This is a sample appeal letter 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 it is not intended to substitute or influence your independent medical judgment as a physician.

Based on your clinical judgment, you may use this letter as an example of the type of information that may be helpful when appealing a denial of coverage for NEXLIZET from a patient's health plan. This sample letter serves as an appeal stating that your patient's condition warrants treatment with NEXLIZET.

INDICATION

NEXLIZET is indicated:

- As an adjunct to diet, alone or in combination with other LDL-C lowering therapies, to reduce LDL-C in adults with primary hyperlipidemia, including HeFH
- The bempedoic acid component of NEXLIZET 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.

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. 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, is associated with an increased risk of tendon rupture or injury. Tendon rupture occurred in 0.5% of patients treated with bempedoic acid in hyperlipidemia trials, versus 0% on placebo. In the cardiovascular outcomes trial, the rates were 1.2% for bempedoic acid and 0.9% for placebo. 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 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) in ≥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 ≥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 ≥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 (a component of NEXLIZET) at an incidence of ≥2% and 0.5% greater than placebo were hyperuricemia, renal impairment, anemia, elevated liver enzymes, muscle spasms, gout, and cholelithiasis.

Discontinue NEXLIZET 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.

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

NEXLIZET® (bempedoic acid and ezetimibe) Tablets: Letter of Medical Necessity for Appeal

[Insurance Company]

[Address Line 1]

[Address Line 2]

RE: [patient name]

[Policy ID] / [Policy Group]

DOB: [mm/dd/yyyy]

Date [mm/dd/yyyy]

Attn: Medical/Pharmacy Director, Department

Dear Medical/Pharmacy Director,

I am writing this letter to appeal the denial of coverage and document the medical necessity for NEXLIZET on behalf of my patient, [Patient Name] .

NEXLIZET is indicated:

- As an adjunct to diet, alone or in combination with other LDL-C lowering therapies, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH).
- The bempedoic acid component of NEXLIZET 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.

On [mm/dd/yyyy] , your organization cited [Indicate Reason for Denial] as the reason for denial. However, based on the FDA-approved indication stated above, I believe that treatment with NEXLIZET is medically necessary for [patient name] .

Listed below are the patient's medical diagnosis, and treatment history which confirm the medical necessity and appropriate treatment with NEXLIZET.

In my opinion, [patient name] requires NEXLIZET due to their history of [primary hyperlipidemia (with established cardiovascular disease (CVD), or at high risk for a CVD event but without established CVD), or a history of statin intolerance]. This patient's current LDL-C is [X mg/dL] on maximally tolerated dose of [statin] , which is above their LDL-C goal and requires additional reduction.

Addendum to Prior Authorization

PATIENT INFORMATION

Patient Name: _____ DOB: _____

Insurance ID#: _____ Policy/Group #: _____ Date: _____

☐ NEXLETOL (bempedoic acid) tablets NDC : 72426-118-03
☐ NEXLIZET (bempedoic acid and ezetimibe) tablets 180mg/10mg NDC: 72426-818-03

☐ Atherosclerotic cardiovascular disease (ASCVD):
☐ Heterozygous familial hypercholesterolemia (HeFH):
☐ Hyperlipidemia with or without CVD

To Whom it May Concern:
I am writing this letter to support my belief that considering this patient's history, condition, and the appropriate use of the medication, at this time it is warranted, appropriate, and medically necessary for Product to be covered and reimbursed for this patient. **As such, I request your immediate consideration for reimbursement and subsequent timely authorization.**

CLINICAL ASSESSMENT

Current LDL-C: _____mg/dL

Last date on lipid-lowering treatment: mm/dd/yyyy: _____

Atherosclerotic cardiovascular disease (ASCVD)
Check all that apply:

☐ Acute coronary syndromes
☐ Clinically significant coronary heart disease diagnosed by invasive or noninvasive testing
☐ Coronary or other arterial revascularization
☐ History of myocardial infarction
☐ Peripheral arterial disease presumed to be of atherosclerotic origin
☐ Stable or unstable angina
☐ Stroke
☐ Carotid artery stenosis
☐ Aortic atherosclerosis
☐ Transient ischemic attack

Heterozygous familial hypercholesterolemia (HeFH): ***Check all that apply:***

☐ Family history of myocardial infarction in first-degree relative: < 60 years of age
☐ Family history of myocardial infarction in second-degree relative: < 50 years of age
☐ Family history of LDL-C greater than 190 mg/dL in first- or second-degree relative
☐ Family history of familial hypercholesterolemia in first- or second-degree relative
☐ Family history of tendinous xanthomata and/or arcus cornealis in first- or second degree relative
☐ Dutch Lipid Score_____
☐ Simon Broom Score_____

Hyperlipidemia:
Check all that apply:

☐ Mixed
☐ Unspecified
☐ Pure hypercholesterolemia
☐ Pure hypercholesterolemia, unspecified
☐ Other hyperlipidemia

Risk Factors for CVD

☐ Diabetes
☐ CAC Score_____
☐ ASCVD Risk Score_____
☐ Framingham Risk Score_____
☐ Reynolds Risk Score_____
☐ Other
☐ Hypertension
☐ Age
☐ Family History
☐ CKD
☐ Ethnicity/Race
☐ Smoker

Check all that apply:

Statins

☐ Decompensated liver disease (development of jaundice, ascites, variceal bleeding, encephalopathy)
☐ Laboratory-confirmed acute liver injury or rhabdomyolysis resulting from statin treatment
☐ Pregnancy, actively trying to become pregnant, or nursing
☐ Immune-mediated hypersensitivity to the HMG-CoA reductase inhibitor drug class (statins) as evidenced by an allergic reaction occurring with at least TWO different statins

Ezetimibe

☐ Moderate or severe hepatic impairment [Child-Pugh classes B and C]
☐ Hypersensitivity to ezetimibe (e.g., anaphylaxis, angioedema, rash, urticaria)

Statin Risk Factors

☐ Multiple or serious comorbidities, including impaired renal or hepatic function
☐ Unexplained alanine transaminase (ALT) elevations > 3 times upper limit of normal, or active liver disease
☐ Concomitant use of drugs adversely affecting statin metabolism
☐ Age > 75 years, or history of hemorrhagic stroke
☐ Asian ancestry
☐ Arcus cornealis before age 45
☐ Functional mutation in LDL (low density lipoprotein) apoB (apolipoprotein B) PCSK9 (proprotein convertase subtilisin/ kexin type 9) gene
☐ Tendinous xanthomata
☐ Intolerance or hypersensitivity to statin therapy
☐ FDA labeled contraindication to all statins

High Intensity Statin Therapy
Daily dose shown to lower LDL-C, on average, by approximately ≥ 50%

	Intolerant	Current
☐ Atorvastatin 40-80 mg	☐	☐
☐ Rosuvastatin 20-40 mg	☐	☐

Moderate Intensity Statin Therapy
Daily dose shown to lower LDL-C, on average, by approximately 30% to 50%

☐ Atorvastatin 10-20mg	☐	☐
☐ Fluvastatin XL 80 mg	☐	☐
☐ Fluvastatin 40 mg BID	☐	☐
☐ Lovastatin 40 mg	☐	☐
☐ Pitavastatin 1-4 mg	☐	☐
☐ Pravastatin 40-80 mg	☐	☐
☐ Rosuvastatin 5-10 mg	☐	☐
☐ Simvastatin 20-40 mg	☐	☐

Low Intensity Statin Therapy
Daily dose shown to lower LDL-C, on average, by < 30%

☐ Simvastatin 10 mg	☐	☐
☐ Pravastatin 10-20 mg	☐	☐
☐ Lovastatin 20 mg	☐	☐
☐ Fluvastatin 20-40 mg	☐	☐

I certify that documentation is maintained in my files and the information given is true and accurate for the medication requested.

Prescriber's Name: _____ NPI Number: _____

Signature of Prescriber: _____ Title: _____ Date: _____

Please sign to validate.