Washington State Health Care Authority

Antihyperlipidemics – Adenosine Triphosphate-Citrate Lyase Inhibitors

Medical policy no. 39.38.00-1 Effective Date: Month, 1, Year

Note: *New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class documentation of inadequate response to ONE preferred agent is needed. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.*

To see the list of the current Apple Health Preferred Drug List (AHPDL), please visit: https://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx

Medical necessity

Drug	Medical Necessity
Bempedoic acid (Nexletol) Bempedoic acid/Ezetimibe (Nexlizet)	**Antihyperlipidemics- Adenosine Triphosphate-Citrate Lyase Inhibitors** may be considered medically necessary in patients who meet the criteria described in the clinical policy below. • Non-Preferred brand name products on the Apple Health Drug List with an A-rated generic, biosimilar or interchangeable biosimilar must also meet criteria in Non-Clinical Policy No 0001 (NC-001). If all criteria are not met, the clinical reviewer may determine there is a medically necessary need and approve on a case-by-case basis. The clinical reviewer may choose to use the reauthorization criteria when a patient has been previously established on therapy and is new to Apple Health.

Clinical policy:

Clinical Criteria	
To reduce the risk of myocardial infarction (MI) and coronary revascularization in patients who are unable to take statin therapy (including those not taking a statin) with: • **established cardiovascular disease (CVD), or** • **a high risk for a CVD event but without established CVD**	Bempedoic acid (Nexletol) and bempedoic acid/ezetimibe (Nexlizet) may be approved when all the following documented criteria are met: 1. Patient is 18 years of age or older; **AND** 2. Patient meets one of the following (a or b): a. Patient has established CVD defined as any of the following: i. Coronary artery disease; **OR** ii. Symptomatic peripheral artery disease; **OR** iii. Cerebrovascular atherosclerotic disease; **OR** b. Patient is at high risk for CVD with one or more of the following:

Bempedoic acid (Nexletol) Bempedoic acid/Ezetimibe (Nexlizet)	i. Reynolds Risk score > 30%; or SCORE Risk score > 7.5% over 10 years; **OR** ii. Coronary artery calcium score > 400 Agatston units (AU) at any time in the past; **OR** iii. Patients with Type 1 or Type 2 diabetes, aged > 65 years (women) or > 60 years (men); **AND** 3. Patient meets one of the following (a or b) unless contraindicated: a. Patient has tried one high-intensity statin (i.e., atorvastatin ≥40 mg daily, rosuvastatin ≥ 20 mg daily) [minimum trial of 12 weeks]; **AND** i. Low-density lipoprotein cholesterol (LDL-C) remains ≥ 70 mg/dL; **OR** b. Patient is statin intolerant defined as either of the following: i. Experienced statin-related rhabdomyolysis along with end organ damage or myoglobinuria to at least two different statins; **OR** ii. Experienced skeletal muscle symptoms which occurred while receiving separate trials of both atorvastatin and rosuvastatin and symptoms resolved upon discontinuation of each medication If ALL criteria are met, the request will be authorized for **12 months.**
	Criteria (Reauthorization) Bempedoic acid (Nexletol) and bempedoic acid/ezetimibe (Nexlizet) may be approved when all the following documented criteria are met: 1. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., decrease in LDL-C or achievement of patient LDL-C goal). If ALL criteria are met, the request will be authorized for **12 months.**
To reduce LDL-C in adults with primary hyperlipidemia including heterozygous familial hypercholesterolemia (HeFH) Bempedoic acid (Nexletol) Bempedoic acid/Ezetimibe (Nexlizet)	Bempedoic acid (Nexletol) and bempedoic acid/ezetimibe (Nexlizet) may be approved when all the following documented criteria are met: 1. Patient is 18 years of age or older, **AND** 2. Patient has a diagnosis of either of the following (a or b): a. Diagnosis of primary hyperlipidemia; **OR** b. Diagnosis of HeFH; **AND** 3. Patient is currently taking a maximally tolerated statin unless contraindicated or not tolerated; **AND** 4. LDL-C remains ≥ 70 mg/dL If ALL criteria are met, the request will be authorized for **12 months.**

	Criteria (Reauthorization)
	Bempedoic acid (Nexletol) and bempedoic acid/ezetimibe (Nexlizet) may be approved when all the following documented criteria are met: 1. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., decrease in LDL-C or achievement of patient LDL-C goal). If ALL criteria are met, the request will be authorized for **12 months.**

Dosage and quantity limits

Drug	Indication	Approved Dose	Dosage Form and Quantity Limit
Nexletol	To reduce the risk of myocardial infarction (MI) and coronary revascularization in patients who are unable to take statin therapy (including those not taking a statin) with: • established cardiovascular disease (CVD), or • a high risk for a CVD event but without established CVD	180 mg once daily	• 180 mg tablets: 1 tablet per day
Nexletol	To reduce LDL-C in adults with primary hyperlipidemia including heterozygous familial hypercholesterolemia (HeFH)	180 mg once daily	• 180 mg tablets: 1 tablet per day
Nexlizet	To reduce the risk of myocardial infarction (MI) and coronary revascularization in patients who are unable to take statin therapy (including those not taking a statin) with: • established cardiovascular disease (CVD), or	180 mg bempedoic acid/10 mg ezetimibe once daily	• 180 mg bempedoic acid/10 mg ezetimibe tablets: 1 tablet per day

	a high risk for a CVD event but without established CVD		
Nexlizet	To reduce LDL-C in adults with primary hyperlipidemia including heterozygous familial hypercholesterolemia (HeFH)	180 mg bempedoic acid/10 mg ezetimibe once daily	• 180 mg bempedoic acid/10 mg ezetimibe tablets: 1 tablet per day

Coding:

HCPCS Code	Description
<HCPCS Code>	Formulation, generic name, max fill

Background:

CVD is a leading cause of morbidity and mortality worldwide. Atherosclerotic cardiovascular disease (ASCVD) is defined as individuals who have experienced acute coronary syndrome, history of MI, stable or unstable angina or coronary or other revascularizations, stoke, transient ischemic attack or peripheral artery disease. Lowering LDL-C has been strongly correlated to reduce the risk of CV disease in patients with ASCVD.

Familial hypercholesterolemia is an autosomal dominant genetic disease that is characterized by elevated LDL-C and premature ASCVD. It is estimated that 620,000 people in the U.S. have familial hypercholesterolemia which includes HeFH and homozygous familial hypercholesterolemia (HoFH) with HeFH being the most common. LDL-C ≥ 190 md/dL in adults suggests a diagnosis of HeFH. Since publication of the 2018 AHA/ACC/multisociety cholesterol Guideline on the Management of Blood Cholesterol, three additional non-statin therapies have received FDA approval for management of hypercholesterolemia (bempedoic acid, evinacumab, inclisiran). The 2022 ACC Consensus Decision Pathway was designed to address current gaps in care for LDL-C lowering to reduce ASCVD risk and provides further recommendations regarding the use of newer non-statin therapies. The key updates that the 2022 ACC Consensus Pathway recommend are for adults with ASCVD at very high risk on a maximally tolerated statin therapy that requires additional lowering of LDL-C (patient has achieved <50% reduction in LDL-C or LDL- greater than or equal to 55 mg/dL or non–HDL-C greater than or equal to 85 mg/ dL) despite maximally tolerated statin therapy, a PCSK9 inhibitor and/or ezetimibe are preferred as the initial non-statin therapy followed by bempedoic acid or inclisiran for further LDL-C lowering. For adults with ASCVD NOT at very high risk on a maximally tolerated statin therapy that require additional lowering of LDL-C C (patient has achieved<50% reduction in LDL-C or LDL-C greater than or equal to 70 mg/dL or non–HDL-C greater than or equal to 100 mg/dL) despite maximally tolerated statin therapy, when considering the addition of a non-statin therapy, ezetimibe is the preferred initial non-statin followed by adding or replacing with a PCSK9 inhibitor, then trying bempedoic acid or inclisiran.

The CLEAR Outcomes trial was a double-blind trial conducted in 32 countries and included 13,970 patients who were unable or unwilling to take guideline-recommended doses of statins that were randomized to oral bempedoic acid 180 mg daily or placebo and followed for a median of 3.4 years that was completed November 7th, 2022. The primary end point was a four-component composite of major adverse cardiovascular events, defined as cardiovascular death, nonfatal myocardial infarction, nonfatal stroke, or coronary revascularization. The trial demonstrated that bempedoic acid significantly reduced the risk of major adverse cardiovascular events (MACE) in patients who were intolerant to statins. Specifically, the primary outcome—a composite of cardiovascular death, nonfatal myocardial infarction, nonfatal stroke, or coronary revascularization—occurred in 11.7% of patients receiving bempedoic acid, compared to 13.3% in the placebo group, reflecting a hazard ratio of 0.87 (95% CI, 0.79 to 0.96;P=0.004).

References

1. Nissen SE, Lincoff AM, Brennan DM, et al. Bempedoic acid and cardiovascular outcomes in StatinIntolerant patients. The New England Journal of Medicine. 2023;388(15):1353-1364. doi:10.1056/nejmoa2215024
2. Nexletol (bempedoic acid) [prescribing information]. Ann Arbor, MI: Esperion Therapeutics, Inc.; July 2025.
3. Nexlizet (bempedoic acid and ezetimibe) [prescribing information]. Ann Arbor, MI: Esperion Therapeutics, Inc.; July 2025.
4. Lloyd-Jones DM, Morris PB, Ballantyne CM, et al. 2022 ACC Expert Consensus Decision Pathway on the role of nonstatin therapies for LDL-Cholesterol Lowering in the management of atherosclerotic cardiovascular Disease risk. Journal of the American College of Cardiology. 2022;80(14):1366- 1418. doi:10.1016/j.jacc.2022.07.006
5. 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. Circulation. 2019;139(25). doi:10.1161/cir.0000000000000625

History

Approved Date	Effective Date	Version	Action and Summary of Changes
MM/DD/YYY	MM/DD/YYYY	39.38.00-1	Pending Approval (draft/unpublished version) -New policy created

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Please provide the information below, please print your answer, attach supporting documentation, sign, date, and return to our office as soon as possible. **Without this information, we may deny the request in seven (7) working days.**
Apple Health Preferred Drug list: https://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx
For policy criteria, see: https://www.hca.wa.gov/billers-providers-partners/program-information-providers/apple-health-medicaid-drug-coverage-criteria

Date of request:	Reference #:	MAS:	
Patient	Date of birth	ProviderOne ID	
Pharmacy name	Pharmacy NPI	Telephone number	Fax number
Prescriber	Prescriber NPI	Telephone number	Fax number
Medication and strength	Directions for use	Qty/Days supply	

1. Is this request for a continuation of therapy? ☐ Yes ☐ No
   If yes, does patient have clinical documentation demonstrating disease stability or a positive clinical response (e.g., decrease in LDL-C or achievement of patient LDL-C goal)? ☐ Yes ☐ No

2. Indicate patient's diagnosis:
   - ☐ Established cardiovascular disease (CVD). Indicate the following for patient. Check all that apply:
     - ☐ Coronary artery disease
     - ☐ Symptomatic peripheral artery disease
     - ☐ Cerebrovascular atherosclerotic disease
   - ☐ High risk for CVD. Indicate the following for patient. Check all that apply:
     - ☐ Reynolds Risk score > 30%; or SCORE Risk score > 7.5% over 10 years
     - ☐ Coronary artery calcium score > 400 Agatston units (AU) at any time in the past
     - ☐ Patients with Type 1 or Type 2 diabetes, aged > 65 years (women) or > 60 years (men)
   - ☐ Primary hyperlipidemia
   - ☐ Heterozygous familial hypercholesterolemia (HeFH)
   - ☐ Other. Specify: _____

3. Indicate the following for patient. Check all that apply:
   - ☐ Has had trial of one high-intensity statin (i.e., atorvastatin ≥40 mg daily, rosuvastatin ≥ 20 mg daily) for a minimum trial of 12 weeks.
   - ☐ Statin intolerant. Indicate the following for patient. Check all that apply:
     - ☐ Experienced statin-related rhabdomyolysis along with end organ damage or myoglobinuria to at least two different statins.
     - ☐ Experienced skeletal muscle symptoms which occurred while receiving separate trials of both atorvastatin and rosuvastatin and symptoms resolved upon discontinuation of each medication.
     - ☐ Other. Specify: _____
   - ☐ Currently taking a maximally tolerated statin dose
   - ☐ Maximally tolerated statin dose is contraindicated. Explain: _____

4. What is patient's low-density lipoprotein cholesterol (LDL-C)? _____mg/dL Date taken:_____

CHART NOTES ARE REQUIRED WITH THIS REQUEST

Prescriber signature	Prescriber specialty	Date