

SENTARA COMMUNITY PLAN (MEDICAID)

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 1-800-750-9692. 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)

<input type="checkbox"/> Nexletol™ (bempedoic acid)	<input type="checkbox"/> Nexlizet® (bempedoic acid/ezetimibe)
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Preferred Medication (must be tried and failed FIRST)

ezetimibe

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

Member Name: _____

Member Sentara #: _____ 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.

Specialty: Is the drug prescribed by or in consultation with a specialist?

<input type="checkbox"/> Cardiologists	<input type="checkbox"/> Lipidologists
<input type="checkbox"/> Endocrinologists	<input type="checkbox"/> Other: _____

(Continued on next page)

1. Is Patient \geq 18 years of age? Yes No
2. For what indications the drug is being prescribed? Check all that apply:
 - Member can be classified into ONE of the following risk factor groups:
 - Extremely high risk ASCVD: (defined as extensive or active burden of ASCVD, or ASCVD with extremely high burden of adverse or poorly controlled risk cardio-metabolic risk factors including HeFH or severe hypercholesterolemia [SH] LDL-C > 220 mg/dl) with an LDL-C \geq 70 mg/dL; **OR**
 - Very high risk ASCVD: (defined as less extensive ASCVD and poorly controlled cardiometabolic risk factors) with an LDL-C \geq 100 mg/dL; **OR**
 - High risk ASCVD: (defined as either less extensive ASCVD and well controlled risk factors or primary prevention HeFH or SH >220 mg/dl with poorly controlled risk factors) with LDL-C \geq 130 mg/dL;
 - To reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults without established cardiovascular disease.
 - As an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia (HeFH)) to reduce low-density lipoprotein cholesterol (LDL-C)
3. Member has failed to achieve a target LDL-C despite physician attestation that the member is adherent to maximally tolerated doses of statins prior to the lipid panel demonstrating suboptimal reduction Yes No
4. Member is not able to use a maximum dose of atorvastatin or rosuvastatin due to muscle symptoms? Documentation of a causal relationship must be established between statin use and muscle symptoms. Documentation must demonstrate that the member experienced pain, tenderness, stiffness, cramping, weakness, and/or fatigue and all of the following (**please attach documentation**):
 - a. Muscle symptoms resolved after discontinuation of statin;
AND
 - b. Muscle symptoms occurred when re-challenged at a lower dose of the same statin;
AND
 - c. Muscle symptoms occurred after switching to an alternative statin;
AND
 - d. Documentation ruling out non-statin causes of muscle symptoms (e.g., hypothyroidism, reduced renal function, reduced hepatic function, rheumatologic disorders, such as polymyalgia rheumatica, steroid myopathy, vitamin D deficiency, or primary muscle disease);
OR
 - e. Member has been diagnosed with statin-induced rhabdomyolysis Yes No
5. Is this request for a new start or continuation of therapy? (If **New Start**, go to diagnosis section.)
 New Start Continuation

(Continued on next page)

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

6. 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 \geq 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
7. 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) \geq 40 mg daily
 - High intensity statin therapy rosuvastatin (generic Crestor) \geq 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 **OR**)
 - Member has been determined to be statin intolerant and meets all clinical criteria in question #4.
8. If applicable: Member's LDL-C after 8-week trial of maximally tolerated statin therapy remains \geq 70 mg/dL Yes No
9. Please provide member's LDL levels below (submit labs with request):
LDL baseline: _____

❑ Diagnosis and Lab Values for Cardiovascular Event Risk Reduction (CVD)

10. Does member have a history of clinical atherosclerotic cardiovascular disease (ASCVD) or a cardiovascular event listed below? Yes No
- Acute coronary syndromes
 - Myocardial infarction
 - Stable or unstable angina
 - Stroke of presumed atherosclerotic origin
 - Transient ischemic attack (TIA)
 - Coronary or other arterial revascularization procedure (e.g., percutaneous transluminal coronary angioplasty (PTCA), coronary artery bypass graft (CABG))
 - Peripheral arterial disease of presumed atherosclerotic origin
 - Findings from computerized tomography (CT) angiogram or catheterization consistent with clinical ASCVD
11. Please provide member's LDL levels below (**submit labs with request**):
LDL baseline: _____

Diagnosis and Lab Values for Heterozygous Familial Hypercholesterolemia (HEFH)

12. Does member have a **definite** diagnosis of heterozygous familial hypercholesterolemia (HeFH) as defined by the Dutch Lipid Clinical Network criteria (total score greater than 8)?

ACTION REQUIRED: If YES, please provide a copy of the lab report with LDL-C level at time of diagnosis and other documentation supporting clinical/family history and/or physical findings (e.g., chart notes, medical records).

Yes No

13. Does member have a definite diagnosis of HeFH as defined by Simon Broome diagnostic criteria?

Yes No

Reauthorization Approval

14. Was this drug previously authorized for this member and are they stable on the medication?

Yes No

15. How long has the member been receiving treatment with these medications?

3 to 5 months (or first renewal request after initial authorization)

6 months or more (or second and subsequent renewal requests)

16. Has the member achieved at least a 15% to 20% reduction in LDL-C since the beginning of treatment? (If Yes, please attach clinical notes and laboratory results that support reduction in LDL-C after initiation of therapy.)

Yes No

17. Does the member continue to benefit from treatment as measured by either continued decrease in LDL-C levels or maintenance of optimum of LDL-C levels? (If Yes, please attach clinical notes and laboratory results that support continued benefit of Nexletol[®], Nexlizet[™] therapy.)

Yes No

18. Member is not able to use a maximum dose of atorvastatin or rosuvastatin due to muscle symptoms; documentation of a causal relationship must be established between statin use and muscle symptoms. Documentation must demonstrate that the member experienced pain, tenderness, stiffness, cramping, weakness, and/or fatigue. (Please provide documentation/chart notes)

Yes No

Medication being provided by Specialty Pharmacy - PropriumRx

**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.