

## Nexlizet™ (bempedoic acid/ezetimibe) – New drug approval

- On February 26, 2020, [Esperion](#) announced the [FDA approval](#) of [Nexlizet \(bempedoic acid/ezetimibe\)](#), as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of low-density lipoprotein cholesterol (LDL-C).
  - The effect of Nexlizet on cardiovascular morbidity and mortality has not been determined.
- Nexlizet contains bempedoic acid and [ezetimibe](#) and lowers elevated LDL-C through complementary mechanisms of action by inhibiting cholesterol synthesis in the liver and absorption in the intestine.
- The single-ingredient formulation of bempedoic acid ([Nexletol™](#)) was also recently approved and Esperion plans to launch Nexletol on March 30, 2020.
- The efficacy of Nexlizet was evaluated in a single, randomized, double-blind, placebo-controlled study in 301 patients with heterozygous familial hypercholesterolemia, established atherosclerotic cardiovascular disease, or multiple risk factors for cardiovascular disease on maximally tolerated statin therapy. Patients received either Nexlizet, bempedoic acid alone, ezetimibe alone, or placebo. The primary efficacy outcome was the percent change from baseline to week 12 in LDL-C.
  - The difference between Nexlizet and placebo in mean percent change in LDL-C from baseline to week 12 was -38% (95% CI: -47%, -30%;  $p < 0.001$ ).
- The approval of Nexlizet was also supported by the safety data from the Nexletol clinical studies and the existing ezetimibe safety profile.
- Warnings and precautions for Nexlizet include hyperuricemia and tendon rupture.
- The most common adverse reactions ( $\geq 2\%$  and greater than placebo) with Nexlizet use were upper respiratory tract infection, muscle spasms, hyperuricemia, back pain, abdominal pain or discomfort, bronchitis, pain in extremity, anemia, elevated liver enzymes, diarrhea, arthralgia, sinusitis, fatigue, and influenza.
- The recommended dose of Nexlizet, in combination with maximally tolerated statin therapy, is one tablet orally once daily.
- Esperion plans to launch Nexlizet in July 2020. Nexlizet will be available as a fixed-dose combination tablet containing 180 mg of bempedoic acid and 10 mg of ezetimibe.