UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1072-13
Program	Prior Authorization/Notification
Medication	Vascepa® (icosapent ethyl)*
P&T Approval Date	7/2010, 5/2011, 4/2012, 11/2012, 8/2013, 7/2014, 7/2015, 7/2016, 7/2017, 7/2018, 10/2019, 2/2020, 3/2021, 3/2022, 3/2023, 3/2024, 3/2025
Effective Date	6/1/2025

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.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Severe Hypertriglyceridemia**

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

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

-AND-

2) Patient is on an appropriate lipid-lowering diet and exercise regimen

Authorization will be issued for 12 months

2. **Cardiovascular risk reduction**

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

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

-AND-

2) Patient is receiving maximally tolerated statin therapy

-AND-

3) Used to reduce the risk of myocardial infarction, stroke, coronary revascularization,

and unstable angina requiring hospitalization

-AND-

4) **<u>One</u>** of the following:

a) Established cardiovascular disease (CVD)

- OR-

b) Both of the following:

i. Diagnosis of diabetes mellitus

-AND-

ii. **<u>Two</u>** additional risk factors for cardiovascular disease, for example:

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

Authorization will be issued for 12 months

B. Reauthorization

1. **Severe Hypertriglyceridemia**

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

1) Documentation of positive clinical response to therapy

-AND-

2) Patient is on an appropriate lipid-lowering diet and exercise regimen

Authorization will be issued for 12 months

2. **Cardiovascular risk reduction**

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

1) Documentation of positive clinical response to therapy

-AND-

2) 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.

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.

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

4. References:

1. Vascepa [package insert]. Bridgewater, NJ: Amarin Pharma Inc.; 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/Notification - Vascepa® (icosapent ethyl)
Change Control	
Date	Change
8/2013	Removed grandfathering criteria and replaced with reauthorization criteria. Changed criteria to note documentation of hypertriglyceridemia and added criteria to require patient to be on an appropriate lipid-lowering diet and exercise regimen.
7/2014	Added Omtryg and Epanova to criteria. Removed notation that Vascepa typically excluded from coverage.
7/2015	Updated references. Added notation that multi-source brand Lovaza is typically excluded from coverage.
7/2016	Updated to mirror indications and usage section in prescribing information. Added note that criteria applies to brand and generic Lovaza. Updated references.
7/2017	Annual review. Updated references.
7/2018	Annual review. Removed Epanova and Omtryg since products have never launched.
10/2019	Annual review. Updated references.
2/2020	Removed Lovaza from criteria. Added new indication for Vascepa and updated references.
3/2021	Modified pre-treatment triglyceride levels for cardiovascular risk

	reduction. Noted that Vascepa is typically excluded from coverage.
3/2022	Annual review. No changes.
3/2023	Annual review. Added state mandate language. Updated references.
3/2024	Annual review. No changes.
3/2025	Annual review. No changes.