

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Bempedoic Acid and Ezetimibe (Nexlizet)

Notes:

- Quantity Limits: Yes
- * Per Kaiser National Clinical Practice Guideline, ASCVD refers to any of the following conditions:
 - i. Coronary heart disease (CHD, CAD) such as acute coronary syndrome, myocardial infarction, angina, and coronary revascularization
 - ii. Cerebrovascular disease, such as transient ischemic attack, ischemic stroke, and carotid revascularization
 - iii. Symptomatic peripheral artery disease, such as claudication or peripheral artery revascularization
- § High risk of cardiovascular event includes any of the following:
 - i. Reynolds Risk score > 30% or a SCORE risk score > 7.5% over 10 years
 - ii. Coronary artery calcium score > 400 Agatston units (AU)
 - iii. Type 1 or Type 2 diabetes, aged > 65 years (women) or > 60 years (men)
- # Hydrophilic statin includes pravastatin or rosuvastatin. Low intensity statin includes simvastatin 10 mg, lovastatin 20 mg, or pravastatin 10-20 mg

Initiation (new start) criteria: Non-formulary **Bempedoic Acid and Ezetimibe (Nexlizet)** will be covered on the prescription drug benefit when the following criteria are met:

Reduction of Risk of Cardiovascular Disease

- Age 18 years or older – AND-
- History of atherosclerotic cardiovascular disease* (ASCVD) or high risk of cardiovascular event[§] – AND-
- Documentation of one of the following regarding statins:
 - History of statin intolerance defined as mild adverse effect to a trial of 3 or more statins or a trial of 2 statins comprised of 1 hydrophilic statin and 1 low intensity statin[#]
 - History of severe adverse effect to statin such as statin-induced rhabdomyolysis or statin-induced necrotizing myositis
 - Receiving maximally tolerated dose of statin therapy
- AND -
- Receiving ezetimibe therapy – AND-
- LDL greater than or equal to 100 mg/dL

Heterozygous Familial Hypercholesterolemia

- Age 18 years or older – AND-
- History of heterozygous familial hypercholesterolemia – AND-
- Receiving maximally tolerated statin therapy – AND-
- Receiving ezetimibe or has contraindication or intolerance to ezetimibe – AND-

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Revised: 06/08/23
Effective: 08/17/23

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- LDL greater than or equal to 70 mg/dL

Criteria for current Kaiser Permanente members already taking the medication who have not been reviewed previously: Non-formulary **Bempedoic Acid and Ezetimibe (Nexlizet)** will be covered on the prescription drug benefit when the following criteria are met:

Reduction of Risk of Cardiovascular Disease

- Age 18 years or older – AND-
- History of atherosclerotic cardiovascular disease* (ASCVD) or high risk of cardiovascular event^{\$} – AND-
- Documentation of one of the following regarding statins:
 - History of statin intolerance defined as mild adverse effect to a trial of 3 or more statins or a trial of 2 statins comprised of 1 hydrophilic statin and 1 low intensity statin[#]
 - History of severe adverse effect to statin such as statin-induced rhabdomyolysis or statin-induced necrotizing myositis
 - Receiving maximally tolerated dose of statin therapy
- AND -
- Receiving ezetimibe therapy – AND-
- LDL greater than or equal to 100 mg/dL

Heterozygous Familial Hypercholesterolemia

- Age 18 years or older – AND-
- History of heterozygous familial hypercholesterolemia – AND-
- Receiving maximally tolerated statin therapy – AND-
- Receiving ezetimibe therapy – AND-
- LDL greater than or equal to 70 mg/dL

Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: Non-formulary **Bempedoic Acid and Ezetimibe (Nexlizet)** will be covered on the prescription drug benefit when the following criteria are met:

Reduction of Risk of Cardiovascular Disease

- Age 18 years or older – AND-

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- History of atherosclerotic cardiovascular disease* (ASCVD) or high risk of cardiovascular event^{\$} – AND-
- Documentation of one of the following regarding statins:
 - History of statin intolerance defined as mild adverse effect to a trial of 3 or more statins or a trial of 2 statins comprised of 1 hydrophilic statin and 1 low intensity statin[#]
 - History of severe adverse effect to statin such as statin-induced rhabdomyolysis or statin-induced necrotizing myositis
 - Receiving maximally tolerated dose of statin therapy- AND -
- Receiving ezetimibe therapy – AND-
- LDL greater than or equal to 100 mg/dL

Heterozygous Familial Hypercholesterolemia

- Age 18 years or older – AND-
- History of heterozygous familial hypercholesterolemia – AND-
- Receiving maximally tolerated statin therapy – AND-
- Receiving ezetimibe therapy – AND-
- LDL greater than or equal to 70 mg/dL