

New Hampshire Medicaid Fee-for-Service Program

Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitor Criteria

Approval Date: July 12, 2022

Indications

Bempedoic acid (Nexletol®) is an adenosine triphosphate-citrate lyase (ACL) inhibitor and bempedoic acid/ezetimibe (Nexlizet™) contains an ACL inhibitor and a cholesterol absorption inhibitor. Both agents are 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).

Medications

Brand Names	Generic Names	Dosage
Nexletol®	bempedoic acid	180 mg
Nexlizet™	bempedoic acid/ezetimibe	180 mg/10 mg

Criteria for Approval

1. Patient is ≥ 18 years old; **AND**
2. Patient has diagnosis of HeFH or established ASCVD; **AND**
3. Patient has failed to achieve a target LDL-C despite physician attestation that the patient is adherent to maximally-tolerated doses of statins prior to the lipid panel demonstrating suboptimal reduction; **AND**
4. Patient can be classified into **one** of the following risk factor groups:
 - a. Extremely high risk ASCVD with an LDL-C ≥ 70 mg/dL:
 - i. Defined as extensive or active burden of ASCVD, or ASCVD with extremely high burden of adverse or poorly controlled cardio-metabolic risk factors including HeFH or severe hypercholesterolemia [SH] with untreated LDL-C > 220 mg/dL); **OR**
 - b. Very high risk ASCVD with an LDL-C ≥ 100 mg/dL:
 - i. Defined as less extensive ASCVD and poorly controlled cardiometabolic risk factors: **OR**

- c. High risk ASCVD with LDL-C \geq 130 mg/dL:
 - i. Defined as either less extensive ASCVD and well-controlled risk factors or primary prevention HeFH or SH > 220 mg/dL with poorly controlled risk factors; **AND**
5. Therapy will be used in conjunction with maximally-tolerated doses of a statin; **AND**
6. Therapy will not be used with concurrent doses of simvastatin > 20 mg or pravastatin > 40 mg; **AND**
7. **For patients prescribed bempedoic acid/ezetimibe (Nexlizet™):** patient does not have a hypersensitivity to ezetimibe (Zetia®); **AND**
8. **For patients prescribed bempedoic acid/ezetimibe (Nexlizet™):** therapy will also not be used with concurrent fibrate therapy (excluding fenofibrate)

Length of Authorization

Initial six months, extended approval for 12 months if additional criteria are met.

Quantity Limit

30 tablets/30 days

Criteria for 12-Month Renewal

1. Patient continues to meet the initial approval criteria listed above; **AND**
2. Patient is absent of unacceptable toxicity from therapy (examples of unacceptable toxicity include the following: hyperuricemia, tendon rupture); **AND**
3. Laboratory analysis demonstrate a reduction in LDL-C when compared to the baseline values (prior to initiating bempedoic acid or bempedoic acid/ezetimibe); **AND**
4. Patient has shown continued adherence to maximally-tolerated statin dosage.

Criteria for Denial

1. Above criteria are not met; **OR**
2. Patient is an active smoker; **OR**
3. Failure to be compliant with current regimen as evidenced by review of claims history; **OR**
4. Patient has unacceptable toxicity from therapy.

References

Available upon request.

Revision History

Reviewed by	Reason for Review	Date Approved
DUR Board	New	12/15/2020
Commissioner Designee	Approval	02/24/2021
DUR Board	Revision	06/02/2022
Commissioner Designee	Approval	07/12/2022