

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

Omega-3 Fatty Acid

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

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

APPROVAL CRITERIA

Requests for Lovaza/Triklo (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 confirmed 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);

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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 ≤ 40 mg/dL for men or ≤ 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. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: February 2, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. 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. *J Am Coll Cardiol*. 2018. <https://doi.org/10.1016/j.jacc.2018.11.003>.
5. Jellinger PS, Handelsman Y, Rosenblit PD, et al. American Association of Clinical Endocrinologists and American College of Endocrinology guidelines for management of dyslipidemia and prevention of cardiovascular disease. *Endocr Pract*. 2017;23(Suppl 2):1-87.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
7. Lloyd-Jones DM, Morris PB, Ballantyne CM, et al. 2016 ACC expert consensus decision pathway on the role of non-statin therapies for LDL-cholesterol lowering in the management of atherosclerotic cardiovascular disease risk: a report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents. *J Am Coll Cardiol*. 2016;68:92–125.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply