AETNA BETTER HEALTH® Coverage Policy/Guideline			
Name:	Icosapent Ethyl	Page:	1 of 2
Effective Date:	4/1/2024	Last Review Date:	3/2024
Applies to:	☐Illinois ☒New Jersey ☒Pennsylvania Kids	☐Florida ☒Maryland ☒Virginia	☒Florida Kids ☐Michigan ☐Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for icosapent ethyl under the patient's prescription drug benefit.

Description:

FDA-Approved Indications

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.

Applicable Drug List:

Icosapent ethyl

Policy/Guideline:

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 with the requested drug

AND

- 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, the patient is unable to take omega-3-acid ethyl esters (generic Lovaza) for the given

diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication **AND**

- The request is NOT for continuation of therapy
  OR
- The request is for continuation of therapy **AND**
  - The patient has achieved or maintained a reduction in triglyceride (TG) levels from baseline

OR

- The request is for Vascepa **AND**
  - 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) **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

Approval Duration and Quantity Restrictions:

Approval: 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.; 2023. https://online.lexi.com. Accessed October 10, 2023.
4. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 10/10/2023).
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. *Circulation.* 2019;139: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. Journal of Clinical Lipidology 2015;9:129-169.