

# Criteria-Based Consultation Prescribing Program

## CRITERIA FOR DRUG COVERAGE

### Bempedoic Acid (Nexletol)

#### 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 (Nexletol)** 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 or has contraindication or intolerance to ezetimibe – 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-
- LDL greater than or equal to 70 mg/dL

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

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### Bempedoic Acid (Nexletol)

**Criteria for current Kaiser Permanente members already taking the medication who have not been reviewed previously:** Non-formulary **Bempedoic Acid (Nexletol)** 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<sup>§</sup> – 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<sup>#</sup>
  - 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 or has contraindication or intolerance to ezetimibe – 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-
- 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 (Nexletol)** 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<sup>§</sup> – AND-

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### Bempedoic Acid (Nexletol)

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  - History of severe adverse effect to statin such as statin-induced rhabdomyolysis or statin-induced necrotizing myositis
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#### **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-
- LDL greater than or equal to 70 mg/dL