Lovaza®, formerly Omacor(omega-3 acid ethyl esters) Criteria for Nonformulary Use
VHA Pharmacy Benefits Management Strategic Healthcare Group and the Medical Advisory Panel
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The following recommendations are based on current medical evidence. The content of the document is dynamic and will be revised as new clinical data become 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, however, must make the ultimate judgment regarding the propriety of any course of treatment in light of individual patient situations.

Lovaza, formerly Omacor, is the first marine-derived omega-3 polyunsaturated fatty acid (n-3 PUFA, fish oil, omega-3 fatty acid) to be approved by the FDA. It was approved as an adjunct to diet in patients with very high triglyceride (TG) levels (≥500 mg/dL). For additional information, refer to the National PBM Lovaza monograph at http://www.pbm.va.gov or http://vaww.pbm.va.gov

Candidates for Lovaza®

Patients Receiving Statins:

- Patients with TG Levels ≥ 500 mg/dL

AND

- Inadequate TG lowering response to a therapeutic trial of niacin (1-2 grams/day), unable to tolerate niacin or are not a candidate for niacin therapy.[a]

Patients NOT Receiving Statins:

- Patients with TG Levels ≥ 500 mg/dL

AND

- Inadequate response to a therapeutic trial of monotherapy with both a fibrate (gemfibrozil 600 mg twice daily) and niacin (1-2 grams daily), unable to tolerate a fibrate and niacin or are not candidates for fibrates and niacin therapy (see bottom of table for contraindications) [a,b]

***Lovaza is not FDA approved for the primary or secondary prevention of coronary heart disease (see the Omacor monograph for details)**

Recommendations: Prior to initiating drug therapy for hypertriglyceridemia

- Institute therapeutic lifestyle changes (e.g. cessation of alcohol, weight loss, exercise and diet including elimination of sugar-sweetened beverages)

AND

- Address secondary causes of hypertriglyceridemia (e.g. poorly controlled diabetes mellitus, nephrotic syndrome, alcoholism, hypothyroidism, high intake of sugar sweetened beverages and medications (Especially protease inhibitors. Others may include corticosteroids, estrogens, beta-blockers and thiazide diuretics).

Dosing

For patients with TG levels ≥500 mg/dL, the dose of Lovaza is 4 grams daily given as 4 capsules once daily or 2 capsules twice daily. In many of the trials, Lovaza was taken with a meal.

Monitoring

- TGs should be monitored within 8 weeks of initiation of Lovaza and then periodically to determine response to treatment.

- ALT should be monitored within 8 weeks of initiation of Lovaza and then periodically during

treatment. ALT was observed to increase in some patients during Lovaza therapy.

- ❑ LDL-C should be monitored within 8 weeks of initiation of Lovaza and then periodically during treatment. An increase in LDL-C can occur with fish oil supplementation, including Lovaza.

- ❑ Although data are inconclusive on the interaction and risk for bleeding between fish oils and warfarin, close monitoring is recommended in patients receiving the combination.

Discontinuation of Lovaza®

Lovaza should be discontinued if an adequate TG lowering response (20-30%) has not been observed within 2 months of treatment.

[a]Not candidates for niacin: Those with a history of confirmed peptic ulcer disease [perforation, ulceration or upper GI bleeding] gouty attacks [as evidenced by the presence of intra-articular uric acid crystals in the affected joint] and/or poorly controlled diabetes.
[b]Not candidates for fibrates: Those with hepatic or severe renal dysfunction including primary biliary cirrhosis and preexisting gallbladder disease.

Acquisition Costs (prices as of 1-10-06) Each agent may lower TG 20-50%

Product	Usual Daily Dose	Cost per Capsule ($)	Cost/Day ($)	Cost/30 Days ($)
Lovaza	4 grams[a]	0.71*	2.84	85.20
Fish Oil Supplement	4 grams[c]	0.08	0.64	19.20
Niaspan	1-2 grams	0.44	0.44-0.88	13.20-26.40
Gemfibrozil [b]	600 mg twice daily	0.10	0.20	6.00
Fenofibrate [b]	130 mg (Antara) or 145 mg (Tricor)	2.10-1.09	2.10-1.36	63.00-32.70

[a]Dose for TGs ≥500 mg/dL, given as 2 grams twice a day or 4 grams once. *Estimated FSS cost per capsule is $0.71
[b]In patients receiving statins, the statin-fibrate combination can increase the risk for muscle toxicity (http://www.pbm.va.gov/Safety%20Reports/87ry38statin-fibrate-Final.pdf). Niacin and fish oils should be considered first.
[c]SeaOmega 50 pricing, 8 capsules/day provides 4 grams of n-3 PUFAs.

List of N-3 PUFA Supplements (table does not include all available products)

Product	Mg/Capsule*	Eicosapentaenoic Acid (EPA) mg/capsule	Docosahexaenoic Acid (DHA) mg/capsule	Number of Capsules/Day to Provide Approx. 3.5 grams/day of n-3 PUFAs
Promega Pearls	600	168	72	14-15
Cardi-Omega 3 EPA Capsules Max EPA	1000	180	120	11-12
Promega	1000	280	120	8-9
Sea-Omega 50	1000	300	200	7
Sea-Omega 30	1200	180	140	10-11
Marine Lipid Concentrate Softgels	1200	360	240	5-6
SuperEPA 1200	1200	360	240	5-6
SuperEPA 2000	1000	563	312	4

Most products contain small quantities of vitamin E to prevent loss due to problems with absorption of vitamin E or increased utilization by other tissues to block free radicals and prevent oxidative damage with n-3 PUFAs.[36]
*Total number of milligrams, contained in each capsule, does not represent the dose of EPA and DHA in a particular product. Daily doses of n-3 PUFAs are calculated by adding the amounts of EPA and DHA in each capsule. (Table adapted from Facts and Comp)