Nexletol® (bempedoic acid), Nexlizet® (bempedoic acid/ezetimibe) – New/expanded indications

- On March 22, 2024, Esperion announced the FDA approval of Nexletol (bempedoic acid), to reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with: (1) established cardiovascular disease (CVD), or (2) a high risk for a CVD event but without established CVD.

- Nexletol's other indication was also expanded to adjunct to diet, in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, **or alone** when concomitant LDL-C lowering therapy is not possible, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH).

    — Nexletol was previously approved as an adjunct to diet and statin therapy for the treatment of primary hyperlipidemia in adults with HeFH or atherosclerotic cardiovascular disease, who require additional lowering of LDL-C.

- In addition, similar updates were made to the label for Nexlizet, a combination of bempedoic acid and ezetimibe.

- Nexletol and Nexlizet are the first oral non-statin LDL-C lowering drugs to be approved to reduce the risk of cardiovascular events in both primary and secondary prevention patients.

- The approval of Nexletol and Nexlizet for the new and updated indications were based on CLEAR Outcomes, a randomized, double-blind, placebo-controlled, event-driven study in 13,970 adult patients with established CVD or at high risk for a CVD event but without CVD who were not receiving recommended statin dosages. Patients were randomized to either oral Nexletol or placebo, alone or as an add on to other background lipid-lowering therapies. The primary composite endpoint was time to first occurrence of cardiovascular death, nonfatal myocardial infarction, nonfatal stroke, or coronary revascularization (MACE-4).

    — A primary composite event occurred in 11.7% of patients with Nexletol vs. 13.3% with placebo (hazard ratio 0.87, 95% CI: 0.79, 0.96; p = 0.0037).

- The most common adverse reactions (≥ 2% and 0.5% greater than placebo) with bempedoic acid use in the CLEAR Outcomes study were hyperuricemia, renal impairment, anemia, elevated liver enzymes, muscle spasms, gout, and cholelithiasis.

- The recommended dosage of Nexletol is 180 mg administered orally once daily.

- The recommended dosage of Nexlizet is one tablet orally once daily. One tablet of Nexlizet contains 180 mg of bempedoic acid and 10 mg of ezetimibe.