## New Hampshire Medicaid Fee-for-Service Program

# Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitor Criteria

**Approval Date: January 22, 2024**

## 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 ≥ 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

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 |