UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Omega-3 Acid Derivatives

Program	Prior Authorization
Medication	Lovaza® (omega-3-acid ethyl esters)*, Vascepa® (icosapent ethyl)
Markets in Scope	California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York CHIP, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	9/2010
Pharmacy and Therapeutics Approval Date	2/2021
Effective Date	4/2021

*Generic Lovaza is preferred. Other omega-3 acid derivatives are non-preferred.

1. Background:

Omega-3-acid derivatives, Lovaza® and Vascepa® are highly purified ethyl ester concentrates. Lovaza is a combination of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). Vascepa is composed primarily of eicosapentaenoic acid (EPA). These medications are indicated as adjunctive therapy to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia. Vascepa is also 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) who either have established cardiovascular disease (CVD) or diabetes mellitus and two or more additional risk factors for cardiovascular disease.

2. Coverage Criteria:

A. Severe Hypertriglyceridemia

1. Initial Authorization

a. Approval will be based on **all** of the following criteria:

i. Diagnosis of severe hypertriglyceridemia (pre-treatment triglyceride level of greater than or equal to 500 mg/dL)

-AND-

ii. Patient is on an appropriate lipid-lowering diet and exercise regimen

-AND-

iii. **One** of the following:

a) History of failure to at least 90 days of a fibric acid derivative

-OR-

b) Contraindication or intolerance to a fibric acid derivative

-AND-

iv. If the request is for a non-preferred product the patient must have a history of failure, intolerance, or contraindication to omega-3-acid ethyl esters (generic Lovaza)

Authorization will be issued for 12 months.

2. Reauthorization

a. Approval will be based on **both** of the following criteria:

i. Documentation of positive clinical response to therapy

-AND-

ii. Patient is on an appropriate lipid-lowering diet and exercise regimen

Authorization will be issued for 12 months.

B. Cardiovascular Risk Reduction

1. Initial Authorization

a. Vascepa will be approved based on **all** of the following criteria:

i. Moderate hypertriglyceridemia (pre-treatment triglyceride level 150 mg/dL to 499 mg/dL)

-AND-

ii. Patient currently has or is considered high or very high risk for cardiovascular disease (CVD) as evidenced by **one** of the following:

a) **Both** of the following:

i) Age ≥ 45

-AND-

ii) Established CVD confirmed by **one** of the following:

1. Acute coronary syndrome
2. History of myocardial infarction
3. Stable or unstable angina
4. Coronary or other arterial revascularization
5. Stroke
6. Transient ischemic attack
7. Peripheral arterial disease

-OR-

b) **All** of the following:
i) Diagnosis of Type 2 diabetes

-AND-

ii) **Two** of the following risk factors for developing cardiovascular disease:
1. Men ≥55 years and women ≥65 years
2. Cigarette smoker or stopped smoking within the past 3 months
3. Hypertension (pretreatment blood pressure ≥140 mmHg systolic or ≥90 mmHg diastolic)
4. HDL-C ≤40 mg/dL for men or ≤50 mg/dL for women
5. High-sensitivity C-reactive protein >3.0 mg/L
6. Creatinine clearance >30 and <60 mL/min
7. Retinopathy
8. Micro- or macro-albuminuria
9. Ankle-brachial index (ABI) <0.9 without symptoms of intermittent claudication

-AND-

iii. Submission of medical records (e.g., chart notes, laboratory values) documenting **one** of the following (prescription claims history may be used in conjunction as documentation of medication use, dose, and duration):

a) Patient has been receiving at least 12 consecutive weeks of high-intensity statin therapy (i.e. atorvastatin 40-80 mg, rosuvastatin 20-40 mg) and will continue to receive a high-intensity statin at maximally tolerated dose

-OR-

b) **Both** of the following:

i) Patient is unable to tolerate high-intensity statin as evidenced by **one** of the following intolerable and persistent (i.e. more than 2 weeks) symptoms:

1. Myalgia (muscle symptoms without CK elevations)
2. Myositis (muscle symptoms with CK elevations < 10 times upper limit of normal [ULN])

-AND-

ii) **One** of the following:

1. Patient has been receiving at least 12 consecutive weeks of **moderate-intensity** [i.e. atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin ≥ 20 mg, pravastatin ≥ 40 mg, lovastatin 40 mg, fluvastatin XL 80 mg, fluvastatin 40 mg twice daily or Livalo (pitavastatin) ≥ 2 mg] statin therapy and will continue to receive a moderate-intensity statin at maximally tolerated dose

-OR-

2. Patient has been receiving at least 12 consecutive weeks of **low-intensity** [i.e. simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-40 mg, or Livalo (pitavastatin) 1 mg] statin therapy and will continue to receive a low-intensity statin at maximally tolerated dose

-AND-

iv. Submission of medical record (e.g., chart notes, laboratory values) documenting **one** of the following (prescription claims history may be used in conjunction as documentation of medication use, dose, and duration):

a) Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia®) therapy as adjunct to maximally tolerated statin therapy

-OR-

b) Patient has a history of contraindication or intolerance to ezetimibe

-OR-

c. Patient has an LDL-C less than 100 mg/dL while on maximally tolerated statin therapy

-AND-

v. Used as an adjunct to a low-fat diet and exercise

-AND-

vi. Prescribed by or in consultation with **one** of the following:
a) Cardiologist
b) Endocrinologist
c) Lipid specialist

-AND-

vii. Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided

Authorization will be issued for 12 months

2. Reauthorization

a. Vascepa will be approved based on **all** of the following criteria:

i. Documentation of positive clinical response to therapy

-AND-

ii. Patient is on an appropriate low-fat diet and exercise regimen

-AND-

iii. Patient is receiving maximally tolerated statin therapy

-AND-

iv. Prescribed by or in consultation with **one** of the following:
a) Cardiologist
b) Endocrinologist
c) Lipid specialist

Authorization will be issued for 12 months

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Lovaza [package insert]. Research Triangle Park, NC: GlaxoSmithKline; September 2020.
2. Vascepa [package insert]. Bridgewater, NJ : Amarin Pharma Inc.; December 2019.
3. Rosenson RS, Kastelein JP. Hypertriglyceridemia. Freeman MW (Ed). UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com (Accessed on January 11, 2021.)
4. Orringer, CE, Jacobson TA, Maki KC. National Lipid Association scientific statement on the use of icosapent ethyl in statin-treated patients with elevated triglycerides and high or very-high ASCVD risk. *J Clin Lipidol.* 2019;13(6):860-72.

Program	Prior Authorization –Omega-3 Acid Derivatives
Change Control	
Date	Change
9/2010	New drug policy
6/2011	Annual Review, no changes
6/2012	Annual Review, no changes
7/2016	Updated clinical criteria to align with E&I notification policy and updated policy to new template
2/2017	Updated policy to add generic Lovaza as a preferred product. Added step through generic Lovaza for non-preferred products.
7/2017	Annual review. Updated references.
7/2018	Annual review. Removed Epanova and Omtryg since the products never launched. Updated references.
10/2019	Annual review. Updated references
1/2020	Renamed policy. Updated criteria to include a step through fibric acid derivatives.

2/2020	Updated policy to include new indication for Vascepa.
2/2021	Annual review, updated references.