

Initial Prior Authorization

Omega-3 Fatty Acids

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Lovaza	omega-3-acid ethyl esters
Vascepa	icosapent ethyl

Indications

FDA-approved Indications

Lovaza

Lovaza (omega-3-acid ethyl esters capsules) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (greater than or equal to 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 therapy with Lovaza. 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 TG-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

Cardiovascular Risk Reduction

Authorization may be granted when the requested drug 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 or equal to 150 mg/dL at baseline) when ALL of the following criteria are met:

- The patient will be on an appropriate lipid-lowering diet and exercise regimen during treatment with the requested drug.
- The request is for Vascepa.
- Vascepa is being prescribed as an adjunct to maximally tolerated statin therapy and ONE of the following criteria are met:
 - The patient has established cardiovascular disease.
 - The patient has diabetes mellitus and TWO or more additional risk factors for cardiovascular disease.

Severe Hypertriglyceridemia

Authorization may be granted when the requested drug is being prescribed to reduce triglyceride (TG) levels in a patient with severe (greater than or equal to 500 mg/dL at baseline) hypertriglyceridemia when the following criteria is met:

- The patient will be on an appropriate lipid-lowering diet and exercise regimen during treatment with the requested drug.

Continuation of Therapy

Cardiovascular Risk Reduction

All patients (including new patients) requesting authorization for continuation of therapy must meet ALL requirements in the coverage criteria section.

Severe Hypertriglyceridemia

Authorization may be granted when the requested drug is being prescribed to reduce triglyceride (TG) levels in a patient with severe (greater than or equal to 500 mg/dL at baseline) hypertriglyceridemia when ALL of the following criteria are met:

- The patient will be on an appropriate lipid-lowering diet and exercise regimen during treatment with the requested drug.
- The patient has achieved or maintained a reduction in TG levels from baseline.

Duration of Approval (DOA)

- 972-A: DOA: 36 months
- 797-A: DOA: 12 months

References

1. Lovaza [package insert]. Wixom, MI: Woodward Pharma Services LLC; February 2021.
2. Vascepa [package insert]. Bridgewater, NJ: Amarin Pharma Inc.; September 2021.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed October 24, 2024.
4. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 10/24/2024).
5. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation 2019 Jun 18;139(25):e1082-1143.
6. Jacobson TA, Ito MK, Maki KC et. al. National Lipid Association Recommendations for Patient-Centered Management of Dyslipidemia: Part 1 – Full Report. J Clin Lipidol. 2015;9(2):129-169.

Document History

Written by: UM Development (RP)

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Revised: 03/2013, 11/2013, 05/2014 (add Epanova and Omtryg); (JH) 11/2014; (RP) 11/2015 (no clinical changes); (MS) 11/2016, (ME) 11/2017 (removed Omtryg from target drug box), 11/2018 (no clinical changes), 11/2019 (removed MDC designation from title/document), 12/2019 (added new indication for Vascepa), 11/2020 (removed Epanova from target drug box), 04/2021 (Created two new Ref #s [from 972-A & 797-A] for BOG Strategy for Brand only Vascepa), 11/2021 (no clinical changes), (DFW) 11/2022 (added COT criteria for hypertriglyceridemia indication); (KMB) 11/2023 (no clinical changes), 05/2023 (removed BOG due to retirement, updated document title), 11/2024 (no clinical changes)

Reviewed: Medical Affairs (DC) 08/2012, 03/2013, (LB) 11/2013, 05/2014; (DHR) 12/2014; (ME) 01/2017, (AN) 11/2018, (CHART) 11/21/2019, 01/02/2020, 12/3/20, 4/22/21, 12/2/2021, 12/01/2022, 11/30/2023, 11/21/2024

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CRITERIA FOR APPROVAL

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| 1 | Will the patient be on an appropriate lipid-lowering diet and exercise regimen during treatment with the requested drug?
[If Yes, then go to 2. If No, then no further questions.] | Yes | No |
| 2 | Is the requested drug being prescribed to reduce triglyceride (TG) levels in a patient with severe (greater than or equal to 500 mg/dL at baseline) hypertriglyceridemia?
[If Yes, then go to 3. If No, then go to 5.] | Yes | No |
| 3 | Is this request for continuation of therapy?
[If Yes, then go to 4. If No, then no further questions.] | Yes | No |
| 4 | Has the patient achieved or maintained a reduction in triglyceride (TG) levels from baseline?
[No further questions] | Yes | No |
| 5 | 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 or equal to 150 mg/dL at baseline)? | Yes | No |

[If Yes, then go to 6. If No, then no further questions.]

6	Does the patient have established cardiovascular disease?	Yes	No
	[If Yes, then go to 8. If No, then go to 7.]		

7	Does the patient have diabetes mellitus and TWO or more additional risk factors for cardiovascular disease?	Yes	No
	[If Yes, then go to 8. If No, then no further questions.]		

8	Is Vascepa being prescribed as an adjunct to maximally tolerated statin therapy?	Yes	No
	[No further questions]		

Mapping Instructions			
	Yes	No	DENIAL REASONS
1.	Go to 2	Deny	<p>Your plan only covers this drug if you will be taking this drug as a part of a certain treatment plan. We have denied your request because you are not (or will not be) taking this drug in addition to being on a diet and exercise regimen. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Not a component of a regimen]</p>
2.	Go to 3	Go to 5	
3.	Go to 4	Approve, 12 Months	
4.	Approve, 12 Months	Deny	<p>Your plan only covers this drug if it works well for you. We have denied your request because you have not achieved or maintained a reduction in triglyceride levels from baseline. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the</p>

			<p>drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Continuation: Efficacy]</p>
5.	Go to 6	Deny	<p>Your plan only covers this drug when it is used for certain health conditions. Covered uses for Vascepa are severe hypertriglyceridemia (greater than or equal to 500 mg/dL at baseline) and to lower your risk of heart attack, stroke, coronary revascularization or unstable angina needing hospitalization when you have an elevated triglyceride (TG) level of greater than or equal to 150 mg/dL at baseline. Covered use for Lovaza is severe hypertriglyceridemia (greater than or equal to 500 mg/dL at baseline). Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Diagnosis]</p>
6.	Go to 8	Go to 7	
7.	Go to 8	Deny	<p>Your plan only covers this drug if you have heart disease or diabetes and at least two other risk factors for heart disease. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Disease category/stage/severity]</p>
8.	Approve, 12 Months	Deny	<p>Your plan only covers this drug if you will be taking it with maximally tolerated statin therapy. We have denied your request because: A) You are not (or will not be) taking it, and B) You do not have a medical reason not to take it. We reviewed the information</p>

Reference number(s)
972-A, 797-A

			<p>we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Not on required concurrent therapy]</p>
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