

## Omega-3-acid ethyl esters Prior Authorization Criteria

Omega-3-acid ethyl esters (Omacor®) is indicated as an adjunct to diet to reduce very high (>500 mg/dL) triglyceride (TG) levels in adult patients.

The daily dose of Omega-3-acid ethyl esters (Omacor®) is 4 g per day. The daily dose may be taken as a single 4-gm dose (4 capsules) or as two 2-g doses (2 capsules given twice daily).

Source - <http://www.fda.gov/cder/foi/label/2004/21654bl.pdf>

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### Criteria:

1. Treatment of high triglyceride levels ( $\geq 400$ mg/dL) not responsive to, or not a candidate for, other lipid lowering agents (e.g. HMG CoA therapy)
2. Treatment of high triglyceride level ( $\geq 400$ mg/dL) when patient is intolerant or not responsive to, or not a candidate for nicotinic acid or fibrate therapy.

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### ATP III Classification of Serum Triglycerides (mg/dL)

< 150	Normal
150-199	Borderline high
200-499	High
$\geq 500$	Very high

### Treatment of elevated triglycerides ( $\geq 150$ mg/dL)

- Primary aim of therapy is to reach LDL goal.
- Intensify weight management.
- Increase physical activity.
- If triglycerides are  $\geq 200$  mg/dL after LDL goal is reached, set secondary goal for non-HDL cholesterol (total - HDL) 30 mg/dL higher than LDL goal.

### Comparison of LDL Cholesterol and Non-HDL Cholesterol Goals for Three Risk Categories

Risk Category	LDL Goal (mg/dL)	Non-HDL Goal (mg/dL)
CHD and CHD Risk Equivalent (10-year risk for CHD >20%)	<100	<130
Multiple (2+) Risk Factors and 10-year risk $\leq 20\%$	<130	<160
0-1 Risk Factor	<160	<190

### If triglycerides 200-499 mg/dL after LDL goal is reached, consider adding drug if needed to reach non-HDL goal:

- intensify therapy with LDL-lowering drug, or
- add nicotinic acid or fibrate to further lower VLDL.

### If triglycerides $\geq 500$ mg/dL, first lower triglycerides to prevent pancreatitis:

- very low-fat diet ( $\leq 15\%$  of calories from fat)
- weight management and physical activity

- fibrate or nicotinic acid
- when triglycerides <500 mg/dL, turn to LDL-lowering therapy.

### **Treatment of low HDL cholesterol (<40 mg/dL)**

- First reach LDL goal, then:
- Intensify weight management and increase physical activity.
- If triglycerides 200-499 mg/dL, achieve non-HDL goal.
- If triglycerides <200 mg/dL (isolated low HDL) in CHD or CHD equivalent, consider nicotinic acid or fibrate.

From: U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Public Health Service  
National Institutes of Health  
National Heart, Lung, and Blood Institute  
<http://www.nhlbi.nih.gov/guidelines/cholesterol/atglance.htm>