Lovaza® (omega-3-acid ethyl esters capsules)

Policy # 00336
Original Effective Date: 01/09/2013
Current Effective Date: 09/09/2024

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 brand Lovaza®‡ (omega-3-acid ethyl esters capsules) to be **eligible for coverage**** when the following patient selection criteria are met:

Patient Selection Criteria

Coverage eligibility will be considered for brand Lovaza (omega-3-acid ethyl esters capsules) when the following criteria are met:

- Patient has a fasting baseline (pretreatment) triglyceride (TG) level of ≥ 150 mg/dL; AND
- 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); AND
  (*Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met*)
- Patient has tried and failed (e.g., intolerance or inadequate response) the generic equivalent prescription omega-3-acid ethyl esters capsules unless there is clinical evidence or patient history that suggests the use of the generic equivalent will be ineffective or cause an adverse reaction to the patient.
  (*Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met*)

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When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of brand Lovaza (omega-3-acid ethyl esters capsules) 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 OTC omega-3 fatty acid product (e.g., fish oil supplements) to be **not medically necessary**.**

Based on review of available data, the Company considers the use of brand Lovaza (omega-3-acid ethyl esters capsules) when the patient has not tried and failed the generic equivalent prescription omega-3-acid ethyl esters capsules to be **not medically necessary**.**

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 brand Lovaza (omega-3-acid ethyl esters capsules) for a baseline (TG) level of < 150 mg/dL to be **investigational.***

Background/Overview

Lovaza is a combination of omega-3 fatty acids and is indicated as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia. Lovaza is available in generic form at a much more economical value and is considered equally efficacious to the brand name product. Another product, Vascepa®‡, is available in this class of drugs. Results from the REDUCE-IT trial demonstrated a 25% relative risk reduction in first occurrence of a major cardiovascular event in patients taking Vascepa as add on therapy to a statin when compared to placebo in patients with triglyceride levels greater than or equal to 135 mg/dl. Based on the generic availability of Lovaza and the positive results with Vascepa, branded Lovaza is not a preferred treatment option.

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Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The intent of this policy is to require other more economical and/or efficacious products (e.g., generic omega 3 products or Vascepa) prior to branded Lovaza.

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; April 2019.
3. Vascepa capsules [prescribing information]. Bedminster, NJ: Amarin; February 2017.
4. Vascepa Website: https://www.vascepahcp.com/vascepa-efficacy/reduce-it/.

Policy History

Original Effective Date: 01/09/2013
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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.
01/08/2015	Medical Policy Committee review
01/21/2015	Medical Policy Implementation Committee approval. Added Omtryg and Epanova to policy.
01/07/2016	Medical Policy Committee review

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01/22/2016	Medical Policy Implementation Committee approval. Added the term "brand or generic" now that there are generic products available. No coverage change.
01/05/2017	Medical Policy Committee review
01/18/2017	Medical Policy Implementation Committee approval. No coverage change.
01/04/2018	Medical Policy Committee review
01/17/2018	Medical Policy Implementation Committee approval. No coverage change.
01/10/2019	Medical Policy Committee review
01/23/2019	Medical Policy Implementation Committee approval. No coverage change.
08/01/2019	Medical Policy Committee review
08/14/2019	Medical Policy Implementation Committee approval. Changed Title to Lovaza (omega-3-acid ethyl esters capsules). Updated criteria and background to reflect the removal of Vascepa and generic omega 3 products from the policy. Also removed products that have not come to market yet (Omtryg, Epanova).
08/06/2020	Medical Policy Committee review
08/12/2020	Medical Policy Implementation Committee approval. No change to coverage.
08/05/2021	Medical Policy Committee review
08/11/2021	Medical Policy Implementation Committee approval. Added a requirement to try and fail the generic equivalent of Lovaza.
08/04/2022	Medical Policy Committee review
08/10/2022	Medical Policy Implementation Committee approval. No change to coverage.
08/03/2023	Medical Policy Committee review
08/09/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/01/2024	Medical Policy Committee review
08/14/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 08/2025

*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:

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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:
    1. Consultation with 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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.