

Nexletol (bempedoic acid)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Nexletol (bempedoic acid)	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Nexletol (bempedoic acid) may be approved when the following criteria are met:

- I. Individual is at high risk for atherosclerotic cardiovascular disease (ASCVD) events as identified by one of the following:
 - A. Individual has Heterozygous Familial Hypercholesterolemia (HeFH) confirmed by (Singh 2015; WHO 1999):
 1. Presence of a mutation in LDLR, ApoB, PCSK9 or ARH adaptor protein (LDLRAP1) gene; **OR**
 2. WHO/Dutch Lipid Clinic Network criteria with score of greater than eight points;

OR

- B. Individual has a history of clinical atherosclerotic cardiovascular disease (ASCVD), including **one or more** of the following (AHA/ACC 2018):
 1. Acute coronary syndrome;
 2. Coronary artery disease (CAD);
 3. History of myocardial infarction (MI);
 4. Stable or unstable angina;
 5. Coronary or other arterial revascularization;
 6. Stroke;
 7. Transient ischemic attack (TIA);
 8. Peripheral arterial disease (PAD);

AND

- II. Individual meets one of the following:
 - A. Individual is using in combination with statin therapy at the maximum tolerated dose; **OR**
 - B. Individual is statin intolerant based on one of the following:
 1. Inability to tolerate at least two statins, with at least one started at the lowest starting daily dose, demonstrated by adverse effects associated with statin therapy that resolve or improve with dose reduction or discontinuation (NLA 2022); **OR**

2. Statin associated rhabdomyolysis or immune-mediated necrotizing myopathy (IMNM) after a trial of one statin;

OR

- C. Individual has a contraindication for statin therapy including but not limited to active liver disease, unexplained persistent elevation of hepatic transaminases or pregnancy;

AND

- III. Individual meets one of the following:
 - A. Individual is on concomitant ezetimibe therapy (AHA/ACC 2018); **OR**
 - B. Individual has had a trial of and was unable to tolerate ezetimibe therapy;

AND

- IV. Individual has achieved suboptimal lipid lowering response to lipid lowering therapy and lifestyle modifications as defined (AHA/ACC 2018):
 - A. For individuals where initial LDL-C is known:
 1. Less than 50% reduction in LDL-C;
 - OR**
 - B. For individuals where initial LDL-C is unknown:
 1. ASCVD and LDL-C remains greater than or equal to 70 mg/dL; **OR**
 2. No history of ASCVD and LDL-C remains greater than or equal to 100 mg/dL.

Continuation requests for Nexletol (bempedoic acid) may be approved when the following criteria are met:

- I. Individual continues to use in combination with maximally tolerated statin therapy (unless contraindicated or not tolerated); **AND**
- II. Individual continues to use in combination with ezetimibe therapy (unless contraindicated or not tolerated); **AND**
- III. Confirmation of LDL reduction has been provided.

Key References:

1. Cheeley MK, Saseen JJ, Agarwala A, et. al. NLA scientific statement on statin intolerance: a new definition and key considerations for ASCVD risk reduction in the statin intolerant patient. *J Clin Lipidol*. 2022. <https://doi.org/10.1016/j.jacl.2022.05.068>.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: July 14, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ ADA/AGS/APHa/ASPC/NLA/ PCNA guideline on the management of blood cholesterol: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol* 2019;73:e285–350.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
6. Rosenson RS, Durrington P. Familial hypercholesterolemia in adults: Overview. Last updated: September 21, 2020. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: July 15, 2022.
7. Singh S, Bittner V. Familial hypercholesterolemia—epidemiology, diagnosis, and screening. *Curr Atheroscler Rep*. 2015; 17(2):482.
8. World Health Organization. Familial hypercholesterolemia—report of a second WHO Consultation. Geneva, Switzerland: World Health Organization, 1999. Available at: http://whqlibdoc.who.int/hq/1999/WHO_HGN_FH_CONS_99.2.pdf?ua=1. Accessed: July 17, 2022.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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