

This is an appeal letter 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 could be necessary 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.

INDICATION

NEXLETOL is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C.

Limitations of Use: The effect of NEXLETOL on cardiovascular morbidity and mortality has not been determined.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions: Hyperuricemia: NEXLETOL may increase blood uric acid levels. Hyperuricemia may occur early in treatment and persist throughout treatment, and may lead to the development of gout, especially in patients with a history of gout. 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. In clinical trials, tendon rupture occurred in 0.5% of patients treated with NEXLETOL versus 0% of patients treated with placebo, and involved the rotator cuff (the shoulder), biceps tendon, or Achilles tendon. Tendon rupture occurred within weeks to months of starting NEXLETOL. Tendon rupture may occur more frequently in patients over 60 years of age, patients taking corticosteroid or fluoroquinolone drugs, patients with renal failure, and patients with previous tendon disorders. Discontinue NEXLETOL at the first sign of tendon rupture. Avoid NEXLETOL in patients who have a history of tendon disorders or tendon rupture.

Adverse Reactions: In clinical trials, the most commonly reported adverse reactions were upper respiratory tract infection, muscle spasms, hyperuricemia, back pain, abdominal pain or discomfort, bronchitis, pain in extremity, anemia, and elevated liver enzymes. Reactions reported less frequently, but still more often than with placebo, included benign prostatic hyperplasia and atrial fibrillation.

Drug Interactions: Simvastatin and Pravastatin: Concomitant use results in increased concentrations and increased risk of simvastatin or pravastatin-related myopathy. Use with greater than 20 mg of simvastatin or 40 mg of pravastatin should be avoided.

Lactation and Pregnancy: It is not recommended that NEXLETOL be taken during breastfeeding. Discontinue NEXLETOL when pregnancy is recognized, unless the benefits of

therapy outweigh the potential risks to the fetus. Based on the mechanism of action, NEXLETOL may cause fetal harm.

Please see full Prescribing Information for NEXLETOL.

NEXLETOL® (bempedoic acid) Tablets Appeals Letter

RE:

DOB:

Attn:

Dear _____,

I am writing this letter to appeal the denial of coverage for NEXLETOL on behalf of my patient _____. NEXLETOL is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or established atherosclerotic cardiovascular disease (ASCVD) who require additional lowering of low-density lipoprotein cholesterol (LDL-C). *Limitations of Use:* The effect of NEXLETOL on cardiovascular morbidity and mortality has not been determined.

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

NEXLETOL is medically necessary as documented by:

- **History of HeFH or established ASCVD:**

- **History of statin therapy:**

In summary, based on my clinical opinion, NEXLETOL is medically necessary for
. This is fully consistent with the FDA-approved indication.

Please call my office at _____ if I can provide you with any additional
information to approve my request.

Sincerely,