Clinical Policy: Icosapent ethyl (Vascepa)

Reference Number: PA.CP.PMN.187
Effective Date: 01.19
Last Review Date: 01.19 Revision Log

Description
Icosapent ethyl (Vascepa®) is an ethyl ester of eicosapentaenoic acid (EPA).

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

Limitation(s) 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.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health & Wellness® that Vascepa is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Hypertriglyceridemia (must meet all)**:**

1. Diagnosis of hypertriglyceridemia;
2. Age ≥ 18 years;
3. Fasting triglycerides ≥ 500 mg/dL (lab must be dated within 90 days);
4. Failure of a ≥ 3 consecutive month trial of fibrate therapy in the last 6 months at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of omega-3-acid ethyl esters (generic Lovaza®) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
6. Dose does not exceed 4 g (4 capsules) per day.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

II. Continued Therapy

A. Hypertriglyceridemia (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy as evidenced by:
   a. Initial re-authorization: 20% reduction in TG levels from baseline;
   b. Subsequent re-authorizations: continued reduction or maintenance in reduction of TG levels from baseline;
3. If request is for a dose increase, new dose does not exceed 4 g (4 capsules) per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation Key
EPA: eicosapentaenoic acid
FDA: Food and Drug Administration
TG: triglyceride

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
fenofibrate (TriCor®)	48-145 mg PO QD	145 mg/day
gemfibrozil (Lopid®)	600 mg PO BID	1,200 mg/day
omega-3-acid ethyl esters (Lovaza®)	4 g PO QD or 2 g PO BID	4 g/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): known hypersensitivity (e.g., anaphylactic reaction) to Vascepa or any of its components

- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Hypertriglyceridemia	2 g PO BID	4 g/day

VI. Product Availability

Capsules: 0.5 g, 1 g

VII. References

1. Vascepa Prescribing Information. Bedminster, NJ: Amarin Pharma, Inc.; February 2017. Available at: www.vascepa.com. Accessed November 13, 2018.
2. Stone NJ, Robinson JG, 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. Circulation. 2014; 129: S1.
3. Miller M, Stone NJ, Ballantyne C, et al. Triglycerides and cardiovascular disease: a scientific statement from the American Heart Association. Circulation. 2011; 123: 2292-2333.
4. Jellinger PS, Handelsman Y, Rosenblit PD, et al. American Association of Clinical Endocrinologists and American College of Endocrinology Guidelines for management of dyslipidemia and prevention of cardiovascular disease. Endocr Pract 2017;23(Suppl 2):1-87.
5. Berglund L, Brunzell JD, Goldberg AC, et al. Evaluation and treatment of hypertriglyceridemia: an Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab 2012;97(9):2969-2989.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2019 Policy created.	01.19	