

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	OMEGA-3 FATTY ACIDS
BRAND NAME (generic)	EPANOVA (omega-3-carboxylic acids)
	LOVAZA (omega-3-acid ethyl esters)
	OMTRYG (omega-3-acid ethyl esters A)
	VASCEPA (icosapent ethyl)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Epanova

Epanova (omega-3-carboxylic acids) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.

Usage Considerations: Patients should be placed on an appropriate lipid-lowering diet before receiving Epanova and should continue this diet during treatment with Epanova.

Laboratory studies should be done to ascertain that the triglyceride levels are consistently abnormal before instituting Epanova therapy. Every attempt should be made to control serum lipids with appropriate diet, exercise, weight loss in obese patients, and control of any medical problems such as diabetes mellitus and hypothyroidism that are contributing to the lipid abnormalities. Medications known to exacerbate hypertriglyceridemia (such as beta blockers, thiazides, estrogens) should be discontinued or changed if possible prior to consideration of triglyceride-lowering drug therapy.

Limitations of Use

The effect of Epanova on the risk for pancreatitis has not been determined.

The effect of Epanova on cardiovascular mortality and morbidity has not been determined.

Lovaza

Lovaza (omega-3-acid ethyl esters) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.

Usage Considerations: Patients should be placed on an appropriate lipid-lowering diet before receiving Lovaza and should continue this diet during treatment with Lovaza.

Laboratory studies should be done to ascertain that the lipid levels are consistently abnormal before instituting Lovaza therapy. Every attempt should be made to control serum lipids with appropriate diet, exercise, weight loss in obese patients, and control of any medical problems such as diabetes mellitus and hypothyroidism that are contributing to the lipid abnormalities. Medications known to exacerbate hypertriglyceridemia (such as beta blockers, thiazides, estrogens) should be discontinued or changed if possible prior to consideration of triglyceride-lowering drug therapy.

Omega-3 Fatty Acids Policy 972-A, MDC-2 797-A 11-2016_4.12.17

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Limitations of Use

The effect of Lovaza on the risk for pancreatitis has not been determined.

The effect of Lovaza on cardiovascular mortality and morbidity has not been determined.

Omtryg

Omtryg (omega-3-acid ethyl esters A) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.

Usage Considerations: Patients should be placed on an appropriate lipid-lowering diet before receiving Omtryg and should continue this diet during treatment with Omtryg.

Laboratory studies should be done to ascertain that the lipid levels are consistently abnormal before instituting Omtryg therapy. Every attempt should be made to control serum lipids with appropriate diet, exercise, weight loss in obese patients, and control of any medical problems, such as diabetes mellitus and hypothyroidism, that are contributing to the lipid abnormalities. Medications known to exacerbate hypertriglyceridemia (such as beta blockers, thiazides, estrogens) should be discontinued or changed if possible prior to consideration of triglyceride-lowering drug therapy.

Limitations of Use

The effect of Omtryg on the risk for pancreatitis has not been determined.

The effect of Omtryg on cardiovascular mortality and morbidity has not been determined.

Vascepa

Vascepa (icosapent ethyl) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.

Usage Considerations: Patients should be placed on an appropriate lipid-lowering diet and exercise regimen before receiving Vascepa and should continue this diet and exercise regimen with Vascepa.

Attempts should be made to control any medical problems such as diabetes mellitus, hypothyroidism, and alcohol intake that may contribute to lipid abnormalities. Medications known to exacerbate hypertriglyceridemia (such as beta blockers, thiazides, estrogens) should be discontinued or changed, if possible, prior to consideration of TG-lowering drug therapy.

Limitations of Use

The effect of Vascepa on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined.

The effect of Vascepa on cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia has not been determined.

COVERAGE CRITERIA

Omega-3 Fatty Acids will be covered with prior authorization when the following criteria are met:

- The patient has, or did have prior to the start of a triglyceride lowering drug, a triglyceride level greater than or equal to 500 mg/dL
- AND**
- The patient will be on an appropriate lipid-lowering diet and exercise regimen during treatment

REFERENCES

1. Epanova [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; October 2016.
2. Lovaza [package insert]. Research Triangle Park, NC: GlaxoSmithKline; September 2015.
3. Omtryg [package insert]. Arlington, VA: Trygg Pharma, Inc.; March 2016.
4. Vascepa [package insert]. Bedminster, NJ: Amarin Pharma Inc.; June 2015.
5. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed November 2016.
6. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed November 2016.
7. Stone NJ, Robinson J, Lichtenstein AH, et al. 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol* 2013. [Epub Ahead of Print].
8. Miller, M., Stone, N.J., Ballantyne, C., et al. Triglycerides and Cardiovascular Disease: A Scientific Statement From the American Heart Association. *Circulation*. 2011;123:2293-2333.
9. Berglund L, Brunzell JD, Goldberg AC, et al, "Evaluation and Treatment of Hypertriglyceridemia: An Endocrine Society Clinical Practice Guideline," *J Clin Endocrinol Metab*, September 2012, 97: 2969–2989.
10. Grundy, SM, Cleeman JI, Merz NB, et al. Implications of Recent Clinical Trials for the National Cholesterol Education Program Adult Treatment Panel III Guidelines. *Circulation*. July 13, 2004;110:227-239.