



Division: Pharmacy Policy	Subject: State of Florida's Agency for Health Care Administration's Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	September 10, 2020

**NEXLETOL™ (bempedoic acid) and NEXLIZET™ (bempedoic acid and ezetimibe)**

**LENGTH OF AUTHORIZATION:** Initial Therapy: 6 months  
Continuation of Therapy: 1 year

**REVIEW CRITERIA:**

- Patient is  $\geq 18$  years of age, **AND**
- Diagnosis of atherosclerotic cardiovascular disease (ASCVD) or heterozygous familial hypercholesterolemia (HeFH), **AND**
- Adherence to highest available dose or maximally tolerated dose of high intensity statin (i.e., atorvastatin or rosuvastatin) for at least three continuous months. If request is for Nexlizet, patient must also have concurrent trial with ezetimibe. If patient is using simvastatin, dose should not exceed 20 mg/day; if patient is using pravastatin, dose should not exceed 40 mg/day, **OR**
- Patient has demonstrated statin intolerance as defined by statin-related rhabdomyolysis or skeletal related muscle symptoms, **AND**
- Baseline lipid panel demonstrating failure to reach target LDL-C (70 mg/dL for patients with clinical ASCVD and 100 mg/dL for patients with HeFH and no history of clinical ASCVD), **AND**
- Patient (if eligible) will continue adjunct therapy with maximally tolerated high intensity statin. If patient is using simvastatin, dose should not exceed 20 mg/day; if patient is using pravastatin, dose should not exceed 40 mg/day

**CONTINUATION OF THERAPY:**

- Patient meets initial review criteria; **AND**
- Lipid panel showing a reduction in LDL-C compared to baseline labs; **AND**
- Patient is absent of unacceptable toxicity from therapy (i.e. hyperuricemia and tendon rupture); **AND**
- Continued adherence to maximally tolerated statin dose (if eligible)

**DOSING AND ADMINISTRATION:**

Nexletol recommended starting dose: one tablet orally once daily  
Available as tablets: 180mg

Nexlizet recommended starting dose: one tablet orally once daily  
Available as tablets: 180 mg/10 mg