Prescriber: Patient: Patient Date of Birth:	(bempedoic acid) tablets	L° <b>(bempedoic acid and ezetimibe) tablets</b>
WHEN SUBMITTING PRIOR AUTHORIZATIONS, CONSIDER INCLUDING THE FOLLOWING INFORMATION IF APPROPRIATE:		
NEXLETOL (bempedoic acid)       NEX         Dose: 180 mg once daily       Dose	KLIZET (bempedoic acid a se: 180 mg bempedoic acid a	<b>cid and ezetimibe)</b> nd 10 mg ezetimibe once daily
Diagnosis of Clinical Atherosclerotic Cardiovascular Disease (ASCVD):		
I24.9: ACS     I20: Angina       I21: MI     G45.9: TIA	173.9: PAD 170.8: Atherosclerosis/ Revascularization	☐ I63: Stroke ☐ I25.10: CAD
Lipid Lowering Therapy: Current Statin & Dose: Past Statin(s) & Dose(s):	E: Y Y	zetimibe: ES NO SO
Recent LDL–C Level		
INDICATION NEXLETOL and NEXLIZET are indicated as adjuncts to diet and maximally tolerated stat heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular <i>Limitations of Use</i> : The effect of NEXLETOL and NEXLIZET on cardiovascular morbidity	in therapy for the treatment of adults with disease who require additional lowering of LDL-C. and mortality has not been determined.	

## IMPORTANT SAFETY INFORMATION

### Contraindications:

 NEXLETOL has no contraindications. NEXLIZET is contraindicated in patients with a known hypersensitivity to ezetimibe tablets. Hypersensitivity reactions including anaphylaxis, angioedema, rash, and urticaria have been reported with ezetimibe.

Please see additional Important Safety Information on reverse side

## To learn more, visit NEXLIZETHCP.com

# **IMPORTANT SAFETY INFORMATION**

#### Warnings and Precautions:

- Hyperuricemia: Bempedoic acid, a component of NEXLIZET, and NEXLIZET, 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: Bempedoic acid is associated with an increased risk of tendon rupture or injury. In clinical trials, tendon rupture occurred in 0.5% of patients treated with bempedoic acid 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 bempedoic acid. Tendon rupture may occur more frequently in patients ower 60 years of age, patients taking corticosteroid or fluoroquinolone drugs, patients with real failure, and patients with previous tendon disorders. Discontinue NEXLETOL or NEXLIZET at the first sign of tendon rupture. Avoid NEXLETOL and NEXLIZET in patients who have a history of tendon disorders or tendon rupture.

#### Adverse Reactions:

- In NEXLETOL 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.
- In the NEXLIZET clinical trial, the most commonly reported adverse reactions observed with NEXLIZET, but not observed in clinical trials of bempedoic acid or ezetimibe, a component of NEXLIZET, and occurring more frequently than with placebo, were urinary tract infection, nasopharyngitis, and constipation.
- Adverse reactions reported in clinical trials of ezetimibe, and occurring at an incidence greater than with placebo, included upper respiratory tract infection, diarrhea, arthralgia, sinusitis, pain in
  extremity, fatigue, and influenza. Other adverse reactions reported in postmarketing use of ezetimibe included hypersensitivity reactions, including anaphylaxis, angioedema, rash, and urticaria;
  erythema multiforme; myalgia; elevated creatine phosphokinase; myopathylrhabdomyolysis; elevations in liver transaminases; hepatitis; abdominal pain; thrombocytopenia; pancreatitis;
  nausea; dizziness; paresthesia; depression; headache; cholelytitis.

#### Drug Interactions:

- Simvastatin and Pravastatin: Concomitant use with bempedoic acid results in increased concentrations and increased risk of simvastatin or pravastatin-related myopathy. Use of either NEXLETOL or NEXLIZET with greater than 20 mg of simvastatin or 40 mg of pravastatin should be avoided.
- Cyclosporine: Caution should be exercised when using NEXLIZET and cyclosporine concomitantly due to increased exposure to both ezetimibe and cyclosporine. Monitor cyclosporine concentrations in patients receiving NEXLIZET and cyclosporine, the potential effects of the increased exposure to ezetimibe from concomitant use should be carefully weighed against the benefits of alterations in lipid levels provided by NEXLIZET.
- Fibrates: Coadministration of NEXLIZET with fibrates other than fenofibrate is not recommended. Fenofibrate and ezetimibe may increase cholesterol excretion into the bile, leading to
  cholelithiasis. If cholelithiasis is suspected in a patient receiving NEXLIZET and fenofibrate, gallbladder studies are indicated and alternative lipid-lowering therapy should be considered.
- Cholestyramine: Concomitant use of NEXLIZET and cholestyramine decreases ezetimibe concentration. This may result in a reduction of efficacy. Administer NEXLIZET either at least 2 hours before, or at least 4 hours after, bile acid sequestrants.

#### Lactation and Pregnancy:

It is not recommended that NEXLETOL or NEXLIZET be taken during breastfeeding. Discontinue NEXLETOL or NEXLIZET when pregnancy is recognized, unless the benefits of therapy outweigh
the potential risks to the fetus. Based on the mechanism of action of bempedoic acid, NEXLETOL and NEXLIZET may cause fetal harm.

References: 1. NEXLIZET. Prescribing information. Esperion Therapeutics, Inc.; 09/2021. 2. NEXLETOL. Prescribing information. Esperion Therapeutics, Inc.; 12/2022. 3. Pinkosky SL, Newton RS, Day EA, et al. Liver-specific ATP-citrate lyase inhibition by bempedoic acid decreases LDLC and attenuates atherosclerosis. Nat Commun. 2016;7(13457):1-13. 4. Pinkosky SL, Filippov S, Srivastava RA, et al. AMP-activated protein kinase and ATP-citrate lyase are two distinct molecular targets for ETC-1002, a novel small molecule regulator of lipid and carbohydrate metabolism. J Lipid Res. 2013;54(1):134-151. 5. Saeed A, Ballantyne CM. Bempedoic acid (ETC-1002): a current review. Cardiol Clin. 2018;36(2):257-264.

Please see accompanying full prescribing information

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