

Clinical Pharmacy Program Guidelines for Omega

Program	Prior Authorization
Medication	Lovaza [®] (omega-3-acid ethyl esters)*, Epanova [®] (omega-3-carboxylic acids), Omtryg [™] (omega-3-acid ethyl esters A), Vascepa [®] (icosapent ethyl)
Issue Date	9/2010
Pharmacy and Therapeutics Approval Date	7/2017
Effective Date	9/2017

*Generic Lovaza is preferred. Other Omega products are non-preferred.

1. Background:

Omega-3-acid derivatives - Lovaza[®], Epanova[®], Omtryg[™], and Vascepa[®], are highly purified ethyl ester concentrates. Lovaza, Epanova, and Omtryg are a combination of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). Vascepa is composed primarily of eicosapentaenoic acid (EPA). These medications are indicated as adjunctive therapy to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia. Omega-3-acid derivatives should be administered at a dose of 4 grams per day for the treatment of severe hypertriglyceridemia. The effect of omega-3-acid derivatives on the risk of pancreatitis and cardiovascular morbidity and mortality has not been determined.

2. Coverage Criteria:

A. Initial Authorization

1. Approval will be based on **all** of the following criteria:

a. Diagnosis of severe hypertriglyceridemia (pre-treatment triglyceride level greater than or equal to 500 mg/dL)

-AND-

b. Patient is on an appropriate lipid-lowering diet and exercise regimen

-AND-

c. If the request is for a non-preferred product the patient must have a history of failure, intolerance, or contraindication to generic Lovaza.

Authorization will be issued for 12 months

B. Reauthorization

1. Approval will be based on **both** of the following criteria:

a. Documentation of positive clinical response to therapy

-AND-

b. Patient is on an appropriate lipid-lowering diet and exercise regimen

Authorization will be issued for 12 months

3. References:

1. Lovaza prescribing information. GlaxoSmithKline. Research Triangle Park, NC. September 2015.
2. Epanova prescribing information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. May 2014.
3. Omtryg prescribing information. Trygg Pharma Inc. Arlington, WA. March 2016.
4. Vascepa prescribing information. Amarin Pharma Inc. Bedminster, NJ. February 2017.

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Change Control	
Date	Change
9/2010	New drug policy
6/2011	Annual Review, no changes
6/2012	Annual Review, no changes
7/2016	Updated clinical criteria to align with E&I notification policy and updated policy to new template
2/2017	Updated policy to add generic Lovaza as a preferred product. Added step through generic Lovaza for non-preferred products.
7/2017	Annual review. Updated references.