



## Esperion Secures Additional Commercial and Medicare Formulary Coverage for NEXLETOL® (bempedoic acid) and NEXLIZET® (bempedoic acid and ezetimibe)

September 3, 2024

- *New Additions to Medicare Formularies at Optum/United AARP and CVS/SilverScript Coupled with Humana Provides Access to More Than 65% of Medicare Insured Lives and More Than 92% of Commercially Insured Lives –*
- *Increased Coverage and Improved Prior Authorization Processes Make Prescribing NEXLETOL and NEXLIZET Easier for Healthcare Providers –*
- *NEXLETOL and NEXLIZET are the Only Non-Statins FDA Approved to Lower LDL Cholesterol and Reduce Risk of Myocardial Infarction and Coronary Revascularization in Both Primary and Secondary Prevention Patients –*

ANN ARBOR, Mich., Sept. 03, 2024 (GLOBE NEWSWIRE) -- Esperion today announced that NEXLETOL® (bempedoic acid) and NEXLIZET® (bempedoic acid and ezetimibe) have achieved additional coverage on national and large regional formularies since the U.S. Food and Drug Administration's (FDA) approval of the expanded indications, increasing total coverage to more than 136 million commercially insured lives (92% of all commercial lives) and 34 million Medicare lives (65% of all Medicare lives). Additionally, many payers have accelerated alignment of utilization management criteria since the FDA approval of the expanded indications to the new labels.

"We are pleased with the response from insurance providers and large pharmacy benefit managers in embracing the CLEAR Outcomes trial data and aligning their utilization management criteria to the most recent FDA approved label indications for primary and secondary prevention," said Sheldon Koenig, President and CEO. "Garnering optimal patient access with a breadth of coverage accounting for 90% of all national commercial and Medicare plans at an accessible price point allows healthcare providers to prescribe NEXLETOL and NEXLIZET with confidence."

NEXLETOL and NEXLIZET are the only non-statin FDA-approved to lower LDL cholesterol and reduce the risk of myocardial infarction and coronary revascularization in primary prevention and secondary prevention patients.

### INDICATION

NEXLIZET and NEXLETOL are indicated:

- The bempedoic acid component of NEXLIZET and NEXLETOL is indicated 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:
  - established cardiovascular disease (CVD), or
  - at high risk for a CVD event but without established CVD.
- As an adjunct to diet:
  - NEXLIZET, alone or in combination with other LDL-C lowering therapies, to reduce LDL-C in adults with primary hyperlipidemia, including HeFH.
  - NEXLETOL, in combination with other 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 HeFH.

### IMPORTANT SAFETY INFORMATION

NEXLIZET and NEXLETOL are contraindicated in patients with a prior hypersensitivity to bempedoic acid or ezetimibe or any of the excipients. Serious hypersensitivity reactions including anaphylaxis, angioedema, rash, and urticaria have been reported.

**Hyperuricemia:** Bempedoic acid, a component of NEXLIZET and NEXLETOL, may increase blood uric acid levels, which may lead to gout. Hyperuricemia may occur early in treatment and persist throughout treatment, returning to baseline following discontinuation of treatment. Assess uric acid levels periodically as clinically indicated. Monitor for signs and symptoms of hyperuricemia, and initiate treatment with urate-lowering drugs as appropriate.

**Tendon Rupture:** Bempedoic acid, a component of NEXLIZET and NEXLETOL, is associated with an increased risk of tendon rupture or injury. Tendon rupture may occur more frequently in patients over 60 years of age, in those taking corticosteroid or fluoroquinolone drugs, in patients with renal failure, and in patients with previous tendon disorders. Discontinue NEXLIZET or NEXLETOL at the first sign of tendon rupture. Consider alternative therapy in patients who have a history of tendon disorders or tendon rupture.

The most common adverse reactions in the primary hyperlipidemia trials of bempedoic acid, a component of NEXLIZET and NEXLETOL, in  $\geq 2\%$  of patients and greater than placebo were upper respiratory tract infection, muscle spasms, hyperuricemia, back pain, abdominal pain or discomfort, bronchitis, pain in extremity, anemia, and elevated liver enzymes.

Adverse reactions reported in  $\geq 2\%$  of patients treated with ezetimibe (a component of NEXLIZET) and at an incidence greater than placebo in clinical trials were upper respiratory tract infection, diarrhea, arthralgia, sinusitis, pain in extremity, fatigue, and influenza.

In the primary hyperlipidemia trials of NEXLIZET, the most commonly reported adverse reactions (incidence  $\geq 3\%$  and greater than placebo) observed with NEXLIZET, but not observed in clinical trials of bempedoic acid or ezetimibe, were urinary tract infection, nasopharyngitis, and constipation.

The most common adverse reactions in the cardiovascular outcomes trial for bempedoic acid, a component of NEXLIZET and NEXLETOL, at an

incidence of  $\geq 2\%$  and 0.5% greater than placebo were hyperuricemia, renal impairment, anemia, elevated liver enzymes, muscle spasms, gout, and cholelithiasis.

Discontinue NEXLIZET or NEXLETOL when pregnancy is recognized unless the benefits of therapy outweigh the potential risks to the fetus. Because of the potential for serious adverse reactions in a breast-fed infant, breastfeeding is not recommended during treatment with NEXLIZET or NEXLETOL.

Report pregnancies to Esperion Therapeutics, Inc. Adverse Event reporting line at 1-833-377-7633.

Please see full Prescribing Information for [NEXLIZET](#) and [NEXLETOL](#).

### **Esperion Therapeutics**

At Esperion, we discover, develop, and commercialize innovative medicines to help improve outcomes for patients with or at risk for cardiovascular and cardiometabolic diseases. The status quo is not meeting the health needs of millions of people with high cholesterol – that is why our team of passionate industry leaders is breaking through the barriers that prevent patients from reaching their goals. Providers are moving toward reducing LDL-cholesterol levels as low as possible, as soon as possible; we provide the next steps to help get patients there. Because when it comes to high cholesterol, getting to goal is not optional. It is our life's work. For more information, visit [esperion.com](#) and [esperionscience.com](#) and follow us on X at [twitter.com/EsperionInc](#).

### **Forward-Looking Statements**

This press release contains forward-looking statements that are made pursuant to the safe harbor provisions of the federal securities laws, including statements regarding marketing strategy and commercialization plans, current and planned operational expenses, future operations, commercial products, clinical development, including the timing, designs and plans for the CLEAR Outcomes study and its results, plans for potential future product candidates, financial condition and outlook, including expected cash runway, and other statements containing the words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “suggest,” “target,” “potential,” “will,” “would,” “could,” “should,” “continue,” and similar expressions. Any express or implied statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Forward-looking statements involve risks and uncertainties that could cause Esperion's actual results to differ significantly from those projected, including, without limitation, the net sales, profitability, and growth of Esperion's commercial products, clinical activities and results, supply chain, commercial development and launch plans, the outcomes and anticipated benefits of legal proceedings and settlements, and the risks detailed in Esperion's filings with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof, and Esperion disclaims any obligation or undertaking to update or revise any forward-looking statements contained in this press release, other than to the extent required by law.

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