



Prior Authorization Criteria for Lovaza (Omega-3/DHA)

Background

Lovaza (Omega-3/DHA) is the first and only prescription marine-derived omega-3 polyunsaturated fatty acid product approved by the FDA (in 2004). Lovaza is approved as an adjunct to diet in patients with very high triglyceride (TG) levels (>500 mg/dL). Lovaza decreases TG 20-45% but is also associated with increases in LDL. Appropriate LDL-lowering therapy (e.g., statins) is recommended when Lovaza is prescribed.

The following criteria were established by the DoD Pharmacy & Therapeutics (P&T) Committee.

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All current and new users of Lovaza (Omega-3/DHA) must meet one of the following criteria in order for coverage to be approved:

1. Patients with TG > 500 mg/dL who are receiving statins AND have had an inadequate TG-lowering response to a therapeutic trial of niacin (1-2 g/day) or fibrates, are unable to tolerate niacin or fibrates, or are not candidates for niacin or fibrate therapy (see below for contraindications)^{a, b}.
2. Patients with TG > 500 mg/dL who are not receiving statins AND who have had an inadequate TG-lowering response to a therapeutic trial of monotherapy with both a fibrate and niacin, are unable to tolerate niacin and fibrates, or are not candidates for niacin and fibrate therapy (see below for contraindications)^{a, b}.
3. Coverage is approved for patients with TG Levels > 500 mg/dL or for patients with TG Levels < 500 mg/dL with an inadequate TG-lowering response to niacin or fibrates, or who are unable to tolerate/are not candidates for niacin or fibrates.
 - Coverage is not approved for Lovaza for use in non-FDA approved conditions, including the following: Attention Deficit Hyperactivity Disorder, Alzheimer's disease, bipolar disease, Crohn's disease, cystic fibrosis, dementia, depression, inflammatory bowel disease, intermittent claudication, metabolic syndrome, osteoporosis, post-traumatic stress disorder, renal disease (immunoglobulin A nephropathy), rheumatoid arthritis, schizophrenia, Type 2 diabetes mellitus, and ulcerative colitis

^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.

Criteria approved through the DoD P&T Committee process February 2011

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