

EVH Clinical Guideline 5067.CC for Leqvio (inclisiran)

Guideline Number: EVH_CG_5067.CC	<u>Applicable Codes</u>	
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STATEMENT

General Information

- *It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.*
- *If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.*

Purpose

The purpose of this guideline is to define the prior authorization process for the following drug: Leqvio (inclisiran).

Scope

This guideline applies to all practitioners who are involved in providing the requested drug. This guideline is specific to the Health Plan's medical benefit.

INITIAL REVIEW CRITERIA

The request must meet all of the criteria listed below:

General Criteria

- Must meet the age requirements below based on the member's diagnosis:
 - Hypercholesterolemia: Must be 18 years or older
 - Heterozygous familial hypercholesterolemia (HeFH): Must be 12 years or older
 - Homozygous familial hypercholesterolemia (HoFH): Must be 12 to 17 years of age
- Must provide chart documentation, or an attestation from the provider, showing the following:
 - The requested medication will be used in combination with diet and exercise
 - The member will NOT use inclisiran concurrently with other PCSK9 therapies (e.g., evolocumab [Repatha] and alirocumab [Praluent])
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling
- Must have one of the following diagnoses (and meet the associated criteria with the given diagnosis):
 - Heterozygous familial hypercholesterolemia (HeFH)

- Homozygous familial hypercholesterolemia (HoFH)
- Hypercholesterolemia in setting of Atherosclerotic Cardiovascular Disease (ASCVD) or at increased risk of ASCVD

Heterozygous Familial Hypercholesterolemia (HeFH)

- Must have previously had an untreated LDL-C level of the following (based on the member's age and level must be from before member was on any lipid-lowering therapy):
 - *18 years of age or older*: LDL-C level $\geq$ 190mg/dL
 - *Less than 18 years of age*: LDL-C level $\geq$ 160mg/dL
- Must have a current LDL-C level $\geq$ 100 mg/dL
- Must have chart note documentation showing the member is receiving maximally tolerated statin therapy OR has a contraindication or intolerance to all statin therapy

Homozygous Familial Hypercholesterolemia (HoFH)

- Must have documentation of genotyping that confirms the diagnosis of HoFH
- Must have a current LDL-C level $>$ 130mg/dL
- Must have chart note documentation showing the member is receiving maximally tolerated statin therapy OR has a contraindication or intolerance to all statin therapy

Hypercholesterolemia in Setting of ASCVD/Increased Risk of ASCVD

- Must have chart documentation showing the member has one of the following (see **Appendix** for definitions):
 - A history of 2 or more ASCVD events OR
 - 1 major ASCVD event and two or more high-risk conditions
- Must have a current LDL-C level $\geq$ 70 mg/dL
- Must have chart note documentation showing the member is receiving maximally tolerated statin therapy OR has a contraindication or intolerance to all statin therapy

REAUTHORIZATION CRITERIA

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. The request must meet all of the criteria listed below.

- Must have documentation of an updated lipid panel (since last authorization) indicating a reduction in LDL-C and/or stabilization of LDL-C below the member's goal
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on

diagnosis, weight, etc.) listed in the FDA approved labeling

- Must provide chart documentation, or an attestation from the provider, showing the member will NOT use inclisiran concurrently with other PCSK9 therapies (e.g., evolocumab [Repatha] and alirocumab [Praluent])

APPROVAL DURATIONS

Initial Authorization	Up to one year
Reauthorization	Same as initial

APPENDIX – ASCVD EVENTS/CONDITIONS

ASCVD Event	High-Risk Conditions
• Recent ACS (Within the past 12 months) • History of MI (other than recent ACS) • History of ischemic stroke • History of coronary revascularization (PCI or CABG) • History of prior percutaneous or surgical carotid artery revascularization • Symptomatic PAD (history of claudication with ABI <0.85, or previous revascularization or amputation) • Angiographic or CT-imaging (e.g., MDCT/CTA) evidence of coronary atherosclerosis (>70% stenosis in at least one major epicardial coronary artery) • Carotid artery stenosis >70% on prior angiography or ultrasound	• Age ≥ 65 years old • Heterozygous familial hypercholesterolemia • Diabetes Mellitus • Hypertension • CKD (eGFR 15-59 mL/min/1.73²) • Current smoker • Persistently elevated LDL-C ≥ 100 despite max statin and ezetimibe therapy • History of Congestive Heart failure

CODING AND STANDARDS

Codes

Code	Brand	Description
J1306	Leqvio	Injection, inclisiran, 1 mg

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☐	Commercial
☐	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

BACKGROUND

Leqvio (inclisiran) is indicated, in adjunct to diet and exercise, for patients who require additional lowering of low-density lipoprotein cholesterol (LDL-C) for the treatment of:

- Heterozygous familial hypercholesterolemia (HeFH)
- Homozygous familial hypercholesterolemia (HoFH)
- Hypercholesterolemia

Definitions

Acute Coronary Syndrome (ACS) – a spectrum of conditions with acute myocardial ischemia and/or infarction that are usually due to an abrupt reduction in coronary blood flow, including ST-elevation myocardial infarction (STEMI), non-STEMI (NSTEMI), and unstable angina (UA)

ASCVD – atherosclerotic cardiovascular disease

ACC/AHA – American College of Cardiology/American Heart Association

Arcus Cornealis – white deposit of lipids in the outer rim of the iris due to high LDL-C levels

Clinical ASCVD – acute coronary syndromes, a history of MI, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin

Dutch Lipid Clinic Network/WHO Criteria for Familial Hypercholesterolemia – scoring system developed to calculate a numeric score that predicts the probability of the diagnosis of

familial hypercholesterolemia (FH). Diagnosis of FH is certain when the score is >8, probable when the score is 6-8, and possible when the score is 3-6.

Heterozygous FH (HeFH) – a common genetic cause of premature coronary heart disease due to lifelong elevated LDL-C

High Intensity Statin – daily dose lowers LDL-C by approximately $\geq 50\%$

Moderate Intensity Statin – daily dose lowers LDL-C by approximately 30% to < 50%

Tendon Xanthoma – cholesterol deposit formation on the Achilles tendon and/or extensor tendons of hands and feet, or on the knees and elbows, caused by increased LDL-C levels

Statin Intensity (Per 2013 ACC/AHA Guidelines)

High-intensity Statin (lowers cholesterol by $\geq 50\%$)	Moderate-intensity Statin (lowers cholesterol by 30-50%)	Low-intensity Statin (lowers cholesterol by <30%)
- Atorvastatin 40-80 mg a day - Rosuvastatin 20-40mg a day	- Atorvastatin 10-20 mg a day - Rosuvastatin 5-10 mg a day - Simvastatin 20-40 mg a day - Pravastatin 40-80 mg a day - Lovastatin 40mg a day - Fluvastatin XL 80mg a day - Fluvastatin 40mg twice a day - Pitavastatin 2-4mg a day	- Simvastatin 10 mg a day - Pravastatin 10-20 mg a day - Lovastatin 20 mg a day - Fluvastatin 20-40 mg a day - Pitavastatin 1 mg a day

POLICY HISTORY

Date	Summary
July 2026	- Updated criteria for all indications - Removed prerequisite trial of ezetimibe - Added HoFH indication
September 2023	New Guideline

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Administrative Services Medical Policy Committee

Disclaimer

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