

Omega-3 Fatty Acid

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Omega-3-acid ethyl esters - generic Lovaza Vascepa (icosapent ethyl)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for omega-3-acid ethyl esters may be approved if the following criteria are met:

- I. Individual is using as an adjunct to diet to reduce triglyceride levels; **AND**
- II. Individual has a triglyceride level greater than or equal to 500 mg/dL.

Requests for Vascepa (icosapent ethyl) may be approved if the following criteria are met:

- I. Individual has a triglyceride level greater than or equal to 500 mg/dL; **AND**
- II. Individual is using as an adjunct to diet to reduce triglyceride levels;

OR

- III. Individual has a triglyceride level greater than or equal to 150 mg/dL; **AND**
- IV. Individual is using as an adjunct to maximally tolerated statin therapy; **AND**
- V. Individual has a diagnosis of:
 - A. Established cardiovascular disease including one or more of the following (AHA/ACC 2018):
 - 1. Acute coronary syndrome;
 - 2. Coronary artery disease (CAD);
 - 3. History of myocardial infarction (MI);
 - 4. Stable or unstable angina;
 - 5. Coronary or other arterial revascularization;
 - 6. Stroke;
 - 7. Transient ischemic attack (TIA);
 - 8. Peripheral arterial disease (PAD);

OR

- B. Diabetes mellitus **AND** two or more of the following risk factors for cardiovascular disease (Bhatt 2019):
 - 1. Age ≥ 55 years for men or ≥ 65 years for women;
 - 2. Cigarette smoker;
 - 3. Hypertension (blood pressure $\geq 140/90$) or being treated with antihypertensive medication;

4. HDL-C \leq 40 mg/dL for men or \leq 50 mg/dL for women;
5. High-sensitivity C-reactive protein (Hs-CRP) $>$ 3 mg/L;
6. Renal dysfunction (creatinine clearance $<$ 60 mL/min);
7. Retinopathy;
8. Microalbuminuria or macroalbuminuria;
9. Ankle-brachial index (ABI) $<$ 0.9 without symptoms of intermittent claudication.

Key References:

1. Bhatt DL, Steg PG, Miller M et al. Cardiovascular risk reduction with icosapent ethyl for hypertriglyceridemia. *N Engl J Med*. 2019;380(1):11-22.
2. *N Engl J Med*. 2019;380(1):11-22.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: July 8, 2023.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA guideline on the management of blood cholesterol: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol* 2019;73:e285–350.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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