

# New Hampshire Medicaid Fee-for-Service Program Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitor Criteria

Approval Date: June 5, 2025

## 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 or when statins are not able to be tolerated 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
<b>Nexletol</b>	bempedoic acid	180 mg
<b>Nexlizet</b>	bempedoic acid/ezetimibe	180 mg/10 mg

## Criteria for Approval

1. Patient is  $\geq 18$  years of age; **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 **or** the physician attests that the patient is unable to tolerate any statin; **AND**
4. Patient can be classified into **one** of the following risk factor groups:
  - a. Extremely high risk ASCVD with an LDL-C  $\geq 70$  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  $\geq 100$  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 if patient is able to tolerate.

## Criteria for Denial

Above criteria are not met.

## 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
DUR Board	Revision	12/08/2023
Commissioner Designee	Approval	01/22/2024
DUR Board	Revision	04/08/2025
Commissioner Designee	Approval	06/05/2025