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Vascepa (icosapent ethyl) Prior Authorization with Quantity Limit Program Summary

FDA APPROVED INDICATIONS AND DOSAGE[1]

Agent(s)	Indication(s)	Dosage
Vascepa® (icosapent ethyl)[a] Capsule	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 Adjunct to diet to reduce triglyceride (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.	4 grams daily taken as four 0.5 gram capsules or two 1 gram capsules twice daily with food.

a – available as generic

CLINICAL RATIONALE

Efficacy

Vascepa was studied in the REDUCE-IT phase 3b randomized, double blind, placebo-controlled trial comparing icosapent ethyl 2 grams twice daily with food with placebo that contained mineral oil. Patients could be enrolled if they 45 years of age or older and had established cardiovascular disease. Patients 50 years of age or older who had diabetes mellitus and at least one additional risk factor (see table 1 below) were also enrolled. Eligible patients had a fasting triglyceride level of 135 to 499 mg per deciliter (1.69 to 5.63 mmol per liter) and a low-density lipoprotein (LDL) cholesterol level of 41 to 100 mg per deciliter (1.06 to 2.59 mmol per liter) and had been receiving a stable dose of a statin for at least 4 weeks. The primary efficacy endpoint was a composite of cardiovascular death, nonfatal myocardial infarction (including silent myocardial infarction), nonfatal stroke, coronary revascularization, or unstable angina in a time-to-event analysis. Secondary endpoints included a key endpoint of composite of cardiovascular death, nonfatal myocardial infarction, or nonfatal stroke in a time-to-event analysis; a composite of cardiovascular death or nonfatal myocardial infarction; fatal or nonfatal myocardial infarction; emergency or urgent revascularization; cardiovascular death; hospitalization for unstable angina; fatal or nonfatal stroke; a composite of death from any cause, nonfatal myocardial infarction, or nonfatal stroke; and death from any cause. A total of 8,179 patients were randomized. A primary end-point event occurred in 17.2% of the patients in the icosapent ethyl group, as compared with 22.0% of the patients in the placebo group (hazard ratio, 0.75; 95% confidence interval [CI], 0.68 to 0.83; P<0.001). The corresponding rates of the key secondary endpoint were 11.2% and 14.8% (hazard ratio, 0.74; 95% CI, 0.65 to 0.83; P<0.001). The rates of additional ischemic end points, as assessed according to a

prespecified hierarchical schema, were significantly lower in the icosapent ethyl group than in the placebo group, including the rate of cardiovascular death (4.3% vs. 5.2%; hazard ratio, 0.80; 95% CI, 0.66 to 0.98; P = 0.03). A larger percentage of patients in the icosapent ethyl group than in the placebo group were hospitalized for atrial fibrillation or flutter (3.1% vs. 2.1%, P = 0.004). Serious bleeding events occurred in 2.7% of the patients in the icosapent ethyl group and in 2.1% in the placebo group (P = 0.06).[2]

Table 1. Cardiovascular risk factor included in REDUCE-IT[3]

Age ≥55 years for men or ≥65 years for women
Cigarette smoker or stopped smoking within 3 months
Hypertension (≥140 mm Hg systolic or ≥90 mm Hg diastolic) or on antihypertensive medication
HDL-C ≤40 mg/dL for men or ≤50 mg/dL for women
hsCRP >3.00 mg/L
Renal dysfunction CrCl >30 and <60 mL/min
Retinopathy defined as any of the following: nonproliferative retinopathy, preproliferative retinopathy, proliferative retinopathy, maculopathy, advanced diabetic eye disease, or a history of photocoagulation
Micro- or macroalbuminuria

Safety

Vascepa is contraindicated in the following:[1]

- Patients with known hypersensitivity (e.g., anaphylactic reaction) to Vascepa or any of its components.

Vascepa has no black box warnings.[1]

References

1. Vascepa prescribing information. Amarin Pharma, Inc. July 2020.
2. Bhatt DL, Steg PG, Miller M, et al. Cardiovascular risk reduction with icosapent ethyl for hypertriglyceridemia. *New England Journal of Medicine*. DOI: 10.1056/NEJMoa1812792. 11/10/2018. Available at: https://www.nejm.org/doi/full/10.1056/nejmoa1812792 Accessed March 31, 2021.
3. Bhatt DL, Steg PG, Brinton EA, et al. Rationale and design of REDUCE-IT: Reduction of Cardiovascular Events with Icosapent Ethyl–Intervention Trial. *Clinical Cardiology.* 2017;40:138-148. Available at: https://onlinelibrary.wiley.com/doi/epdf/10.1002/clc.22692 Accessed: March 31, 2021.

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TARGET AGENT(S)

Vascepa® (icosapent ethyl)[a]

a- Generic equivalent available

Preferred Agents	Non-Preferred Agents
Vascepa	icosapent ethyl

Brand (generic)	GPI	Multisource Code	Quantity Limit (per day or as listed)
Vascepa (icosapent ethyl)			
0.5 g capsule	39500035100110	M, N, O, Y	8 capsules
1 g capsule[a]	39500035100120	M, N, O, Y	4 capsules

a - available as generic

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Initial Evaluation

Target Agent(s) will be approved when ALL of the following are met:

1. ONE of the following:
    a. The patient has a pre-treatment triglyceride (TG) level of greater than or equal to 500 mg/dL
    OR
    b. The patient is using the requested agent to reduce the risk of myocardial infarction, stroke, coronary revascularization, or unstable angina requiring hospitalization AND ALL of the following:
        i. ONE of the following:
            1. The patient is on maximally tolerated statin therapy
            OR
            2. The patient has an intolerance or hypersensitivity to statin therapy
            OR
            3. The patient has an FDA labeled contraindication to ALL statins
        AND
        ii. The patient's triglyceride (TG) level is greater than or equal to 150 mg/dL
        AND
        iii. ONE of the following:
            1. The patient has established cardiovascular disease
            OR
            2. The patient has diabetes mellitus AND 2 or more additional risk factors for cardiovascular disease (e.g. hypertension, premature family history, chronic kidney disease)
    OR
    c. The patient has another FDA approved indication for the requested agent and route of administration
    OR
    d. The patient has another indication that is supported in compendia for the requested agent and route of administration

AND

2. ONE of the following:
    a. The patient's age is within FDA labeling for the requested indication for the requested agent
    OR

b. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication

AND

3. If the client has preferred agent(s), then ONE of the following:
    a. The requested agent is a preferred agent
    OR
    b. The patient has an intolerance or hypersensitivity to the preferred agent(s) that is not expected to occur with the non-preferred agent
    OR
    c. The patient has an FDA labeled contraindication to the preferred agent(s) that is not expected to occur with the non-preferred agent

AND

4. The patient does NOT have any FDA labeled contraindications to the requested agent

AND

5. ONE of the following:
    a. The requested quantity (dose) does NOT exceed the program quantity limit
    OR
    b. ALL of the following:
        i. The requested quantity (dose) is greater than the program quantity limit
        AND
        ii. The requested quantity (dose) does NOT exceed the FDA maximum labeled dose for the requested indication
        AND
        iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit
    OR
    c. ALL of the following:
        i. The requested quantity (dose) is greater than the program quantity limit
        AND
        ii. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication
        AND
        iii. The prescriber has provided information in support of therapy with a higher dose for the requested indication

Compendia Allowed: AHFS, or DrugDex 1 or 2a level of evidence

Length of Approval: 12 months

Renewal Evaluation

Target Agent(s) will be approved when ALL of the following are met:

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process
AND
2. The patient has had clinical benefit with the requested agent
AND
3. If the client has preferred agent(s), then ONE of the following:
    a. The requested agent is a preferred agent
    OR
    b. The patient has an intolerance or hypersensitivity to the preferred agent(s) that is not expected to occur with the non-preferred agent

 Effective: 05/15/2022

OR

c. The patient has an FDA labeled contraindication to the preferred agent(s) that is not expected to occur with the non-preferred agent

AND

4. The patient does NOT have any FDA labeled contraindications to the requested agent
AND
5. ONE of the following:
    a. The requested quantity (dose) does NOT exceed the program quantity limit
    OR
    b. ALL of the following:
        i. The requested quantity (dose) is greater than the program quantity limit
        AND
        ii. The requested quantity (dose) does NOT exceed the FDA maximum labeled dose for the requested indication
        AND
        iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit
    OR
    c. ALL of the following:
        i. The requested quantity (dose) is greater than the program quantity limit
        AND
        ii. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication
        AND
        iii. The prescriber has provided information in support of therapy with a higher dose for the requested indication

Length of Approval: 12 months

