

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  $\geq 2\%$  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.

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) Tablet Letter of Medical Necessity for Appeal

RE:

/

DOB:

Date

**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, .

## **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 , your organization cited as the reason for denial. However, based on the FDA-approved indication stated above, I believe that treatment with NEXLIZET is medically necessary for .

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

In my opinion, requires NEXLIZET due to their history of and current LDL-C level of on dose of , 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
<input type="checkbox"/> Atorvastatin 40-80 mg	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Rosuvastatin 20-40 mg	<input type="checkbox"/>	<input type="checkbox"/>

#### Moderate Intensity Statin Therapy

*Daily dose shown to lower LDL-C, on average, by approximately 30% to 50%*

<input type="checkbox"/> Atorvastatin 10-20mg	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Fluvastatin XL 80 mg	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Fluvastatin 40 mg BID	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Lovastatin 40 mg	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Pitavastatin 1-4 mg	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Pravastatin 40-80 mg	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Rosuvastatin 5-10 mg	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Simvastatin 20-40 mg	<input type="checkbox"/>	<input type="checkbox"/>

#### Low-Intensity Statin Therapy

*Daily dose shown to lower LDL-C, on average, by < 30%*

<input type="checkbox"/> Simvastatin 10 mg	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Pravastatin 10-20 mg	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Lovastatin 20 mg	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Fluvastatin 20-40 mg	<input type="checkbox"/>	<input type="checkbox"/>

In summary, based on my clinical opinion, NEXLIZET is appropriate and medically necessary for \_\_\_\_\_, and this is fully consistent with the FDA-approved indication.

Please call my office at \_\_\_\_\_ if I can provide you with any additional information to support an approval.

Sincerely,