Pharmacy Medical Necessity Guidelines:
Vascepa (icosapent ethyl)

Effective: April 14, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

Vascepa (icosapent ethyl) is an ethyl ester of eicosapentaenoic acid (EPA) indicated:

- As an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary resvascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride levels (≥150 mg/dL) and
    - Established cardiovascular disease, or
    - Diabetes mellitus and 2 or more additional risk factors for cardiovascular disease
- As an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.

The effect of Vascepa on the risk of pancreatitis in patients with severe hypertriglyceridemia has not been determined.

COVERAGE GUIDELINES

The plan may authorize coverage of Vascepa (icosapent ethyl) for Members when **ALL** of the following criteria are met:

Reduction of Risk of Cardiovascular Disease:

1. Member is 18 years of age or older

AND

2. Member has fasting blood triglyceride levels ≥ 150 mg/dL

AND

3. Member is on maximally tolerated statin therapy or a clinical rationale why the member cannot take a statin is provided

AND

4. Documentation of one of the following:
    a. Diagnosis of cardiovascular disease as defined by one of the following conditions: coronary artery disease, cerebrovascular or carotid disease, or peripheral artery disease

    OR

    b. Diagnosis of diabetes mellitus and at least 2 or more risk factors for cardiovascular disease including:
        i. Men ≥ 55 years of age and women ≥ 65 years of age
        ii. Hypertension or on an antihypertensive medication
        iii. HDL-C ≤ 40 mg/dL or men ≤ 50 mg/dL for women
        iv. High-sensitivity C-Reactive Protein (hs-CRP) > 3.00 mg/L (0.3 mg/dL)
        v. Renal insufficiency
        vi. Retinopathy
        vii. Micro- or macroalbuminuria
        viii. Congestive heart failure
        ix. Cigarette smoker

For members with elevated triglyceride levels ≥ 500 mg/dL

1. Member has a diagnosis of hypertriglyceridemia (TGs ≥ 500 mg/dL)

AND

2. Member has had an inadequate response, intolerance, or contraindication to omega-3 ethyl esters

AND

3. Member has had an inadequate response, intolerance, or contraindication to a generic fibric acid derivative (e.g., fenofibrate or gemfibrozil)

LIMITATIONS

1. Requests for brand-name products, which have AB-rated generics, will be reviewed according to Non-covered Medications criteria.

CODES

None

REFERENCES

1. Vascepa (icosapent ethyl) [prescribing information]. Bedminster, NJ: Amarin Pharma, Inc; April 2023.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. July 11, 2023: No changes
2. April 9, 2024: Effective May 1, 2024, updated RxUM fax number.
3. April 8, 2025: No changes
4. April 14, 2026: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services