

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS OMEGA-3 FATTY ACIDS

BRAND NAME*
(generic)

EPANOVA
(omega-3 carboxylic acids)

LOVAZA
(omega-3 acid ethyl esters)

VASCEPA
(icosapent ethyl)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization

Ref # 972-A
Ref # 797-A

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included 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 (≥ 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.

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 maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥ 150 mg/dL) and
 - established cardiovascular disease or
 - diabetes mellitus and 2 or more additional risk factors for cardiovascular disease.
- As an adjunct to diet to reduce TG levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia

Limitations of Use:

The effect of Vascepa on the risk for pancreatitis 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 will be on an appropriate lipid-lowering diet and exercise regimen during treatment
- AND**
- The patient has, or did have prior to the start of treatment with a triglyceride-lowering drug, a triglyceride level greater than or equal to 500 milligrams/deciliter
- OR**
- Vascepa is being prescribed to reduce the risk of myocardial infarction, stroke, coronary revascularization, or unstable angina requiring hospitalization in an adult patient with elevated triglyceride (TG) levels (greater than 150 milligrams/deciliter) **AND**
 - Vascepa is being prescribed as an adjunct to maximally tolerated statin therapy**AND**
 - The patient has established cardiovascular disease**OR**
 - The patient has diabetes mellitus and two or more additional risk factors for cardiovascular disease

RATIONALE

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 (≥ 500 mg/dL) hypertriglyceridemia. Vascepa is also indicated as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥ 150 mg/dL) and established cardiovascular disease or diabetes mellitus and 2 or more additional risk factors for cardiovascular disease.

When triglycerides are very high (≥ 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.¹⁻⁸ Good adherence to various LDL-lowering diets should be promoted along with caloric intake adjustments to avoid weight gain, or in overweight/obese patients, to promote weight loss. In general, adults should be advised to engage in aerobic physical activity 3-4 sessions per week, lasting on average 40 minutes per session and involving moderate-to-vigorous-intensity physical activity.⁶ Therefore, the requested drug may be approved when triglyceride levels are greater than or equal to 500 mg/dL and the patient is on a diet and exercise regimen during treatment. Vascepa may also be approved to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥ 150 mg/dL) and established cardiovascular disease or diabetes mellitus and 2 or more additional risk factors for cardiovascular disease when it is being used as an adjunct to maximally tolerated statin therapy and the patient is on a diet and exercise regimen during treatment.

REFERENCES

1. Epanova [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; March 2017.

2. Lovaza [package insert]. Research Triangle Park, NC: GlaxoSmithKline; April 2019.
3. Vascepa [package insert]. Bedminster, NJ: Anarion Pharmaceuticals; December 2019.
4. Lexi-Comp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. <http://online.lexi.com>. Accessed November 2019.
5. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA <http://www.micromedexsolutions.com>. Accessed November 2019.
6. Grundy SM, Stone NJ, et al. 2018 ACC/AHA Guideline on the Management of Blood Cholesterol. Journal of the American College of Cardiology Nov 2018; 25709; DOI: 10.1016/j.jacc.2018.11.003
7. Miller, M, Stone, NJ., 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, Gidding AC, et al, "Evaluation and Treatment of Hypertriglyceridemia: An Endocrine Society Clinical Practice Guideline," J Clin Endocrinol Metab, September 2012; 97: 2969–2989.

Written by: UM Development (RP)
 Date Written: 08/2012
 Revised: 03/2013, 11/2013, 05/2014 (add Epanova and Ontaryg); (JH) 11/2014; (RP) 11/2015 (no clinical changes); (MS) 11/2016; (ME) 11/2017 (removed Ontaryg from target drug box), 11/2018 (no clinical changes), 11/2019 (removed MDC designation from title of document), 12/2019 (added new indication for Vascepa)
 Reviewed: Medical Affairs (DQ) 08/2012, 03/2013, (LB) 11/2013, 05/2014; (DHR) 12/2014; (ME) 01/2017, (AN) 11/2018, (CHART) 11/21/2019, (CHART) 01/02/2020
 External Review: 09/2012, 06/2013, 02/2014, 02/2015, 02/2016, 02/2017, 02/2018, 02/2019, 02/2020

CRITERIA FOR APPROVAL

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|---|---|-----|----|
| 1 | Does the patient have, or did the patient have prior to the start of treatment with a triglyceride lowering drug, a triglyceride level greater than or equal to 500 milligrams/deciliter?
[If yes, then skip to question 7.] | Yes | No |
| 2 | Is this request for Vascepa? | Yes | No |
| 3 | Is Vascepa being prescribed to reduce the risk of myocardial infarction, stroke, coronary revascularization, or unstable angina requiring hospitalization in an adult patient with elevated triglyceride (TG) levels (greater than 150 milligrams/deciliter)? | Yes | No |
| 4 | Does the patient have established cardiovascular disease?
[If yes, then skip to question 6.] | Yes | No |
| 5 | Does the patient have diabetes mellitus and two or more additional risk factors for cardiovascular disease? | Yes | No |
| 6 | Is Vascepa being prescribed as an adjunct to maximally tolerated statin therapy? | Yes | No |
| 7 | Will the patient be on an appropriate lipid lowering diet and exercise regimen during treatment? | Yes | No |

Mapping Instructions (972-A)

	Yes	No	DENIAL REASONS – DO NOT USE FOR MEDICARE PART D
1.	Go to 7	Go to 2	
2.	Go to 3	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have or had the required triglyceride level. Your request has been denied based on the information we have.

			[Short Description: No approvable diagnosis.]
3.	Go to 4	Deny	You do not meet the requirements of your plan. Your plan covers Vascepa when you meet the following conditions: - It is being prescribed to reduce the risk of myocardial infarction, stroke, coronary revascularization, or unstable angina requiring hospitalization - You have triglyceride (TG) levels greater than 150 milligrams/deciliter Your request has been denied based on the information we have. [Short Description: No approvable diagnosis.]
4.	Go to 6	Go to 5	
5.	Go to 6	Deny	You do not meet the requirements of your plan. Your plan covers Vascepa when you meet any of the following conditions: - You have cardiovascular disease - You have diabetes mellitus and two or more additional risk factors for cardiovascular disease. Your request has been denied based on the information we have. [Short Description: No approvable diagnosis.]
6.	Go to 7	Deny	You do not meet the requirements of your plan. Your plan covers Vascepa when you are also being treated with a statin. Your request has been denied based on the information we have. [Short Description: No statin therapy.]
7.	Approve, 36 Months	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you will be on a diet and exercise regimen during treatment. Your request has been denied based on the information we have. [Short Description: No confirmation of diet and exercise.]

Mapping Instructions (797-A)			
	Yes	No	DENIAL REASONS – DO NOT USE FOR MED CARE PART D
1.	Go to 7	Go to 2	
2.	Go to 3	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have or had the required triglyceride level. Your request has been denied based on the information we have. [Short Description: No approvable diagnosis.]
3.	Go to 4	Deny	You do not meet the requirements of your plan. Your plan covers Vascepa when you meet the following conditions: - It is being prescribed to reduce the risk of myocardial infarction, stroke, coronary revascularization, or unstable angina requiring hospitalization - You have triglyceride (TG) levels greater than 150 milligrams/deciliter Your request has been denied based on the information we have. [Short Description: No approvable diagnosis.]
4.	Go to 6	Go to 5	
5.	Go to 6	Deny	You do not meet the requirements of your plan. Your plan covers Vascepa when you meet any of the following conditions: - You have cardiovascular disease - You have diabetes mellitus and two or more additional risk factors for cardiovascular disease. Your request has been denied based on the information we have. [Short Description: No approvable diagnosis.]
6.	Go to 7	Deny	You do not meet the requirements of your plan. Your plan covers Vascepa when you are also being treated with a statin. Your request has been denied based on the information we have.

			[Short Description: No statin therapy.]
7.	Approve, 12 Months	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you will be on a diet and exercise regimen during treatment. Your request has been denied based on the information we have. [Short Description: No confirmation of diet and exercise.]