failure with a minimum of one agent from ***each*** of the following categories:
    a. Fibric acid derivatives (e.g. fenofibrate, gemfibrozil, etc.)

b. Long-acting niacin agents (e.g. niacin ER, Niaspan®, etc.)
c. HMG-CoA reductase inhibitors (e.g. simvastatin, atorvastatin, rosuvastatin, etc.)

3. The member will maintain a lipid-lowering diet and exercise regimen during treatment

Vascepa® (icosapent ethyl):

Authorization may be granted for members who are currently receiving treatment for an approved indication, excluding when the product is obtained as samples or via manufacturer's patient assistance program.

OR

Authorization may be granted for members with a diagnosis of severe hypertriglyceridemia (≥ 500 mg/dL) and when all the following criteria are met:

a. The member has had a documented side effect, allergy, or treatment failure with a minimum of one agent from ***each*** of the following categories:
   i. Fibric acid derivatives (e.g. fenofibrate, gemfibrozil, etc.)
   ii. Long-acting niacin agents (e.g. niacin ER, Niaspan®, etc.)
   iii. HMG-CoA reductase inhibitors (e.g. simvastatin, atorvastatin, rosuvastatin, etc.)
b. The member has had a documented side effect, allergy, or treatment failure with omega-3-acid ethyl esters (Lovaza®)
c. The member will maintain a lipid-lowering diet and exercise regimen during treatment

OR

Authorization may be granted for members with a diagnosis of elevated triglyceride levels (≥ 150 mg/dL) despite maximally tolerated statin therapy when all the following are met:

a. The member has established cardiovascular disease or diabetes mellitus
b. The member has two or more additional risk factors for cardiovascular disease (see Appendix A)
c. The member will remain on maximally tolerated statin therapy during treatment
d. The member will maintain a lipid-lowering diet and exercise regimen during treatment

Continuation of Therapy

Reauthorization will be granted if documentation is submitted indicating a positive response to therapy

Limitations

1. Approvals will be granted for a duration of 3 years (36 months)
2. The following quantity limits apply:

Vascepa 1gm	120 capsules per 30 days
Vascepa 0.5gm	240 capsules per 30 days
Lovaza 1gm (omega-3-acid ethyl esters oral capsule)	120 capsules per 30 days

Appendices

Appendix A: Additional Risk Factors for Cardiovascular Disease (CVD)

1. Chronic kidney disease, eGFR < 60 mL/min per 1.73 m2
2. Congestive heart failure
3. Current daily cigarette smoking
4. Exposure to mediastinal radiation
5. Family history of development of atherosclerotic CVD or death from CVD in a first-degree relative (i.e., a parent or sibling) prior to age 55 (males) or age 65 (females)
6. HIV infection

7. Hypertension
8. Metabolic syndrome
9. Microalbuminuria

References

1. Omega-3 fatty acids [prescribing information]. Tempe, AZ: Century HealthCare Inc; received July 2018
2. Lovaza (omega-3-acid ethyl esters) [prescribing information]. Wixom, MI: Woodward Pharma Services LLC; February 2021
3. Vascepa (icosapent ethyl) [prescribing information]. Bedminster, NJ: Amarin Pharma Inc; December 2019.
4. Siscovick DS, Barringer TA, Fretts AM, et al; American Heart Association Nutrition Committee of the Council on Lifestyle and Cardiometabolic Health; Council on Epidemiology and Prevention; Council on Cardiovascular Disease in the Young; Council on Cardiovascular and Stroke Nursing; Council on Clinical Cardiology. Omega-3 polyunsaturated fatty acid (fish oil) supplementation and the prevention of clinical cardiovascular disease: a science advisory from the American Heart Association. Circulation. 2017;135(15):e867-e884.[PubMed 28289069]10.1161/CIR.0000000000000482
5. Jacobson TA, Maki KC, Orringer CE, et al; NLA Expert Panel. National Lipid Association recommendations for patient-centered management of dyslipidemia: Part 2 [published correction appears in J Clin Lipidol. 2016;10(1):211]. J Clin Lipidol. 2015;9(6)(suppl):S1-S122.[PubMed 26699442
6. Berglund L, Brunzell JD, Goldberg AC, et al. Evaluation and treatment of hypertriglyceridemia: an Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2012;97(9):2969-2689.[PubMed 22962670]
7. FDA approves use of drug to reduce risk of cardiovascular events in certain adult patient groups. U.S. Food and Drug Administration. https://www.fda.gov/news-events/press-announcements/fda-approves-use-drug-reduce-risk-cardiovascular-events-certain-adult-patient-groups. Published December 13, 2019. Accessed December 16, 2019.
8. Wilson PWF. Overview of established risk factors for cardiovascular disease. UpToDate. https://www.uptodate.com/contents/overview-of-established-risk-factors-for-cardiovascular-disease#H1. Published November 6, 2019. Accessed December 16, 2019.

Review History

11/23/2013: Implemented
11/2016: Reviewed P&T
11/20//2017: Updated P&T
11/26/2018: Reviewed P&T
01/22/2020: Added indication of elevated triglyceride level in established cardiovascular disease for Vascepa, removed previous use of statin, added QL for Vascepa 0.5gm
09/22/2021 – Reviewed P&T; references updated; no clinical changes

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