



BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Omega-3 Fatty Acid Products

Policy # 00336

Original Effective Date: 01/09/2013

Current Effective Date: 01/15/2014

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider prescription omega-3 fatty acid products, including, but not limited to Lovaza[®] ‡ (omega-3-acid ethyl esters capsules) and Vascepa[®] ‡ (icosapent ethyl capsules) to be **eligible for coverage** when the following patient selection criteria are met:

Patient Selection Criteria

Coverage eligibility will be considered for prescription omega-3 fatty acid products when the following criteria are met:

- The patient has a fasting baseline (pretreatment) triglyceride (TG) level of ≥ 150 mg/dL; and
- The patient has tried, or is currently receiving, one of the following products: niacin (immediate-release or extended-release), a fibrate (e.g., gemfibrozil, fenofibrate, fenofibric acid), a statin (e.g., atorvastatin, simvastatin), or an over-the-counter (OTC) omega-3 fatty acid product (e.g., fish oil supplements).

*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of prescription omega-3 fatty acid products for a baseline (TG) level of < 150 mg/dL, or for usage not included in the above patient selection criteria to be **investigational*** (with the exception of those denoted above as **not medically necessary****).

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of prescription omega-3 fatty acid products when the patient has not tried or is not currently receiving, one of the following products: niacin (immediate-release or extended-release), a fibrate (e.g., gemfibrozil, fenofibrate, fenofibric acid), a statin (e.g., atorvastatin, simvastatin), or an over-the-counter (OTC) omega-3 fatty acid product (e.g., fish oil supplements) to be **not medically necessary****.

Background/Overview

These drugs are combinations of omega-3 fatty acids and are indicated as an adjunct to diet to reduce TG levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.



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Rationale/Source

Several organizations including the National Cholesterol Education Program (NCEP), the American Heart Association (AHA), American Association of Clinical Endocrinologists' (AACE), and the Endocrine Society have released statements and/or guidelines which conclude that fibrates have the highest TG lowering effects out of the potential lipid lowering drugs. Other drugs with TG lowering effects include niacin, statins, and omega-3 fatty acid products. In fact, fibrates are considered the first-line treatment for hypertriglyceridemia, and more specifically severe hypertriglyceridemia. Patient selection criteria are based on information collected in a review of the available data.

References

1. Express Scripts Prior Authorization Policy. Omega-3 Fatty Acid Products (Lovaza [omega-3 acid ethyl esters capsules-GlaxoSmithKline] and Vascepa [icosapent ethyl capsules-Amarin]). 09/19/2012.
2. Lovaza[®] capsules [package insert]. Research Triangle Park, NC: GlaxoSmithKline; December 2010.
3. Vascepa[™] capsules [prescribing information]. Bedminster, NJ: Amarin; July 2012.
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5. Miller M, Stone NJ, Ballantyne C, et al. Triglycerides and cardiovascular disease: a scientific statement from the American Heart Association. *Circulation*. 2011;123:2292-2333. Available at <http://circ.ahajournals.org/content/123/20/2292.full.pdf+html>.
6. Jellinger PS, Smith DA, Mehta AE, et al, for the AACE Task Force for the Management of Dyslipidemia and Prevention of Atherosclerosis. American Association of Clinical Endocrinologists' guidelines for management of dyslipidemia and prevention of atherosclerosis. *Endocrin Pract*. 2012;18 (Suppl 1):1-78. Available at <https://www.aace.com/files/lipid-guidelines.pdf>.
7. Berglund L, Brunzell JD, Goldberg AC, et al. Evaluation and treatment of treatment of hypertriglyceridemia: an endocrine society clinical practice guideline. *J Clin Endocrinol Metab*. 2012;97(9):2969-2989. Available at http://www.endo-society.org/guidelines/upload/082312_Hypertriglyceridemia_FinalA.PDF.

Policy History

Original Effective Date: 01/09/2013

Current Effective Date: 01/15/2014

01/03/2013 Medical Policy Committee review

01/09/2013 Medical Policy Implementation Committee approval. New policy.

01/09/2014 Medical Policy Committee review

01/15/2014 Medical Policy Implementation Committee approval. Added a *Note* to the Patient Selection Criteria stating that denials will be not medically necessary if criteria are not met. Made a reference to this not medically necessary *Note* in the investigational section. Coverage eligibility unchanged.

Next Scheduled Review Date: 01/2015

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:



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1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. reference to federal regulations.

****Medically Necessary (or "Medical Necessity")** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. in accordance with nationally accepted standards of medical practice;
- B. clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.