

SENTARA COMMUNITY PLAN (MEDICAID)

MEDICAL 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 1-844-305-2331. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. If information provided is not complete, correct, or legible, authorization can be delayed.

Drug Requested: Leqvio® (inclisiran) (J1306) (Medical)

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: _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization 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

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: _____

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

(Continued on next page)

- 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)
- 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 \geq 70mg/dL, very high risk atherosclerotic cardiovascular disease (ASCVD) member with LDL-C \geq 100mg/dL, and high risk members with LDL-C \geq 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:

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

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

(Continued on next page)

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 \geq 300mg/dL AND cutaneous or tendon xanthoma before age 10 years
- Treated LDL-C \geq 300mg/dL AND untreated elevated LDL-C levels consistent with heterozygous familial hypercholesterolemia in both parents
- None of the above

6. Is age \geq 13 years if diagnosed with homozygous familial hypercholesterolemia (HoFH)?

Yes No

Diagnosis and Lab Values for Cardiovascular Event Risk Reduction

7. 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

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)

(Continued on next page)

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 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

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

Yes No

Reauthorization

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

Yes No

2. 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)

3. 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

4. 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 Leqvio[®], Praluent[®] or Repatha[®] therapy.)

Yes No

5. 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

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Medication being provided by (check applicable box(es) below):

- Location/site of drug administration:** _____
NPI or DEA # of administering location: _____

OR

- Specialty Pharmacy – PropriumRx**

For urgent reviews: Practitioner should call Sentara Health Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health’s definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member’s ability to regain maximum function.

*****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.****