



Initial Prior Authorization

Nexletol, Nexlizet

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Nexletol	bempedoic acid
Nexlizet	bempedoic acid/ezetimibe

Indications

FDA-approved Indications

Nexletol

Nexletol is indicated:

- To reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended 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.
- As an adjunct to diet, in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH).

Nexlizet

Nexlizet, a combination of bempedoic acid and ezetimibe, is indicated:

Reference number(s)
3647-A

- As an adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH).

The bempedoic acid component of Nexlizet is indicated:

- To reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended 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.

Coverage Criteria

Primary Hyperlipidemia, including Heterozygous Familial Hypercholesterolemia (HeFH)

Authorization may be granted when the requested drug is being prescribed to reduce low-density lipoprotein cholesterol (LDL-C) in an adult with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH) when ALL of the following criteria are met:

- The requested drug is being prescribed as an adjunct to diet.
- The patient meets ONE of the following:
 - The requested drug will be used in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies.
 - Concomitant use of the requested drug with other low-density lipoprotein cholesterol (LDL-C) lowering therapies is NOT possible.

Risk Reduction of Myocardial Infarction and Coronary Revascularization

Authorization may be granted when the requested drug is being prescribed to reduce the risk of myocardial infarction and coronary revascularization in an adult when ALL of the following criteria are met:

- The patient has ANY of the following: established cardiovascular disease (CVD), a high risk for a cardiovascular disease (CVD) event but without established CVD.
- The patient meets ONE of the following:
 - The patient experienced an intolerance to the recommended statin therapy.
 - The patient has a contraindication that would prohibit use of statin therapy.

Continuation of Therapy

Primary Hyperlipidemia, including Heterozygous Familial Hypercholesterolemia (HeFH)

Authorization may be granted when the requested drug is being prescribed to reduce low-density lipoprotein cholesterol (LDL-C) in an adult with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH) when ALL of the following criteria are met:

- The requested drug is being prescribed as an adjunct to diet.
- The patient has achieved or maintained a reduction in low-density lipoprotein cholesterol (LDL-C) from baseline.

Risk Reduction of Myocardial Infarction and Coronary Revascularization

All patients (including new patients) requesting authorization for continuation of therapy must meet ALL requirements in the coverage criteria section.

Duration of Approval (DOA)

- 3647-A: DOA: 36 months

References

1. Nexletol [package insert]. Ann Arbor, MI: Esperion Therapeutics, Inc; March 2024.
2. Nexlizet [package insert]. Ann Arbor, MI: Esperion Therapeutics, Inc; March 2024.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed October 24, 2024.
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5. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 10/24/2024).
6. 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 Jun 18;139(25):e1082-1143.
7. Hadelsman Y, Jellinger PS, Guerin CK, et. al. Consensus Statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the Management of Dyslipidemia

and Prevention of Cardiovascular Disease Algorithm -2020 Executive Summary. Endocr Pract. 2020;26(10):1196-1224.

8. 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: A Report of the American College of Cardiology Solution Set Oversight Committee. *J Am Coll Cardiol*. 2022;80:1366-1418.

Document History

Written by: UM Development (DFW)

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External Review: 04/2020, 02/2021, 02/2022, 02/2023, 02/2024, 06/2024 (FYI), 02/2025

CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed to reduce low-density lipoprotein cholesterol (LDL-C) in an adult with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH)? [If Yes, then go to 2. If No, then go to 7.]	Yes	No
2	Is the requested drug being prescribed as an adjunct to diet? [If Yes, then go to 3. If No, then no further questions.]	Yes	No
3	Is this request for continuation of therapy? [If Yes, then go to 4. If No, then go to 5.]	Yes	No
4	Has the patient achieved or maintained a reduction in low-density lipoprotein cholesterol (LDL-C) from baseline? [No further questions]	Yes	No
5	Will the requested drug be used in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies? [If Yes, then no further questions. If No, then go to 6.]	Yes	No

6	Is concomitant use of the requested drug with other low-density lipoprotein cholesterol (LDL-C) lowering therapies not possible? [No further questions]	Yes	No
7	Is the requested drug being used to reduce the risk of myocardial infarction and coronary revascularization in an adult? [If Yes, then go to 8. If No, then no further questions.]	Yes	No
8	Does the patient have ANY of the following: A) established cardiovascular disease (CVD), B) a high risk for a cardiovascular disease (CVD) event but without established CVD? [If Yes, then go to 9. If No, then no further questions.]	Yes	No
9	Has the patient experienced an intolerance to the recommended statin therapy? [If Yes, then no further questions. If No, then go to 10.]	Yes	No
10	Does the patient have a contraindication that would prohibit use of statin therapy? [No further questions]	Yes	No

Mapping Instructions			
	Yes	No	DENIAL REASONS
1.	Go to 2	Go to 7	
2.	Go to 3	Deny	<p>Your plan only covers this drug if you will be taking this drug as a part of a certain treatment plan. We have denied your request because you are not (or will not be) taking this drug in addition to being on a diet. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Not used as a component of an approved regimen]</p>

3.	Go to 4	Go to 5	
4.	Approve, 36 Months	Deny	<p>Your plan only covers this drug when you experience benefits from taking the drug. We have denied your request because you did not have good outcomes from the drug. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Efficacy, Positive Response, Stable or Not Worsening]</p>
5.	Approve, 36 Months	Go to 6	
6.	Approve, 36 Months	Deny	<p>Your plan only covers this drug if you will be taking it with other low-density lipoprotein cholesterol (LDL-C) lowering therapies or use with other low-density lipoprotein cholesterol (LDL-C) lowering therapies is not possible. We have denied your request because you are not (or will not be) taking it. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Not on required concurrent therapy]</p>
7.	Go to 8	Deny	<p>Your plan only covers this drug when it is used for certain health conditions. Covered uses are to reduce cholesterol in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH) and to reduce the risk of heart attack and coronary revascularization in adults. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p>

			[Short Description: Diagnosis]
8.	Go to 9	Deny	<p>Your plan only covers this drug if you have established heart disease, or are at high risk for a heart disease event but do not have established heart disease. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Disease category/stage/severity]</p>
9.	Approve, 36 Months	Go to 10	
10.	Approve, 36 Months	Deny	<p>Your plan only covers this drug if you have tried the recommended statin therapy, and you are not able to take it. We have denied your request because: A) You have not tried it, or B) You do not have a medical reason not to take it. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Step therapy]</p>