

Clinical Policy: Omega-3-Acid Ethyl Esters (Lovaza)

Reference Number: PA.CP.PMN.52

Effective Date: 01/18

Last Review Date: 08/17

Line of Business: Medicaid

[Revision Log](#)

Description

Omega-3-acid ethyl esters (Lovaza[®]) is a combination of ethyl esters of omega 3 fatty acids, principally EPA and DHA.

FDA approved indication

Lovaza is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia (HTG).

Limitation of use:

- The effect of Lovaza on the risk for pancreatitis has not been determined.
- The effect of Lovaza on cardiovascular mortality and morbidity has not been determined.

Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Pennsylvania Health and Wellness[®] that Lovaza is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Hypertriglyceridemia (must meet all):

1. Diagnosis of hypertriglyceridemia;
2. Fasting triglycerides ≥ 500 mg/dL (lab must be dated within 90 days);
3. Failure of a trial of fibrate therapy at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 4 g/day (4 capsules/day).

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Hypertriglyceridemia (must meet all):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Documentation of positive response to therapy (e.g., lowering of triglycerides level);
3. If request is for a dose increase, new dose does not exceed 4 g/day (4 capsules/day).

Approval duration: 12 months

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B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.

Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

DHA: docosahexaenoic acid

EPA: eicosapentaenoic acid

FDA: Food and Drug Administration

HTG: hypertriglyceridemia

TG: triglyceride

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Hypertriglyceridemia	4 g per day as a single 4 g dose (4 capsules) or as two 2 g doses (2 capsules given twice daily)	4 g per day

VI. Product Availability

Capsule: 1 g

VII. References

1. Lovaza Prescribing Information. Research Triangle Park, NC: GlaxoSmithKline; May 2014. Available at <http://www.lovaza.com>. Accessed May 18, 2016.
2. Stone NJ, Robinson JG, Lichtenstein AH, et al. 2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Circulation* 2014; 129:S1.
3. Berglund L et al. Evaluation and treatment of hypertriglyceridemia: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2012; 97(9): 2969-2989.
4. Miller M, Stone NJ, Ballantyne C et al. Triglycerides and cardiovascular disease: a scientific statement from the American Heart Association. *Circulation*. 2011 May 24;123(20):2292-333. doi: 10.1161/CIR.0b013e3182160726. Epub 2011 Apr 18.

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- 5. ATP III At-A-Glance: Quick Desk Reference. NIH: National Heart, Lung, and Blood Institute. <https://www.nhlbi.nih.gov/health-pro/guidelines/current/cholesterol-guidelines/quick-desk-reference-html>. Published May 2001. Accessed March 2016.

Reviews, Revisions, and Approvals	Date	P&T Approval Date