REALRx

PRIOR AUTHORIZATION REQUEST FORM
LEQVIO®

For authorization, please answer each question and fax this form PLUS chart notes back to Real Rx at 385-425-4052.

Failure to submit clinical documentation to support this request will result in a dismissal of the request.

If you have prior authorization questions, please call for assistance 385-425-5094.

Disclaimer: Prior authorization request forms are subject to change in accordance with Federal and State notice requirements.

Date:	Member Name:	ID#:
DOB:	Gender:	Physician:
Office Phone:	Office Fax:	Office Contact:
Height/Weight:		

Member must try formulary preferred drugs before a request for a non-preferred drug may be considered. If treatment with preferred products has not been successful, you must submit which preferred products have been tried, dates of treatment, and reason for failure. Reasons for failure must meet the Health Plan medical necessity criteria.

Product being requested: ☐ Leqvio® (inclisiran)

Dosing/Frequency:_____

If the request is for reauthorization, proceed to reauthorization section.

Questions	Yes	No	Comments/Notes
1. Is this request for an **expedited** review? By checking the **"Yes"** box to request an expedited review (24 hours), you are certifying that applying the standard review time frame (72 hours) may place the member's life, health, or ability to regain maximum function in serious jeopardy.	☐	☐	
HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA			
1. Is the request made by, or in consultation with, a cardiologist, endocrinologist, lipidologist, or a physician who focuses in the treatment of cardiovascular risk management and/or lipid disorders?	☐	☐	**Please provide documentation**
2. Does the member have a diagnosis of heterozygous familial hypercholesterolemia (HeFH) confirmed by either of the following: • Untreated LDL-C level ≥ 190 mg/dL in adults • Untreated LDL-C level ≥ 160 mg/dL and tendon xanthoma in members < 20 years of age	☐	☐	**Please provide documentation**
3. Does the member have one of the following: • Genetic confirmation testing that demonstrates LDL-R mutation, LDLRAP1 mutation, familial defective apo B100, or a PCSK9 mutation • A diagnosis confirmed by the World Health Organization/Dutch Lipid Network Criteria resulting in a score > 8 points	☐	☐	**Please provide documentation**

• A diagnosis meeting the threshold for definite or possible/probable familial hypercholesterolemia per Simon Broome Criteria • Arcus senilis if < 45 years of age • Have a first degree relative with similarly elevated LDL-C, early ASCVD (<55 years of age for men, <65 years of age for women), tendon xanthoma, or corneal arcus			
4. Does clinical documentation show a recent baseline low-density lipoprotein cholesterol (LDL-C) level?	☐	☐	**Please provide documentation**
5. Has the member failed to reach target LDL-C when on high-intensity statin therapy or maximally tolerated statin therapy for at least 8 continuous weeks and LDL-C remains ≥ 100 mg/dL?	☐	☐	**Please provide documentation**
6. Does the member show LDL-C is unresponsive to standard PCSK9 therapy for an adequate duration (i.e., 3-6 months)? Documentation must show trial and failure to Repatha®	☐	☐	**Please provide documentation**
7. Will Leqvio® be used concurrently with a maximally tolerated statin therapy?	☐	☐	**Please provide documentation**
8. If the member has a contraindication to all statins, does documentation show one of the following: • Active liver disease • Diagnosis or history of rhabdomyolysis • Pregnant or nursing mothers • Allergic reaction with rash and/or anaphylactic symptoms	☐	☐	**Please provide documentation**
9. If the member has a hypersensitivity to statins, does documentation show all of the following: • Inability to tolerate at least 2 different statins at the lowest starting dose • Intolerance associated with confirmed, intolerable statin-related adverse effects or significant biomarker abnormalities • Symptom and/or biomarker resolution upon discontinuation • Attestation that adverse effects are not attributable to drug-drug interactions or recognized conditions that can cause similar changes (e.g., hypothyroidism) • Intolerance persists despite trials of all the following: low dose of same or different statin, statin is dosed intermittently, and alternate cholesterol lowering medications such as ezetimibe or a bile-acid sequestrant such as colesevelam is used	☐	☐	**Please provide documentation**
10. Is the member at least 80% compliant for at least 6 months with their baseline therapy (i.e., statins, ezetimibe)?	☐	☐	**Please provide documentation**
11. Has the provider addressed lifestyle modifications (i.e., a heart healthy diet, the importance of exercise, and smoking cessation)?	☐	☐	**Please provide documentation**
12. Will the member be concurrently receiving any of the following medications in combination with Leqvio®: • Praluent® (alirocumab) • Repatha® (evolocumab) • Nexletol® (bempedoic acid) • Nexlizet® (bempedoic acid and ezetimibe)	☐	☐	**Please provide documentation**

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HIGH RISK OF ATHEROSCLEROTIC CARDIOVASCULAR DISEASE (ASCVD)			
1. Is the request made by, or in consultation with, a cardiologist, endocrinologist, lipidologist, or a physician who focuses in the treatment of cardiovascular risk management and/or lipid disorders?	☐	☐	**Please provide documentation**
2. Does the member have a diagnosis of high risk atherosclerotic cardiovascular disease (ASCVD) with one of the following: • History of myocardial infarction • Non-hemorrhagic stroke • Symptomatic peripheral artery disease • Acute coronary syndromes • Coronary artery disease • Stable or unstable angina • Coronary or other arterial revascularization • Transient ischemic attack • Diabetes • 10-year Framingham risk score of 20% or higher	☐	☐	**Please provide documentation**
3. Does clinical documentation show a recent baseline low-density lipoprotein cholesterol (LDL-C) level?	☐	☐	**Please provide documentation**
4. Has the member failed to reach target LDL-C when on high-intensity statin therapy or maximally tolerated statin therapy for at least 8 continuous weeks and LDL-C remains ≥ 70 mg/dL?	☐	☐	**Please provide documentation**
5. Does the member show LDL-C is unresponsive to standard PCSK9 therapy for an adequate duration (i.e., 3-6 months)? Documentation must show trial and failure to Repatha®	☐	☐	**Please provide documentation**
6. Will Leqvio® be used concurrently with a maximally tolerated statin therapy?	☐	☐	**Please provide documentation**
7. If the member has a contraindication to all statins, does documentation show one of the following: • Active liver disease • Diagnosis or history of rhabdomyolysis • Pregnant or nursing mothers • Allergic reaction with rash and/or anaphylactic symptoms	☐	☐	**Please provide documentation**
8. If the member has a hypersensitivity to statins, does documentation show all of the following: • Inability to tolerate at least 2 different statins at the lowest starting dose • Intolerance associated with confirmed, intolerable statin-related adverse effects or significant biomarker abnormalities • Symptom and/or biomarker resolution upon discontinuation • Attestation that adverse effects are not attributable to drug-drug interactions or recognized conditions that can cause similar changes (e.g., hypothyroidism) • Intolerance persists despite trials of all the following: low dose of same or different statin, statin is dosed intermittently, and alternate cholesterol lowering medications such as ezetimibe or a bile-acid sequestrant such as colesevelam is used	☐	☐	**Please provide documentation**

9. Is the member at least 80% compliant for at least 6 months with their baseline therapy (i.e., statins, ezetimibe)?	☐	☐	**Please provide documentation**
10. Has a provider driven discussion regarding lifestyle modifications (i.e., a heart healthy diet, the importance of exercise, and smoking cessation) been completed?	☐	☐	**Please provide documentation**
11. Will the member be concurrently receiving any of the following medications in combination with Leqvio®: • Praluent® (alirocumab) • Repatha® (evolocumab) • Nexletol® (bempedoic acid), • Nexlizet® (bempedoic acid and ezetimibe)	☐	☐	**Please provide documentation**
REAUTHORIZATION			
1. Is the request for reauthorization of therapy?	☐	☐	
2. Does documentation indicate an adequate reduction in LDL-C defined by one of the following: • ≥ 40% reduction in LDL-C level compared to baseline or reduction to LDL goal in members with a diagnosis of ASCVD • Reduction in LDL-C level compared to baseline in members with a diagnosis of HeFH	☐	☐	**Please provide documentation**
3. Is member adherent to concurrent statin therapy at the maximum tolerated dose?	☐	☐	**Please provide documentation**
4. Is member adherent to lifestyle modifications (i.e., a heart healthy diet, the importance of exercise, and smoking cessation)?	☐	☐	**Please provide documentation**
What medications and/or treatment modalities have been tried in the past for this condition? Please document name of treatment, reason for failure, treatment dates, etc.			
Additional information:			
Physician Signature:			

**** Failure to submit clinical documentation to support this request will result in a dismissal of the request.****

Policy: PHARM-130
Origination Date: 02/09/2022
Reviewed/Revised Date: 09/13/2023
Next Review Date: 09/13/2024
Current Effective Date: 10/01/2023

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