UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2186-8
Program	Prior Authorization/Medical Necessity
Medication	Vascepa® (icosapent ethyl)*
P&T Approval Date	2/2020; 10/2020, 12/2020, 3/2021, 3/2022, 10/2023, 3/2024
Effective Date	6/1/2024

1. Background:

Vascepa (icosapent ethyl)* is indicated as adjunctive therapy to diet and exercise 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) and either established cardiovascular disease or diabetes mellitus and 2 or more additional risk factors for cardiovascular disease.

Since the Pharmacy & Therapeutics Committee has determined that use of Vascepa* is not medically necessary for treatment of severe hypertriglyceridemia (TG≥ 500 mg/dL), coverage of Vascepa* will only be provided for cardiovascular risk reduction after meeting these requirements.

2. Coverage Criteria[a]:

A. Cardiovascular Risk Reduction

1. **Initial Authorization**

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

1) Diagnosis of hypertriglyceridemia (pre-treatment triglyceride level ≥ 150 mg/dL)

-AND-

2) 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-

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

-AND-

4) 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 a LDL-C less than 100 mg/dL while on maximally tolerated statin therapy

-AND-

5) Used as an adjunct to a low-fat diet and exercise

Authorization will be issued for 12 months

2. **Reauthorization**

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

1) Used for cardiovascular risk reduction

-AND-

2) Documentation of positive clinical response to therapy

-AND-

3) Patient is on an appropriate low-fat diet and exercise regimen

-AND-

4) Patient is receiving maximally tolerated statin therapy^

Authorization will be issued for 12 months

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.
^Tried/failed alternative(s) are supported by FDA labeling.

* Lovaza (multi-source brand only) and Vascepa (brand and generic) are typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status.

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.

4. References:

1. Vascepa [package insert]. Bridgewater, NJ: Amarin Pharma Inc.; December September 2021.
2. 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/Medical Necessity - Vascepa® (icosapent ethyl)
Change Control	
Date	Change
2/2020	New program.
10/2020	Removed coverage for triglycerides >/= 500.
12/2020	Clarified medically necessary language in the background.
3/2021	Modified pre-treatment triglyceride levels for cardiovascular risk reduction. Noted that Vascepa is typically excluded from coverage.
3/2022	Annual review. Added language that tried/failed alternative(s) are supported by FDA labeling. Updated references.
3/2023	Annual review. Combined low- and moderate- intensity statin language. Removed prescriber requirement. Updated references.
10/2023	Removed the "Routine Audit" language.
3/2024	Annual review. No changes.