PDL NEW DRUG REVIEW

Proprietary Name: Vascepa®
Common Name: icosapent ethyl
PDL Category: Antihyperlipidemics

Comparable Products	Preferred Drug List Status
Lovaza	Non-Preferred

Summary

Indications and Usage: Adjunct treatment to diet to reduce triglyceride (TG) levels in adult patients with severe (≥500mg/dL) hypertriglyceridemia. Patients should be placed on an appropriate lipid-lowering diet and exercise regimen prior to the administration of Vascepa®, and this regimen should be continued during treatment. The effect of Vascepa® on the risk for pancreatitis in those with severe hypertriglyceridemia has not been determined. In addition, its effect on cardiovascular mortality and morbidity in those with severe hypertriglyceridemia has not been determined. This is a pregnancy category C medication. The safety and efficacy of use in children under the age of 18 have not been established.

Drug Interactions: Those receiving treatment with Vascepa® in combination with other drugs affecting coagulation (ie anti-platelet agents) should be monitored periodically.

Dosage Forms: Soft-gelatin Capsules: 1gm

Recommended Dosage: The daily dose is 4gms per day, given as 2 capsules twice daily with food, in combination with appropriate nutritional intake and physical activity. The use in those with renal or hepatic impairment has not been studied; however, in those with hepatic impairment, ALT/AST levels should be monitored periodically during Vascepa® treatment.

Common Adverse Drug Reactions: *Listed % incidence for adverse drug reactions = reported % incidence for drug minus reported % incidence for placebo.* The most common adverse event reported with Vascepa® include arthralgia (1.3%). One additional reported adverse reaction from clinical studies was oropharyngeal pain; however, there was no placebo data or incidence provided.

Contraindications: In those with known hypersensitivity to icosapent ethyl or any component of the compound. Although not a contraindication, Vascepa® should be used with caution in those with known hypersensitivity to fish and/or shellfish, as its active ingredient is obtained from the oil of fish.

Manufacturer: Amarin Pharma, Inc.

Analysis: Icosapent ethyl, the active ingredient of Vascepa®, is an ethyl ester of the omega-3 fatty acid eicosapentaenoic acid (EPA). It has been suggested in studies that EPA reduces hepatic very low-density lipoprotein triglycerides (VLDL-TG) production and/or secretion, as well as enhances TG clearance from circulating VLDL particles. Please note that it is recommended that prior to initiation of TG-lowering drug therapy, all attempts should be made to control any medical problems that may contribute to lipid abnormalities, as well as changing, if possible, medications that may alter or exacerbate hypertriglyceridemia.

One randomized, double-blind, placebo-controlled, parallel-group study was performed to assess the safety and efficacy of Vascepa® in an adult population (N=151) with severe hypertriglyceridemia. Baseline TG levels were between 500-2,000mg/dL. Results of the study for Vascepa® vs placebo for % change from baseline are as follows: TG (-27% vs +10%); LDL-C (-5% vs -3%), Non-HDL-C (-8% vs +8%), TC (-7% vs +8%), HDL-C (-4% vs 0%), VLDL-C (-20% vs +14%), and Apo B (-4% vs +4%).

Vascepa® is indicated only for a specific type of hypertriglyceridemia and its place in therapy relative to current lipotropic agents is not clear as there was no comparator data found. Therefore, it is recommended that Vascepa® remain non-preferred and be available to those who meet the indication and have failed or are unable to tolerate any preferred medications.

PDL Placement:

- ☐ **Preferred**
- ☒ **Non-Preferred**
- ☐ **Preferred with Conditions**

References

[1] Vascepa [package insert]. Bedminster, NJ: Amarin Pharma Inc; 2012.