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; <u>fax to 1-305-671-0200</u>. 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 drug below)

□ Nexletol [™] (bempedoic acid)	□ Nexlizet TM (bempedoic acid/ezetimibe)		
MEMBER & PRESCRIBER INFOR	MATION: Authorization may be delayed if incomplete.		
Member Name:			
Member AvMed #:			
Prescriber Name:			
Prescriber Signature:			
Office Contact Name:			
Phone Number:	Fax Number:		
DEA OR NPI #:			
DRUG INFORMATION: Authorization	n may be delayed if incomplete.		
Drug Form/Strength:			
Dosing Schedule:	Length of Therapy:		
Diagnosis:	ICD Code, if applicable:		
Weight:	Date:		

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 Approval: 6 months

- □ Must be prescribed or in consultation with one of the following:
 - □ Cardiologist
 - □ Endocrinologist
 - □ Lipid Specialist

(Continued on next page)

DIAGNOSIS: select one below:

- □ Atherosclerotic Cardiovascular Disease
- □ Heterozygous Familial Hypercholesterolemia (HeFH)
- □ Other diagnosis:
- □ ICD-10 Code(s) plus description:

Atherosclerotic Cardiovascular Disease – Select if the member has Atherosclerotic cardiovascular disease (ASCVD) confirmed by the following: (Please note: Chart documentation is required to be submitted along with this request form.)

- □ Acute coronary syndrome
- □ History of myocardial infarction
- □ Stable or unstable angina
- □ Coronary or other arterial revascularization (e.g., percutaneous coronary intervention (PCI), angioplasty, coronary stent procedure or coronary bypass graft (CABG) surgery)
- □ Stroke
- □ Transient ischemic attack
- D Peripheral arterial disease presumed to be of atherosclerotic origin

OR

- Heterozygous Familial Hypercholesterolemia (HeFH) Select if the member has Heterozygous familial hypercholesterolemia (HeFH) confirmed by the following: (Please note: Chart documentation is required to be submitted along with this request form.)
 - □ Untreated/pre-treatment LDL cholesterol (LDL-C) \ge 190mg/dL in an adult or \ge 155mg/dL in a child less than 16 years of age

AND (ONE OF THE FOLLOWING)

- □ Family history of myocardial infarction in first-degree relative less than 60 years of age
- □ Family history of myocardial infarction in second-degree relative less than 50 years of age
- □ Family history of familial hypercholesterolemia in first-or second degree relative
- Submission of medical records (e.g., chart notes, laboratory values) documenting LDL-C > 190mg/dL in first or second degree relative.ransient ischemic attack

OR (ONE OF THE FOLLOWING)

- □ Genetic confirmation of functional mutation in the LDL receptor, Apo-B, or PCSK9 gene adaptor protein 1 (i.e., LDLRAP1 or ARH)
- **D** Tendinous xanthomata
- □ Arcus cornealius before age 45

AND

- **Please confirm ALL of the following for ASCVD and/or HeFH:** (Please note: Chart documentation is required to be submitted along with this request form.)
 - □ Member is on high-intensity statin therapy (i.e., atorvastatin 40-80mg daily, rosuvastatin 20-40mg daily) AND ezetimibe concomitantly (unless the addition of ezetimibe is contraindicated) for > 12 continuous weeks (Pharmacy claims will be verified)

OR

□ Member is unable to tolerate high intensity statin therapy and is on maximally tolerated statin therapy AND ezetimibe concomitantly (unless the addition of ezetimibe is contraindicated) for > 12 continuous weeks (Pharmacy claims will be verified)

Statin: _____ Strength: _____ Date started: _____

AND (ONE OF THE FOLLOWING)

- □ LDL-C remains greater than or equal to 70 mg/dL with ASCVD
- □ LDL-C remains greater than or equal to 100 mg/dL without ASCVD

Please document: the LDL levels below (Labs MUST be attached or authorization will be delayed)

LDL baseline: LDL post therapy:

OR

- □ Member is unable to tolerate statin therapy as evidenced by **ONE** of the following intolerable and persistent symptoms with **TWO** different statins (i.e., trial of at least 14 days of each) (documentation **MUST** be provided and claims will be verified):
 - □ Myalgia (muscle symptoms without CK elevations) **OR**
 - □ Myositis (muscle symptoms with CK elevations < 10 times upper limit of normal)

AND

□ Reinitiating of statin therapy at lower dose or reduced frequency of administration must have been attempted and failed (documentation of statin intolerance MUST be provided)

Please document statin therapy below; pharmacy claims will be verified

Statin:	Strength:	Date started:
Statin:	Strength:	Date started:

OR

□ Member has a labeled contraindication to ALL statins as documented in medical records and/or has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations > 10 times upper limit of normal (documentation of labeled contraindication to ALL statins must be provided)

AND

(Continued on next page)

Member has had a <u>90-Day</u> trial of a PCSK9 inhibitor (i.e., Repatha[®] or Praluent[®] - require 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)

OR

□ Member has had a life-threatening adverse reaction to a PCSK9 inhibitors (i.e., Repatha[®] or Praluent[®] – required prior authorization) (documentation of life-threatening adverse reaction MUST be provided)

Please note: Concomitant therapy with PCSK9 inhibitors will not be approved

Reauthorization Approval: 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.

Documentation of positive clinical response to therapy (e.g., reduction in LDL-C levels)

AND

Patient continues to receive other lipid-lowering therapy (e.g., statin, ezetimibe) at a maximally tolerated dose

OR

□ Patient has a documented inability to take other lipid-lowering therapy (e.g., statins, ezetimibe)

Please document: the LDL levels below (Labs MUST be attached or authorization will be delayed)

LDL baseline: _____ LDL post-nexletol/nexlizet: _____

Medication being provided by a Specialty Pharmacy - PropriumRx

Not all drugs may be covered under every Plan

If a drug is non-formulary on a Plan, documentation of medical necessity will be required. **Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.** *<u>Previous therapies will be verified through pha rmacy paid claims or submitted chart notes.</u>*