

## PRIOR AUTHORIZATION CRITERIA

<b>DRUG CLASS</b>	<b>OMEGA-3 FATTY ACIDS</b>	
<b>BRAND NAME* (generic)</b>	<p style="text-align: center;"><b>EPANOVA</b> (omega-3-carboxylic acids)</p> <p style="text-align: center;"><b>LOVAZA</b> (omega-3-acid ethyl esters)</p> <p style="text-align: center;"><b>VASCEPA</b> (icosapent ethyl)</p>	
<b>Status: CVS Caremark Criteria</b>		<b>Ref #</b>
<b>972-A</b>		
<b>Type: Initial Prior Authorization</b>		<b>Ref #</b>
<b>MDC-2 797-A</b>		

*\*Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated*

### 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 ( $\geq 500$ 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 ( $\geq 500$  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, Omega-3 Fatty Acids 972-A, mDC-2 797\_A11.2017

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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 Lovaza on the risk for pancreatitis has not been determined.

The effect of Lovaza 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 ( $\geq 500$  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**

The requested drug 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

#### **RATIONALE**

These criteria meet the Medicare Part D definition of a medically accepted indication. This definition includes uses which are approved by the FDA or supported by a citation included, or approved for inclusion, in one of the Medicare approved compendia

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Epanova, Lovaza, Omtryg, and Vascepa are indicated as an adjunct to diet to reduce triglyceride levels in adult patients with severe ( $\geq 500$  mg/dL) hypertriglyceridemia.

When triglycerides are very high ( $\geq 500$  mg/dL), drugs that raise triglycerides should be identified and preferably discontinued, alcohol should be eliminated, and weight reduction and increased physical activity as components of Therapeutic Lifestyle Changes (TLC) should be emphasized.<sup>1-7</sup> In fact, TLC remain an essential modality in clinical management and any person at high risk or moderately high risk who has lifestyle-related risk factors (e.g., obesity, physical inactivity, elevated triglycerides, low HDL-C, or metabolic syndrome) is a candidate for TLC to modify these risk factors regardless of LDL-C level.<sup>9</sup>

#### **REFERENCES**

1. Epanova [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; March 2017.
2. Lovaza [package insert]. Research Triangle Park, NC: GlaxoSmithKline; September 2015.
3. Vascepa [package insert]. Bedminster, NJ: Arnarin Pharma Inc.; February 2017.

4. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; [http://online.lexi.com/lco/action/index/dataset/complete\\_ashp](http://online.lexi.com/lco/action/index/dataset/complete_ashp) [available with subscription]. Accessed November 2017.
5. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. [www.micromedexsolutions.com](http://www.micromedexsolutions.com) [available with subscription]. Accessed November 2017.
6. 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].
7. 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.
8. 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.
9. 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.

Written by: UM Development (RP)  
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 Reviewed: Medical Affairs (DC) 08/2012, 03/2013, (LB) 11/2013, 05/2014; (DHR) 12/2014; (ME) 01/2017  
 External Review: 09/2012, 06/2013, 02/2014, 02/2015, 02/2016, 02/2017, 02/2018

<b><u>CRITERIA FOR APPROVAL</u></b>		
Does the patient have, or did the patient have prior to the start of a triglyceride lowering drug, a triglyceride level greater than or equal to 500 mg/dL?	Yes	No
Will the patient be on an appropriate lipid-lowering diet and exercise regimen during treatment?	Yes	No

<b>Mapping Instructions (972-A)</b>			
	<b>Yes</b>	<b>No</b>	<b>DENIAL REASONS – DO NOT USE FOR MEDICARE PART D</b>
1	Go to 2	Deny	Your plan covers this drug when you have, or had before you started taking a triglyceride lowering drug, a triglyceride level greater than or equal to 500 mg/dL Your use of this drug does not meet the requirement. This is based on the information we have.
2	Approve, 36 Months	Deny	Your plan covers this drug when you will be on a diet and exercise regimen during treatment. Your use of this drug does not meet the requirement. This is based on the information we have.

<b>Mapping Instructions (MDC-2 797-A)</b>			
	<b>Yes</b>	<b>No</b>	<b>DENIAL REASONS – DO NOT USE FOR MEDICARE PART D</b>
1	Go to 2	Deny	Your plan covers this drug when you have, or had before you started taking a triglyceride lowering drug, a triglyceride level greater than or equal to 500 mg/dL

			Your use of this drug does not meet the requirement. This is based on the information we have.
2	Approve, 12 Months	Deny	Your plan covers this drug when you will be on a diet and exercise regimen during treatment. Your use of this drug does not meet the requirement. This is based on the information we have.

<b>Guidelines for Approval (MDC-2 797-A)</b>	
<b>Duration of Approval</b>	<b>12 Months</b>
<b>Set 1</b>	
<b>Yes to question(s)</b>	<b>No to question(s)</b>
1	None
2	