RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	bempedoic acid
Policy Number:	RxA.651
Drug(s) Applied:	NEXLETOL™/NEXLIZET™
Original Policy Date:	09/14/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

NEXLETOL/NEXLIZET is an adenosine triphosphate-citrate lyase (ACL) inhibitor indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
bempedoic acid (NEXLETOL™)	Indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C.	180 mg once daily	bempedoic acid: 180 mg once daily
bempedoic acid and ezetimibe (NEXLIZET™)	Indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C.	180 mg once daily and 10 mg/day PO ezetimibe	bempedoic acid: 180 mg once daily

Dosage Forms

- Tablets: 180 mg bempedoic acid; 180 mg of bempedoic acid/10 mg of ezetimibe.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Heterozygous familial hypercholesterolemia (must meet all):

1. Diagnosis of heterozygous familial hypercholesterolemia;
2. Age ≥ 18 years;
3. Member meets one of the following (a, b, or c);
    a. Is on concomitant statin therapy at the maximum tolerated dose; or Individual is statin intolerant based on one of the following:
    b. Inability to tolerate at least two statins, with at least one started at the lowest starting daily dose, demonstrated by intolerable symptoms or clinically significant biomarker changes; or statin associated rhabdomyolysis after a trial of one statin;
    c. Has a contraindication for statin therapy including active liver disease, unexplained persistent elevation of hepatic transaminases or pregnancy.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

B. Established ASCVD who require additional lowering of LDL-C (must meet all):

1. Individual has a history of clinical atherosclerotic cardiovascular disease (ASCVD), including one or more of the following:
    a. Acute coronary syndrome;
    b. Coronary artery disease (CAD);
    c. History of myocardial infarction (MI);
    d. Stable or unstable angina;
    e. Coronary or other arterial revascularization;
    f. Stroke;
    g. Transient ischemic attack (TIA);
    h. Peripheral arterial disease (PAD)
2. Member meets one of the following (a, b, or c);
    a. Is on concomitant statin therapy at the maximum tolerated dose; or Individual is statin intolerant based on one of the following:
    b. Inability to tolerate at least two statins, with at least one started at the lowest starting daily dose, demonstrated by intolerable symptoms or clinically significant biomarker changes; or statin associated rhabdomyolysis after a trial of one statin;
    c. Has a contraindication for statin therapy including active liver disease, unexplained persistent elevation of hepatic transaminases or pregnancy.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all):

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;

2. Member is responding positively to therapy;
3. Member continues to receive concomitant maximally tolerated statin therapy
4. Confirmation of LDL reduction has been provided.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
ACL: adenosine triphosphate-citrate lyase
ASCVD: atherosclerotic cardiovascular disease
HeFH: Heterozygous familial hypercholesterolemia

APPENDIX B: Therapeutic Alternatives
Not applicable.

APPENDIX C: Contraindications/Boxed Warnings
- Contraindication(s):
  - None.
- Boxed Warning(s):
  - None.

APPENDIX D: General Information
Not applicable.

References
1. Nexletol (bempedoic acid) [prescribing information]. Ann Arbor, MI: Esperion Therapeutics, Inc. February 2020. Accessed on August 25, 2020.
2. Nexlizet (bempedoic acid and ezetimibe) [prescribing information]. Ann Arbor, MI: Esperion Therapeutics, Inc. February 2020. Accessed on August 25, 2020.
3. Grundy SM, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol. Journal of the American College of Cardiology. 2019; 73(24):e285-e350. doi: doi.org/10.1016/j.jacc.2018.11.003.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	08/27/2020	09/14/2020