

Division: Pharmacy Policy	Subject: State of Florida's Agency for Health Care Administration's
	Prior Authorization Criteria
Original Development Date: Original Effective Date:	August 4, 2021
Revision Date:	

VASCEPA® (icosapent ethyl)

LENGTH OF AUTHORIZATION: Up to one year

INITIAL REVIEW CRITERIA:

- Patient must be ≥ 18 years of age.
- Patient must use as an adjunct to a low-fat diet and exercise.
- If seeking approval for cardiovascular risk reduction:
 - o Triglyceride (TG) levels ≥ 150 mg/dL.

AND

- Established cardiovascular disease as defined as being greater than age 45 with one of the following:
 - history of myocardial infarction
 - stable or unstable angina
 - heart valve disease
 - stroke or transient ischemic attack
 - congestive heart failure
 - arrhythmia
 - peripheral arterial disease

OR

- Diagnosis of Diabetes Mellitus and 2 additional risk factors for cardiovascular disease
 - Men \ge 45 years and women \ge 55 years
 - Cigarette smoker or recently stopped smoking
 - Hypertension
 - Family history of early heart disease
 - Obesity
 - Dyslipidemia

AND

- Patient is stable on maximally tolerated statin therapy and will continue therapy or documented contraindication/intolerance to statin therapy.
- If seeking approval for severe hypertriglyceridemia:
 - TG levels \geq 500 mg/dL.
- Must have supporting documentation of lab values. Lab values should have been measured within 1 month of request.

CONTINUATION OF THERAPY

- Patient met initial review criteria.
- Documentation of improvement of laboratory values compared to baseline values.



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- For cardiovascular risk reduction, patient continues to receive maximally tolerated statin therapy or documented contraindication/intolerance to statin therapy.
- Patient continues to use therapy as an adjunct to a low-fat diet and exercise.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Dosage Forms: 0.5 gram and 1 gram capsules