

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

Pre - PA Allowance

None

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Heterozygous familial hypercholesterolemia (HeFH)
 - a. LDL-C level \geq 100 mg/dL in the past 6 months

AND ONE of the following:

- i. Confirmed diagnosis by LDL-R DNA Sequencing Test or APOB (hypercholesterolemia) Mutation Analysis
- ii. Dutch Lipid Clinic Network Criteria score $>$ 5
- iii. Simon-Broome Diagnostic Criteria for definite familial hypercholesterolemia

2. Atherosclerotic cardiovascular disease (ASCVD)
 - a. LDL-C level \geq 70 mg/dL in the past 6 months

AND ONE of the following:

- i. Documented history of **ONE** of the following ASCVD or cardiovascular events:
 - 1) Acute coronary syndrome (ACS)
 - 2) Myocardial infarction (MI)
 - 3) Stable or unstable angina
 - 4) Coronary or other arterial revascularization procedure (such as PTCA, CABG)
 - 5) Transient ischemic attack (TIA)
 - 6) Peripheral arterial disease (PAD) presumed to be of atherosclerotic origin
 - 7) Findings from CT angiogram or catheterization consistent with clinical ASCVD
- ii. At high risk for ASCVD or cardiovascular event based on 10- year risk score used by **ONE** of the following tools:



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- 1) ASCVD Pooled Cohort Risk Assessment: score \geq 7.5%
- 2) Predicting risk of cardiovascular disease EVENTS (PREVENT): score \geq 7.5%

AND ALL of the following for **ALL** diagnoses:

- 1. Patient will be assessed for response (i.e., LDL-C reduction) and adherence to the prescribed lipid lowering regimen
- 2. Patient has had an inadequate treatment response to statin therapy **OR** patient has an intolerance to higher dose/higher intensity statin therapy
- 3. Used in combination with maximally tolerated statin therapy
- 4. Prescriber agrees to monitor uric acid levels for hyperuricemia
- 5. **NO** dual therapy with another Prior Authorization (PA) lipid lowering agent (see Appendix 1)

Prior - Approval Limits

Quantity

Drug	Quantity
Nexletol	90 tablets per 90 days OR
Nexlizet	90 tablets per 90 days

Duration 12 months

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

- 1. Heterozygous familial hypercholesterolemia (HeFH)
- 2. Atherosclerotic cardiovascular disease (ASCVD)

AND ONE of the following:

- a. Percentage reduction of LDL-C level \geq 20%, compared to the level immediately prior to starting therapy with Nexletol/Nexlizet
- b. Absolute LDL-C < 100mg/dL

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AND ALL of the following:

- a. Patient will be assessed for adherence to the prescribed lipid lowering regimen
- b. Prescriber agrees to monitor uric acid levels for hyperuricemia
- c. **NO** dual therapy with another Prior Authorization (PA) lipid lowering agent (see Appendix 1)

Prior - Approval *Renewal* Limits

Same as above

Appendix 1 - List of PA Lipid Lowering Agents

Generic Name	Brand Name
alirocumab	Praluent
bempedoic acid	Nexletol
bempedoic acid/ezetimibe	Nexlizet
evolocumab	Repatha
inclisiran	Leqvio
lomitapide	Juxtapid

*Dual therapy with Evkeeza (evinacumab-dgnb) is allowed