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.**

Lipotropics, Other (Non-Preferred)

Drug Requested: (Select drug below)

❑ **Leqvio®** (inclisiran)	❑ **Lipfendra®** (enlicitide)
❑ **Praluent®** (alirocumab)	❑ **Repatha®** (evolocumab)

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:** _____

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?

❑ Cardiologists	❑ Lipidologists
❑ Endocrinologists	❑ Other:

(Continued on next page)

FOR ALL DIAGNOSES: Complete Questions 1-3.

1. For what indications the drug is being prescribed? Check all that apply:
   - ❑ To reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with 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)
   - ❑ As an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) in patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C
   - ❑ The member has had prior treatment history with highest available dose or maximally-tolerated dose of high intensity statin (atorvastatin or rosuvastatin) **and** ezetimibe for at least three continuous months with failure to reach target LDL-C **and** is in one of the three groups identified by NLA (i.e., extremely high risk ASCVD members with LDL-C ≥ 70mg/dL, very high risk atherosclerotic cardiovascular disease (ASCVD) member with LDL-C ≥ 100mg/dL, and high risk members with LDL-C ≥ 130mg/dL
   - ❑ Other: _____
2. 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:
   - ❑ Muscle symptoms resolved after discontinuation of statin;

     AND
   - ❑ Muscle symptoms occurred when re-challenged at a lower dose of the same statin;

     AND
   - ❑ Muscle symptoms occurred after switching to an alternative statin;

     AND
   - ❑ 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
   - ❑ Member has been diagnosed with statin-induced rhabdomyolysis

     ❑ Yes ❑ No

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If YES to any, give details:

_____

_____

_____

_____

3. Is this request for a new start or continuation of therapy? (If **New Start**, go to diagnosis section.)

   ❑ New Start ❑ Continuation

Diagnosis and Lab Values for Homozygous Familial Hypercholesterolemia (HOFH)

4. Has genetic testing confirmed the presence of 2 mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus?

   ACTION REQUIRED: If YES, please attach a copy of genetic testing result.

   ❑ Yes ❑ No

5. Has the diagnosis of HoFH been confirmed by **ANY** of the following?

   ACTION REQUIRED: Please indicate below and provide a copy of the laboratory report with LDL-C level at time of diagnosis and other documentation supporting the presence of xanthoma or family history of HoFH (e.g., chart notes, medical records).

   ❑ Untreated LDL-C > 500mg/dL **AND** cutaneous or tendon xanthoma before age 10 years

   ❑ Untreated LDL-C > 500mg/dL **AND** untreated elevated LDL-C levels consistent with heterozygous familial hypercholesterolemia in both parents

   ❑ Treated LDL-C ≥ 300mg/dL **AND** cutaneous or tendon xanthoma before age 10 years

   ❑ Treated LDL-C ≥ 300mg/dL **AND** untreated elevated LDL-C levels consistent with heterozygous familial hypercholesterolemia in both parents

   ❑ None of the above

6. Is the member diagnosed with homozygous familial hypercholesterolemia (HoFH) and meets the FDA approved age for the requested product?

   ❑ Yes ❑ No

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Diagnosis and Lab Values for Cardiovascular Event Risk Reduction

7. Does the member have a history of clinical atherosclerotic cardiovascular disease (ASCVD) or a cardiovascular event listed below OR at increased risk of a major adverse cardiovascular (CV) event? Check all that apply.

   ❑ Yes ❑ No

   - ❑ Acute coronary syndromes
   - ❑ Myocardial infarction
   - ❑ Stable or unstable angina
   - ❑ Stroke of presumed atherosclerotic origin
   - ❑ Transient ischemic attack (TIA)
   - ❑ Increased risk of a major adverse CV event
   - ❑ 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

8. What is the member's pre-treatment LDL-C level (i.e., prior to starting PCSK9 inhibitor therapy)? _____ mg/dL (please attach laboratory results) Date of labs: _____

Diagnosis and Lab Values for Heterozygous Familial Hypercholesterolemia (HEFH)

9. Does member have a **definite** diagnosis of heterozygous familial hypercholesterolemia (HeFH) as defined by the Dutch Lipid Clinical Network criteria (total score greater than 5) or Simon Broome diagnostic criteria?

   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

10. Does the member meet the FDA approved age for the requested product?

    ❑ Yes ❑ No

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Reauthorization Approval

11. How long has the member been receiving treatment with these medications?
    - ❑ 3 to 5 months (for first renewal request after initial authorization)
    - ❑ 6 months or more (for second and subsequent renewal requests)
12. Has the member achieved at least a 30% 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
13. 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 therapy.)

    ❑ 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.

REVISED/UPDATED/REFORMATTED: ~~6/29/2017~~; ~~8/31/2017~~; ~~8/29/2018~~; ~~10/26/2018~~; ~~12/8/2019~~; ~~12/21/2020~~; ~~7/8/2022~~; ~~9/18/2023~~; ~~8/22/2024~~; **9/22/2026**