

# Inclisiran



**Included Products:** Leqvio (inclisiran)

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## Hypercholesterolemia

Initial Criteria		If yes	If no
1.	Is request from a cardiologist, endocrinologist, or lipid specialist?	Continue to #2.	Do not approve.
2.	Does the member have Homozygous Familial Hypercholesterolemia (HoFH) confirmed with a genetic test?	Approve for lifetime.	Continue to #3.
3.	Does the member have established Atherosclerotic Cardiovascular Disease (ASCVD)?	Continue to #4.	Continue to #7.
4.	<p>Does the member have very high risk ASCVD as evidenced by either: 1) history of multiple major ASCVD events or 2) 1 major ASCVD event AND multiple high-risk conditions</p> <p>a. Major ASCVD Events</p> <ul style="list-style-type: none"> <li>i. Recent (past 12 months) acute coronary syndrome (ACS)</li> <li>ii. Prior myocardial infarction (other than recent ACS event listed above)</li> <li>iii. Prior ischemic stroke</li> <li>iv. Symptomatic peripheral arterial disease</li> </ul> <p>b. High-Risk Conditions</p> <ul style="list-style-type: none"> <li>i. Age ≥65 years</li> <li>ii. Heterozygous familial hypercholesterolemia (HeFH)</li> <li>iii. Prior coronary revascularization outside of the major ASCVD event(s)</li> <li>iv. Diabetes mellitus</li> <li>v. Hypertension</li> <li>vi. Chronic kidney disease (eGFR 15-59 mL/min/1.73m<sup>2</sup>)</li> <li>vii. Current smoking</li> <li>viii. LDL-C ≥100 mg/dL despite maximally tolerated statin and ezetimibe</li> <li>ix. History of congestive heart failure</li> </ul>	Continue to #5.	Continue to #6.

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5.	<p>Does the member have an LDL greater than or equal to 55 mg/dL despite maximum tolerated dose of high intensity statin (atorvastatin 40-80 mg, rosuvastatin 20-40 mg) + ezetimibe?</p> <p>a. Yes, continue to #10.</p> <p>b. If physician states statin associated side effects prevent use of high intensity statin therapy, continue to #9.</p> <p>c. No, do not approve and require alternatives OR state member is at goal.</p>		
6.	<p>Does the member have an LDL greater than or equal to 70 mg/dL despite maximum tolerated dose of high intensity statin (atorvastatin 40-80 mg, rosuvastatin 20-40 mg) + ezetimibe?</p> <p>a. Yes, continue to #10.</p> <p>b. If physician states statin associated side effects prevent use of high intensity statin therapy, continue to #9.</p> <p>c. No, do not approve and require alternatives OR state member is at goal.</p>		
7.	<p>Does the member have Heterozygous Familial Hypercholesterolemia (HeFH) or baseline LDL greater than or equal to 190 mg/dL?</p>	Continue to #8.	Do not approve. Not guideline recommended.
8.	<p>Does the member have an LDL greater than or equal to 100 mg/dL despite maximum tolerated dose of high intensity statin (atorvastatin 40-80 mg, rosuvastatin 20-40 mg) + ezetimibe?</p> <p>a. Yes, continue to #10.</p> <p>b. If physician states statin associated side effects prevent use of high intensity statin therapy, continue to #9.</p> <p>c. No, do not approve and require alternatives OR state member is at goal.</p>		
9.	<p>Statin Intolerance: Is the patient unable to tolerate high-intensity statin therapy documented by one of the following?</p> <p>a. Severe statin-associated side effects (rhabdomyolysis, hepatotoxicity-small increases in transaminases are not considered severe)</p> <p>b. If statin-associated side effects are not severe, has re-challenge with an alternate statin been attempted AND have non-statin causes been addressed?</p> <p>c. Medical contraindication to be on a statin regimen due to non-modifiable factors?</p>	Continue to #10.	Do not approve.

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10.	Has the member failed Repatha, or have a medically accepted reason why it can't be used?	Continue to #11.	Do not approve.
11.	Approve for 2 doses in 6 months.		
<b>Renewal Criteria</b>		<b>If yes</b>	<b>If no</b>
1.	Is the patient continuing maximum adjunctive treatment (i.e. statin, ezetimibe/BAS, low fat diet, exercise)?	Continue to #2.	Do not approve.
2.	Has the patient been adherent with the medication?	Continue to #3.	Do not approve.
3.	Has there been a significant* LDL reduction while on Leqvio? *Significant lowering of LDL-C is defined as a >30% decrease in LDL-C.	Continue to #4.	Do not approve.
4.	Approve for 12 months.		