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 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.

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.

[Physician's Letterhead]

NEXLIZET® (bempedoic acid and ezetimibe) Tablets Appeals Letter

[Insurance Company Address Line 1]

[Address Line 2]

RE: [Patient Name]

[Policy ID] / [Policy Group]

DOB: [mm/dd/yyyy]

[mm/dd/yyyy]

Attn: Medical/Pharmacy Director, Department

Dear Medical/Pharmacy Director,

I am writing this letter to appeal the denial of coverage 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 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.

- **Patient diagnosis and medical history**

Indicate summary of how and when the patient was diagnosed with HeFH, ASCVD or Primary Hyperlipidemia. This should include the relevant ICD-10-CM codes, LDL-C values and any relevant comorbidities:

- *HeFH (an autosomal dominant disease characterized by markedly elevated plasma concentrations of LDL-C, typically >190 mg/dL [untreated]) AND still has a documented elevated LDL-C level; OR*
- *ASCVD (history of stroke, TIA, ACS, MI, revascularization, angina [stable or unstable], PAD) AND has an LDL-C value >70 mg/dL*
- *Primary Hyperlipidemia (with established cardiovascular disease (CVD), or at high risk for a CVD event but without established CVD)*

- **Treatment history**

Indicate summary of lipid lowering therapies tried, including dosage, length of treatment, and rationale for discontinuation

Sample verbiage: Patient is currently on statin therapy (X statin X dose for X months). Patient previously tried X statin of X mg dose and had ADRs (rhabdomyolysis, muscle pain or weakness, elevated creatine kinase, elevated liver enzymes, other) and discontinued treatment after X weeks.

- **History of statin therapy:**

Indicate patient's current statin therapy. List all statins tried or that patient is currently on, including dose, duration, and rationale for any dose adjustments or discontinuation, such as adverse events

Statin Name	Dose and Duration	Rationale for Medication Changes

- **History of other lipid lowering therapy:**

List all other non-statin lipid lowering therapies tried, including dose, duration, and rationale for any dose adjustments or discontinuation, such as adverse events. Include history of proprotein convertase subtilisin/kexin type 9 inhibitor (PCSK9i) therapy or history of ezetimibe therapy

Therapy	Dose and Duration	Rationale for Medication Changes

In my opinion, *[patient Name]* requires NEXLIZET due to their history of *[HeFH, ASCVD or primary hyperlipidemia (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.

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

In summary, based on my clinical opinion, NEXLIZET 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 approve my request.

Sincerely,

[Physician Name]