

This is a sample letter of medical necessity for Nexlizet® (bempedoic acid and ezetimibe) tablets. This sample is provided for your guidance only. Use of information in this letter does not guarantee that the health plan will provide reimbursement for NEXLIZET, and is not intended to substitute for or influence your independent medical judgment as a healthcare provider.

Based on your clinical judgement, you may use this letter as an example of the type of information that may be helpful when submitting a prior authorization or appealing a denial of coverage for NEXLIZET from a patient's health plan.

INDICATION

NEXLIZET is indicated:

- as an adjunct to diet and exercise to reduce LDL-C in adults with hypercholesterolemia, including HeFH.
- bempedoic acid, a component of NEXLIZET, is indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, myocardial infarction, stroke, or coronary revascularization) in adults at increased risk for these events who are unable to take recommended statin therapy (including those not taking a statin).

IMPORTANT SAFETY INFORMATION

- NEXLIZET is contraindicated in patients with a prior hypersensitivity to ezetimibe or bempedoic acid or any of the excipients. Serious hypersensitivity reactions, such as anaphylaxis, angioedema, rash, and urticaria have been reported with ezetimibe or bempedoic acid.
- Hyperuricemia: Bempedoic acid, a component of NEXLIZET, may increase blood uric acid levels, which may lead to gout. Monitor as clinically indicated and initiate treatment with urate-lowering drugs as appropriate.
- Tendon Rupture: Bempedoic acid is associated with an increased risk of tendon rupture or injury. Tendon rupture occurred in 0.5% of patients treated with bempedoic acid in primary hypercholesterolemia trials, versus 0% on placebo. In the cardiovascular outcomes trial, the rates were 1.2% for bempedoic acid and 0.9% for placebo. Discontinue NEXLIZET 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 hypercholesterolemia trials of bempedoic acid 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.
- The most common 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 of bempedoic acid, 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.
- Concomitant use of NEXLIZET with greater than 20 mg of simvastatin or 40 mg of pravastatin should be avoided due to the potential for increased risk of simvastatin- or pravastatin-related myopathy. Concomitant use with fibrates may increase triglycerides and decrease high-density lipoprotein cholesterol. Monitor and adjust therapies as recommended.
- Discontinue NEXLIZET when pregnancy is recognized unless the benefits of therapy outweigh the potential risks to the fetus. The benefits of breastfeeding should be considered along with the mother's clinical need for NEXLIZET and any potential adverse effects on the breastfed infant from NEXLIZET or from the underlying maternal condition.

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

Please see the full Prescribing Information for additional information.

Nexlizet® (bempedoic acid and ezetimibe) Letter of Medical Necessity

Insurance Company:
Address Line 1:
Address Line 2:

Patient Name:
Policy ID:
Policy Group:
Date of Birth:

Date:

Attn: _____ ,

Dear _____ :

I am writing this on behalf of my patient, _____ . Based on the FDA-approved indication, I strongly believe that treatment with NEXLIZET is medically necessary.

NEXLIZET is medically necessary for _____ , as documented by:

- **Statin intolerance:** Patient has
 - A labeled contraindication to all statins (active liver disease or unexplained persistent elevations of serum transaminases; pregnancy/lactation)
 - Experienced rhabdomyolysis or muscle symptoms with CK elevations >10 ULN after 1 statin trial
 - Experienced statin-attributed adverse effects after an appropriate statin trial (≥2 statins), 1 of which was at the lowest FDA-approved dose

- **Increased risk of major cardiovascular events in adults at increased risk for these events**

- **Primary hypercholesterolemia, including HeFH**

Furthermore, the need for NEXLIZET in certain patient groups is also supported by the latest treatment recommendations issued by the 2026 ACC/AHA Clinical Guideline for Dyslipidemia.

Lipid-lowering Therapy History

has tried the following maximally tolerated statin therapy:

Statin Name	Dosage	Duration (or currently on)

Ezetimibe (current or prior use):

LDL-C Level

LDL-C of _____ 's LDL-C (mg/dL) is currently at _____ mg/dL on _____. This is above their goal

In summary, based on my clinical opinion, NEXLIZET is medically necessary for _____. This is fully consistent with the FDA-approved indication and the current guideline-recommended standard of care.

Please call my office if any additional information is required to ensure prompt approval of this treatment.

Sincerely,

Attachments / Enclosures (if necessary)