Lovaza® (omega-3 ethyl esters)  
Vascepa® (icosapent ethyl)  
Effective 4/1/2020

<table>
<thead>
<tr>
<th>Plan</th>
<th>Benefit</th>
<th>Program Type</th>
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</table>
| ☑ MassHealth  
☑ Commercial/Exchange | ☑ Pharmacy Benefit  
☐ Medical Benefit (NLX) | ☑ Prior Authorization  
☐ Quantity Limit  
☐ Step Therapy |

Specialty Limitations: N/A

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<th>Contact Information</th>
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<tr>
<td>Non-Specialty Medications</td>
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<td>MassHealth</td>
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<td>Medical Specialty Medications (NLX)</td>
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<tr>
<td>All Plans</td>
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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:

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

**OR**

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

- The member has had a documented side effect, allergy, or treatment failure with omega-3-acid ethyl esters (Lovaza®)
- 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:

<table>
<thead>
<tr>
<th>Vascepa 1gm</th>
<th>120 capsules per 30 days</th>
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<tbody>
<tr>
<td>Vascepa 0.5gm</td>
<td>240 capsules per 30 days</td>
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<tr>
<td>Lovaza 1gm (omega-3-acid ethyl esters oral capsule)</td>
<td>120 capsules per 30 days</td>
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**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]. Research Triangle Park, NC: GlaxoSmithKline; September 2015.

Review History
11/23/2013: Implemented
11/2016: Reviewed P&T
11/2017: Updated P&T
11/26/2018: Reviewed P&T
01/22/2019: Added indication of elevated triglyceride level in established cardiovascular disease for Vascepa, removed previous use of statin, added QL for Vascepa 0.5gm

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