AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: (select ONE drug below)

❑ **Nexletol™** (bempedoic acid)	❑ **Nexlizet™** (bempedoic acid/ezetimibe)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 6 months

Section I. Diagnosis: (select one below)

❑ **Established Atherosclerotic Cardiovascular Disease**

- ❑ Member is 18 years of age or older

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- ❑ Member has Atherosclerotic Cardiovascular Disease (ASCVD) confirmed by at least **ONE** of the following **(submit documentation)**:
  - ❑ Acute Coronary Syndrome
  - ❑ History of myocardial infarction
  - ❑ Stable or unstable angina
  - ❑ Peripheral arterial disease presumed to be of atherosclerotic origin
  - ❑ Coronary artery disease
  - ❑ Member has undergone coronary or other arterial revascularization procedure in the past (e.g., percutaneous coronary intervention (PCI), angioplasty, coronary stent procedure or coronary bypass graft (CABG) surgery)
  - ❑ History of stroke
  - ❑ History of transient ischemic attack
- ❑ Member must meet **ONE** of the following:
  - ❑ Member has tried **ONE** of the following statin therapies as a single-entity or combination product for at least 8 consecutive weeks **(verified by pharmacy paid claims)**:
    - ❑ High intensity statin therapy with atorvastatin (generic Lipitor) ≥ 40 mg daily
    - ❑ High intensity statin therapy rosuvastatin (generic Crestor) ≥ 20 mg daily
    - ❑ Moderate-intensity statin therapy (member unable to tolerate high intensity therapy)
    - ❑ Low intensity statin therapy (member unable to tolerate moderate intensity therapy
  - ❑ Member has been determined to be statin intolerant and meets all clinical criteria in section II below
- ❑ If applicable: Member's LDL-C after 8-week trial of maximally tolerated statin therapy remains ≥ 70 mg/dL
- ❑ Please provide member's LDL levels below **(submit labs with request)**:
  - ❑ **LDL baseline:** _____ **LDL post-treatment:** _____
- ❑ Member must meet **ONE** of the following:
  - ❑ Member has had a **90-Day** trial of a PCSK9 inhibitor (e.g., Repatha® - requires prior authorization) and failed to reach LDL target goal **(documentation of PCSK9 inhibitor failure, including LDL labs after 90 days of therapy, MUST be provided)**
  - ❑ Member has had a life-threatening adverse reaction to a PCSK9 inhibitors (e.g., Repatha® - requires prior authorization) **(documentation of life-threatening adverse reaction MUST be provided)**

❑ High risk for Cardiovascular Disease (CVD) event but WITHOUT established CVD

- ❑ Member is 18 years of age or older
- ❑ Member is at high risk for a CVD event but without established CVD confirmed by at least **ONE** of the following **(submit documentation)**:
  - ❑ Reynolds risk score > 30 %
  - ❑ 10-year ASCVD risk score ≥ 20 %
  - ❑ Coronary artery calcium score > 300 Agatston units
  - ❑ Member is between 40 and 75 years of age and has a diagnosis of Type 1 or 2 diabetes

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- ❑ Member must meet **ONE** of the following:
  - ❑ Member has tried **ONE** of the following statin therapies as a single-entity or combination product for at least 8 consecutive weeks **(verified by pharmacy paid claims)**:
    - ❑ High intensity statin therapy with atorvastatin (generic Lipitor) ≥ 40 mg daily
    - ❑ High intensity statin therapy rosuvastatin (generic Crestor) ≥ 20 mg daily
    - ❑ Moderate-intensity statin therapy (member unable to tolerate high intensity therapy)
    - ❑ Low intensity statin therapy (member unable to tolerate moderate intensity therapy
  - ❑ Member has been determined to be statin intolerant and meets all clinical criteria in section II below
- ❑ If applicable: Member's LDL-C after 8-week trial of maximally tolerated statin therapy remains ≥ 70 mg/dL
- ❑ Please provide member's LDL levels below **(submit labs with request)**:
  - ❑ **LDL baseline:** _____ **LDL post-treatment:** _____
- ❑ Member must meet **ONE** of the following:
  - ❑ Member has had a **90-Day** trial of a PCSK9 inhibitor (e.g., Repatha® - requires prior authorization) and failed to reach LDL target goal **(documentation of PCSK9 inhibitor failure, including LDL labs after 90 days of therapy, MUST be provided)**
  - ❑ Member has had a life-threatening adverse reaction to a PCSK9 inhibitors (e.g., Repatha® - requires prior authorization) **(documentation of life-threatening adverse reaction MUST be provided)**

❑ Heterozygous Familial Hypercholesterolemia (HeFH)

- ❑ Member is 18 years of age or older
- ❑ Member has heterozygous familial hypercholesterolemia (HeFH) as confirmed by the **ONE** of the following **(submit documentation)**:
  - ❑ Member has an untreated low-density lipoprotein cholesterol (LDL-C) ≥ 190 mg/dL (prior to treatment with antihyperlipidemic therapy)
  - ❑ Member has genetic confirmation of heterozygous familial hypercholesterolemia by mutations in the low-density lipoprotein receptor, apolipoprotein B, proprotein convertase subtilisin kexin type 9, or low-density lipoprotein receptor adaptor protein 1 gene
  - ❑ Member has been diagnosed with heterozygous familial hypercholesterolemia by meeting **ONE** of the following diagnostic criteria thresholds:
    - ❑ Dutch Lipid Network criteria score was > 5
    - ❑ Simone Broome criteria met the threshold for "definite" or "possible (or probable)" familial hypercholesterolemia

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- ❑ Member must meet **ONE** of the following:
  - ❑ Member has tried **ONE** of the following statin therapies as a single-entity or combination product for at least 8 consecutive weeks **(verified by pharmacy paid claims)**:
    - ❑ High intensity statin therapy with atorvastatin (generic Lipitor) ≥ 40 mg daily
    - ❑ High intensity statin therapy rosuvastatin (generic Crestor) ≥ 20 mg daily
    - ❑ Moderate-intensity statin therapy (member unable to tolerate high intensity therapy)
    - ❑ Low intensity statin therapy (member unable to tolerate moderate intensity therapy
  - ❑ Member has been determined to be statin intolerant and meets all clinical criteria in section II below
- ❑ If applicable: Member's LDL-C after 8-week trial of maximally tolerated statin therapy remains ≥ 70 mg/dL
- ❑ Please provide member's LDL levels below **(submit labs with request)**:
  - ❑ **LDL baseline:** _____ **LDL post-treatment:** _____
- ❑ Member must meet **ONE** of the following:
  - ❑ Member has had a **90-Day** trial of a PCSK9 inhibitor (e.g., Repatha® - requires prior authorization) and failed to reach LDL target goal **(documentation of PCSK9 inhibitor failure, including LDL labs after 90 days of therapy, MUST be provided)**
  - ❑ Member has had a life-threatening adverse reaction to a PCSK9 inhibitors (e.g., Repatha® - requires prior authorization) **(documentation of life-threatening adverse reaction MUST be provided)**

Section II. For members with contraindication or intolerance to statin therapy

- Select below if the member is unable to tolerate low, moderate, and high intensity statin therapy as evidenced by intolerable and persistent symptoms to **TWO** different statins (i.e., more than 2 weeks); Please provide previously attempted statin name, strength & therapy initiation date below:

Drug Name: _____ **Strength:** _____ **Date started:** _____

Drug Name: _____ **Strength:** _____ **Date started:** _____

- ❑ Member is unable to tolerate statin therapy due to the occurrence of at least **ONE** of the following symptoms **(submit documentation)**:
  - ❑ Myalgia (muscle symptoms without CK elevations)
  - ❑ Myositis (muscle symptoms with CK elevations < 10 times upper limit of normal)
  - ❑ Member has experienced rhabdomyolysis or muscle symptoms with CK elevations > 10 times upper limit of normal
  - ❑ Member has a labeled contraindication to **ALL** statins as documented in medical records
- ❑ Re-initiation of statin therapy has been attempted and failed

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Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Provider must submit documentation of positive clinical response to therapy (e.g., reduction in LDL-C levels)
- ❑ Provider must document member's LDL levels below **(submit labs with request)**:

  LDL baseline: _____ **LDL post-treatment:** _____
- ❑ Member is compliant with therapy **(verified by pharmacy paid claims)**

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.

***Approved by Pharmacy and Therapeutics Committee:** ~~6/18/2020; 3/21/2024; 7/25/2024;~~ **3/26/2026**
REVISED/UPDATED/REFORMATTED: ~~8/31/2020; 10/26/2023; 4/26/2024~~; 8/21/2024; **4/16/2026**