Omega-3-Acid Ethyl Esters (Lovaza/Generics) in Patients with End-Stage Renal Disease (ESRD) on Maintenance Hemodialysis
Criteria for Use
April 2026

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at the *PBM INTRAnet* site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive Lovaza/Omega-3-Acid Ethyl Esters.

☐ None

Inclusion Criteria

All of the following criteria must be met.

☐ Provider is a VA or VA Community Care Nephrologist or locally designed expert in managing patients with end stage renal disease (ESRD) on hemodialysis.

☐ Patient with ESRD receiving chronic maintenance hemodialysis. ^1-3

^1 Lovaza/omega-3-acid ethyl esters is not the omega-3 fatty acid (O3FA) product used in the PISCES trial and is not FDA approved for use in these patients. However, the O3FA used in PISCES is formulated as an ethyl ester, like Lovaza, and the 4 g daily dose contains a total of 1.6 g EPA and 0.8 g DHA, while 4 g daily of Lovaza/generics contains 1.86 g EPA and 1.5 g DHA. It is unknown if the benefit of the O3FA product from PISCES can be extrapolated to Lovaza/generics, but it is the only FDA approved O3FA product available in the US. *Patients on other methods of dialysis (e.g., peritoneal, continuous renal replacement therapy or CRRT) were not included in the PISCES study.*

^2 In the PISCES study, the following were excluded from participation (list is not all-inclusive): Pregnancy; active major bleed within 1 month of enrollment; blood pressure >180/120; receiving 2 antiplatelets or anticoagulants (aspirin and warfarin were permitted); implanted or planned implantable cardioverter-defibrillator (ICD) placement within the year; allergy to fish, soy or corn.

^3 Although not specifically reported in PISCES, an increased risk for new onset or hospitalization for atrial fibrillation or flutter was observed in the REDUCE-IT and STRENGTH trials. Therefore, patients should be closely monitored during treatment.

Lok CE, Farkouh M, Hemmelgarn BR, et al. Fish-Oil Supplementation and Cardiovascular Events in Patients Receiving Hemodialysis. N Engl J Med 2026;394:128-137.

McCausland FR, Charytan DM. Fish Oil for Patients Receiving Hemodialysis-Red Herring or Great Catch?

Bhatt DL, Steg PG, Miller M, et al. Cardiovascular Risk Reduction with Icosapent Ethyl for Hypertriglyceridemia. N Engl J Med 2018;380:11-22.

Nicholls SJ, Lincoff AM, Garcia M, et al. Effect of High-Dose Omega-3 Fatty Acids vs. Corn Oil on Major Adverse Cardiovascular Events in Patients at High Cardiovascular Risk. The STRENGTH Randomized Clinical Trial. JAMA 2020;324:2268-2280.

Revised: N/A

Original: April 2026

Contact: Catherine Kelley, PharmD, National Program Manager, VA Pharmacy Benefits Management Services – Formulary Management (12PBM)