

Leqvio[®] (inclisiran)



Pharmacy Coverage Policy

Effective Date: June 22, 2022

Revision Date: May 24, 2023

Review Date: May 17, 2023

Line of Business: Medicare, Commercial, Medicaid - Ohio

Policy Type: Prior Authorization

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Products Affected

Leqvio subcutaneous syringe

Listed Indications

[Primary Hyperlipidemia](#)

[Clinical Atherosclerotic Cardiovascular Disease](#)

Primary Hyperlipidemia

Does the member meet all of the following criteria?

Criteria #1	Diagnosis of Primary Hyperlipidemia (Note: Includes heterozygous familial hypercholesterolemia [HeFH], pure hypercholesterolemia, and mixed hyperlipidemia)
Criteria #2	<ul style="list-style-type: none">The member must be 18 years of age or older
Criteria #3	<ul style="list-style-type: none">Leqvio (inclisiran) is used as adjunctive therapy to maximally tolerated high intensity statin (e.g., atorvastatin or rosuvastatin) in members who have failed to achieve goal LDL-C reduction ORThe member is determined to have statin-associated muscle symptoms (SAMs) defined by any of the following:<ul style="list-style-type: none">Statin associated rhabdomyolysis ORMember has failed to achieve goal LDL-C reduction due to SAMs despite lowering statin strength AND attempting a different statin ORProvider attestation that statin use has been tried and failed and is not clinically appropriate due to intolerable adverse effects

For continuation of therapy requests, does the member meet all of the following renewal criteria?

Renewal Criteria #1	Maintenance of a reduction in LDL-C from baseline
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Approval Duration

Initial	6 months
Renewal	plan year duration

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Clinical Atherosclerotic Cardiovascular Disease

Does the member meet all of the following criteria?

Criteria #1	<ul style="list-style-type: none">The member must have documentation of a clinical atherosclerotic cardiovascular disease (e.g., acute coronary syndromes, history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack or peripheral arterial disease, all of presumed atherosclerotic origin); AND
Criteria #2	<ul style="list-style-type: none">The member must be 18 years of age or older
Criteria #3	<ul style="list-style-type: none">Leqvio (inclisiran) is used as adjunctive therapy to maximally tolerated high intensity statin (e.g., atorvastatin or rosuvastatin) in members who have failed to achieve goal LDL-C reduction

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	OR
	<ul style="list-style-type: none">• The member is determined to have statin-associated muscle symptoms (SAMs) defined by any of the following:<ul style="list-style-type: none">◦ Statin associated rhabdomyolysis OR◦ Member has failed to achieve goal LDL-C reduction due to SAMs despite lowering statin strength AND attempting a different statin OR◦ Provider attestation that statin use has been tried and failed and is not clinically appropriate due to intolerable adverse effects
For continuation of therapy requests, does the member meet all of the following renewal criteria?	
Renewal Criteria #1	Maintenance of a reduction in LDL-C from baseline
Approval Duration	
Initial	6 months
Renewal	plan year duration

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Background

This is a prior authorization policy about Leqvio (inclisiran).

Statin intolerance is also identified as Statin-Associated Muscle Symptoms (SAMS). According to the 2018 Guideline on the Management of Blood Cholesterol: the large majority of patients with Statin-Associated Muscle Symptoms (SAMS) are able to tolerate statin re-challenge with an alternative statin or alternative regimen.

Leqvio (inclisiran) is a small interfering RNA (siRNA) that is directed to the proprotein convertase subtilisin/kexin type 9 (PCSK9) mRNA.

Leqvio (inclisiran) is a double-stranded siRNA that prevents PCSK9 translation in the liver. This increases low-density lipoprotein cholesterol (LDL-C) receptor recycling and expression on the hepatocyte cell, which increases LDL-C uptake and reduces the LDL-C concentrations in circulation.

Leqvio (inclisiran) is indicated for the treatment of heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease (atherosclerosis) as an adjunct to diet and maximally tolerated statin therapy in patients who require additional lowering of LDL-C.

Inclisiran is available as Leqvio in 284 mg/1.5 mL solution for injection.

Provider Claim Codes

For medically billed requests, please visit www.humana.com/PAL. Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

Medical Terms

Leqvio; inclisiran; heterozygous familial hypercholesterolemia; clinical atherosclerotic cardiovascular disease; hypercholesterolemia; hyperlipidemia; dyslipidemia; subcutaneous; provider; medical; pharmacy

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