This is a sample letter of medical necessity for NEXLETOL® (bempedoic acid) 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 NEXLETOL, 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 NEXLETOL from a patient's health plan. This sample letter serves as an appeal stating that your patient's condition warrants treatment with NEXLETOL.

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, 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

NEXLETOL is contraindicated in patients with a prior serious hypersensitivity reaction to bempedoic acid or any of the excipients. Serious hypersensitivity reactions, such as angioedema, have occurred.

Hyperuricemia: 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: 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 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 NEXLETOL 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.

The most common adverse reactions in the cardiovascular outcomes trial for NEXLETOL at an incidence of ≥2% and 0.5% greater than placebo were hyperuricemia, renal impairment, anemia, elevated liver enzymes, muscle spasms, gout, and cholelithiasis.

Concomitant use of NEXLETOL 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.

Discontinue 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 NEXLETOL.

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

NEXLETOL® (bempedoic acid) 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

DearMedical/PharmacyDirector,

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

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, 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 heterozygous familial hypercholesterolemia (HeFH).

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 NEXLETOL 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 NEXLETOL.

In my opinion, [patient name] requires NEXLETOL due to their history of [HeFH, CVD, or primary hyperlipemia (with established cardiovascular disease (CVD), or at high risk for a CVD event but without established CVD)] and current LDL-C level of [Xmg/dL] on dose of [statin] , which is not sufficient to achieve the patient's goal.

Patient Diagnosis and Medical History

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

Hyperlipidemia: *Check all that apply:*

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

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
- ☐ Medical 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.

[provide any additional notes about why NEXLETOL is medically necessary]

In summary, based on my clinical opinion, NEXLETOL is appropriate and medically necessary for [patient name] , and this is fully consistent with the FDA-approved indication.

Please call my office at [(XXX) XXX-XXXX] if I can provide you with any additional information to support an approval.

Sincerely,

[Physician Name]