Clinical Policy: Omega-3-Aacid eEthyl eEsters (Lovaza)
Reference Number: CP.PMN.52
Effective Date: 08/12 ~~Coding Implications~~
Last Review Date: 08/17 Revision Log
Line of Business: Medicaid

See Important Reminder **at the end of this policy for important regulatory and legal information.**

Description
Omega-3-acide 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 (~~including~~ which may ~~office~~include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation® 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. Age ≥ 18 years;~~
~~3.~~2. Fasting triglycerides ≥ 500 mg/dL (lab must be dated within 90 days);
~~4.~~3. Failure of a ≥ 3 consecutive month trial of fibrate therapy in the last 6 months at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
~~5.~~4. Dose does not exceed 4 g/day (4 capsules/day).

Approval duration: 6 months

B. Other diagnoses/indications
1. Refer to 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 Centene benefit or member has previously met initial approval criteria;

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2. Documentation of positive response to therapy ({e.g., lowering of triglycerides level~~labs, sign/symptom reduction, etc~~});
3. If request is for a dose increase, new dose does not exceed 4 g/day (4 capsules/day).

Approval duration: 12 months

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

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to CP.~~XXX~~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 – CP.PMN.53 or evidence of coverage documents~~;~~

~~**B.** [Indications/diagnoses/situations in which drug is unsafe/ineffective] (This section should contain uses where the drug has been shown to be ineffective or unsafe or both. Do not list uses that are unproven, under investigation, or not studied here)~~

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
H~~h~~ypertriglyceridemia	4 g~~rams~~ per day as a~~s~~ 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. Workflow Document

Lovaza WF.docx

VIII. References

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Field Code Changed

1. Lovaza Prescribing Information. Research Triangle Park, NC: GlaxoSmithKline; May 2014. Available at http://www.lovaza.com. Accessed May 18, 2016.
2. Rosensen RS. Approach to the patient with hypertriglyceridemia. Freeman MW (Ed), UpToDate, Waltham, MA. Accessed May 2016.
3.2. 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.
4.5. 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
References updated	08/14	08/14
Converted to new template The following was added to criteria: lab result must be within the last 30 days; use of fibrate for ≥ 3 consecutive months in the last 6 months; quantity limit of 4 capsules per day was added; Initial approval period was extended to 6 months instead of 3 months to time for provider to evaluate patient's response; Renewal criteria requiring 10% decrease in baseline triglyceride was removed to allow provider to make the decision to discontinue/continue therapy.	08/15	08/15
Updated template and references. Added option for intolerance/contraindication in lieu of failure of fibrate therapy and requirement for previous fulfilment of Centene coverage criteria for continued approval. Modified specific max dosing criteria to generalized statement. Added workflow document.	05/16	08/16
Initial approval period was updated for labs in 90 days instead of 30 days.	11/16	11/16
Non-c[Clinical changes to criteria] N/ARemoved age requirement as age is not an absolute contraindication. References updated	03/17	08/17

Important Reminder

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This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.