Pharmacy Medical Necessity Guidelines: Vascepa (iscosapent ethyl)

Effective: March 16, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit		Department to Review	

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988
MM: 888.415.9055
PRECERT: 617.972.9409

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 revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) 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 TG levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.

The effect of Vascepa on the risk for 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:

For Reduction of Risk of Cardiovascular Disease:

1. Member is 18 years of age or older

AND

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

AND

3. Member is on maximally tolerated statin therapy

AND

4. Documented of one of the following
   - A. Diagnosis of cardiovascular disease as defined by any of these conditions: coronary artery disease, cerebrovascular or carotid disease, or peripheral artery disease

   OR

   - B. Diagnosis of diabetes mellitus and at least 2 more risk factors for cardiovascular disease including:
     - i. Men ≥55 years of age and Women ≥65 years of age
     - ii. Hypertension or on antihypertensive medication
     - iii. HDL-C ≤40 mg/dL for men or ≤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 of ≥ 500 mg/dL:

1. Member has a diagnosis of hypertriglyceridemia (triglyceride levels of ≥ 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

None

CODES

None

REFERENCES

1. Vascepa (icosapent ethyl) [prescribing information]. Bedminster, NJ: Amarin Pharma, Inc; December 2019.

APPROVAL HISTORY

September 10, 2019: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. March 10, 2020: Added additional criteria for members with members with triglyceride levels of ≥ 150 mg/dL.

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.