



Prior Authorization Approval Criteria
Department of Pharmacy Services

Generic Name: omega-3-acid ethyl esters

Brand Name: Lovaza* (previously known as Omacor, see note below)

Medication Class: antilipidemic agent

FDA Approved Uses: Adjunct to diet to reduce very high (≥ 500 mg/dl) triglyceride (TG) levels in adult patients.

Available Dosage Forms: Capsule 1 g

Usual Dose: 4g per day as a single dose or in divided dose 2g po bid.

Duration of Therapy: indefinite

Criteria for Use: *(bullet points below are all inclusive unless otherwise noted)*

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
 - Clinically diagnosed hypertriglyceridemia with a baseline triglyceride (TG) level ≥ 500 mg/dl
 - Must already be on an appropriate lipid lowering diet and should continue during treatment with Lovaza.
 - Failed / intolerant to Niaspan (niacin ER).
 - Failed/ intolerant to at least one fibric acid derivative such as: Antara (fenofibrate) micronized, Tricor (fenofibrate), or Lopid (gemfibrozil).
- Or
- Patient taking a statin and is unable to take a fibric acid derivative due to an increased risk of myopathy

Criteria for Continuation of Therapy:

- Must have an adequate response after two months of treatment.

Cautions:

- Known sensitivity or allergy to fish.
- Prolong bleeding time, caution with anticoagulants.
- Worsening of glycemic control in diabetic patients.
- Increases in LDL cholesterol.

Monitoring:

- Periodic monitoring of ALT and LDL levels since increases in these levels were observed.



Contraindications:

- Patients who exhibit hypersensitivity to any component of this medication.

Not Approved if:

- Patient has any contraindications to the use of Lovaza.
- Patient does not meet the above stated criteria.

Special Considerations:

- Off label uses of omega-3-acid ethyl esters include:
 - TG levels between 200-499 mg/dl
 - Treatment of IgA nephropathy
 - Secondary prevention post MI
- Therapy should be withdrawn if no adequate response after 2 months of treatment.
- Reductions in TG -44.9%, TC -9.7%, VLDL-C - 41.7%, non-HDL-C -13.8%.
- **Increases in LDL-C +44.5% and HDL-C +9.1%.**

It is unknown whether data on *Lovaza* can be extrapolated to OTC fish oil supplements. Currently, there are no studies conducted to compare *Lovaza* to OTC fish oil supplements. There is concern regarding the unregulated manufacturing process of dietary supplements. There is also some concern about environmental contaminants of fish oils. However, a review done by ConsumerLab.com found that all but two of the 42 OTC fish oil supplements tested contained the claimed amounts of EPA and DHA.²¹ In addition, the review found that none of the products contained detectable levels of mercury or unsafe levels of polychlorinated biphenyls (PCBs).²¹ One advantage of using *Lovaza* over OTC fish oil supplements is that the concentrated formulation allows patients to get more omega-3 fatty acids in fewer capsules. *Lovaza* is more expensive than OTC supplements. However, with its prescription status, some insurance health plans may cover part of the cost.

*The name Omacor is now Lovaza. Reliant Pharmaceuticals, Inc. has changed the name of **Omacor** to **Lovaza**. Lovaza is the exact same medicine and formulation as Omacor.

P&T Approval: _____ Date: _____