



Reference number
5120-A

Aetna Medicare Part B Drug Criteria

Leqvio

This policy is for Aetna Medicare members. [Find the Aetna Commercial Medical Drug Criteria.](#)

For Aetna Medicare members, National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) will be applied to Part B drug requests when applicable. Aetna Medicare Part B Drug Criteria documents will be used in the absence of an NCD and LCD.

POLICY

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Leqvio	inclisiran

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications¹

Leqvio is indicated as an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH).

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Documentation

The following documentation must be available, upon request, for all submissions:

Initial requests:

- With clinical atherosclerotic cardiovascular disease (ASCVD): Chart notes confirming clinical ASCVD or ASCVD event(s) (if applicable) (see Appendix A).
- Without ASCVD: Untreated (before any lipid lowering therapy) LDL-C level.

- If member has contraindication or intolerance to statins, chart notes or medical documentation confirming the contraindication or intolerance (see Appendix B).

Both initial and continuation requests:

Current LDL-C level must be dated within six months preceding the authorization request.

Coverage Criteria

Hypercholesterolemia Including Heterozygous Familial Hypercholesterolemia (HeFH)^{1-5,11,12}

Authorization of 12 months may be granted for treatment of hypercholesterolemia when one of the following criteria is met:

- Member meets all of the following criteria:
 - Member has a history of clinical ASCVD (see Appendix A).
 - Member meets either of the following criteria:
 - Member has a current LDL-C level ≥ 70 mg/dL.
 - Member has a current LDL-C level ≥ 55 mg/dL and has multiple ASCVD events (see Appendix A) or high-risk conditions (e.g., 65 years of age or older, familial hypercholesterolemia, diabetes, chronic kidney disease, history of congestive heart failure).
 - Member meets either of the following criteria:
 - Member has received at least three months of treatment with a high-intensity statin. If the member is unable to tolerate a high-intensity statin dose, a moderate-intensity statin dose may be used.
 - Member has a contraindication or intolerance to statin therapy (see Appendix B).
- Member meets all of the following criteria:
 - Member had an untreated (before any lipid-lowering therapy) LDL-C level ≥ 190 mg/dL in the absence of a secondary cause.
 - Member has a current LDL-C level ≥ 100 mg/dL.
 - Member meets either of the following criteria:
 - Member has received at least three months of treatment with a high-intensity statin. If the member is unable to tolerate a high-intensity statin dose, a moderate-intensity statin dose may be used.
 - Member has a contraindication or intolerance to statin therapy (see Appendix B).

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with Leqvio.
- Leqvio is being used to treat an indication in the coverage criteria.
- The member is receiving benefit from therapy. Benefit is defined as achieved or maintained an LDL-C reduction (e.g., LDL-C is now at goal, robust lowering of LDL-C).

Appendix

Appendix A. Clinical ASCVD^{4-6,9,10}

- Acute coronary syndromes
- Myocardial infarction
- Stable or unstable angina
- Coronary or other arterial revascularization procedure (e.g., percutaneous coronary intervention [PCI], coronary artery bypass graft [CABG] surgery)
- Stroke of presumed atherosclerotic origin
- Transient ischemic attack (TIA)
- Non-cardiac peripheral arterial disease (PAD) of presumed atherosclerotic origin (e.g., carotid artery stenosis, lower extremity PAD)
- Obstructive coronary artery disease (defined as $\geq 50\%$ stenosis on cardiac computed tomography angiogram or catheterization)
- Coronary artery calcium (CAC) Score ≥ 300

Appendix B. Contraindications to Statin Therapy^{5,7,8}

- Score of 7 or higher on the Statin-Associated Muscle Symptom Clinical Index (SAMS-CI) and failed statin rechallenge
- Presence of statin-associated muscle symptoms with elevation in creatine kinase (CK) level > 3 times upper limit of normal (ULN)
- Statin-associated elevation in creatine kinase (CK) level ≥ 10 times ULN
- Active liver disease, including unexplained persistent elevations in hepatic transaminase levels (e.g., alanine transaminase [ALT] level ≥ 3 times ULN)
- Pregnancy or planned pregnancy
- Breastfeeding

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Leqvio.
- The available compendium
 - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

- Micromedex DrugDex
- American Hospital Formulary Service- Drug Information (AHFS-DI)
- Lexi-Drugs
- Clinical Pharmacology
- Diagnosis and Treatment of Heterozygous Familial Hypercholesterolemia from the American Heart Association.
- National Lipid Association recommendations for patient-centered management of dyslipidemia.
- 2018 AHA/ACC guideline on the management of blood cholesterol: report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines.
- 2022 American College of Cardiology Expert Consensus Decision Pathway on the Role of Nonstatin therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk.
- 2024 Cardiovascular disease and risk management: standards of care in diabetes from American Diabetes Association.
- 2025 ACC/AHA/ACEP/NAEMSP/SCAI guideline for the management of patients with acute coronary syndromes: a report of the American College of Cardiology/American Heart Association Joint Committee on clinical practice guidelines.

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Leqvio and are included.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for the goal LDL-C to achieve with lipid-lowering therapy can be found in the expert consensus decision pathway on the role of nonstatin therapies published by the American College of Cardiology (ACC), the standard of care in diabetes for cardiovascular disease (CVD) and risk management published by American Diabetes Association (ADA), and the guideline for the management of patients with acute coronary syndromes (ACS) published by American College of Cardiology/American Heart Association (AHA/ACC) joint committee on clinical practice guidelines. According to ACC's report, patients with ASCVD are categorized into 2 groups: not at very high risk and at very high risk. LDL-C goal of ≤ 70 mg/dL is recommended for patients not at very high risk where ≤ 55 mg/dL is recommended for patients at very high risk. Very high-risk is defined as patients with a history of multiple ASCVD events or 1 major ASCVD event and multiple high-risk conditions. High-risk conditions defined by the report include: age 65 years or older, HeFH, history of prior coronary artery bypass surgery or percutaneous coronary intervention outside of the major ASCVD event(s), diabetes, hypertension, chronic kidney disease, current smoking, persistently elevated LDL-C despite on maximally tolerated statin therapy and ezetimibe, and history of congestive heart failure. In the CVD risk and management standards of care in diabetes from ADA, the ADA recommends LDL-C goal of < 55 mg/dL for patients with diabetes and ASCVD with a maximally tolerated statin, with the addition of ezetimibe or a PCSK9 inhibitor if this goal LDL-C is not achieved. If patient is intolerant to statin therapy, PCSK9 inhibitor concomitant therapy with bempedoic acid or Leqvio as an alternative cholesterol-lowering therapy is recommended. Similarly, the ACS guideline recommends adding a nonstatin lipid-lowering agent, including inclisiran, in patients with ACS who are already on maximally tolerated statin therapy with LDL-C ≥ 55 mg/dL or ≥ 70 mg/dL, to reduce the risk of major

adverse cardiovascular events (MACE). The guideline also recommends the use of nonstatin lipid-lowering therapy in those who are statin intolerant.

References

1. Leqvio [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2025.
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3. McGowan MP, Hosseini Dehkordi SH, Moriarty PM, et al. Diagnosis and Treatment of Heterozygous Familial Hypercholesterolemia. *J Am Heart Assoc*. 2019; 8:e013225.
4. Jacobson TA, Ito MK, Maki KC, et al. National Lipid Association recommendations for patient-centered management of dyslipidemia: part 1 — full report. *J Clin Lipidol*. 2015;9:129–169.
5. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA guideline on the management of blood cholesterol: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Circulation*. 2019;139(25):e1082– e1143.
6. Min JK, Labounty TM, Gomez MJ, et al. Incremental prognostic value of coronary computed tomographic angiography over coronary artery calcium score for risk prediction of major adverse cardiac events in asymptomatic diabetic individuals. *Atherosclerosis*. 2014;232(2):298-304.
7. Rosenson RS, Miller K, Bayliss M, et al. The statin-associated muscle symptom clinical index (SAMS-CI): revision for clinical use, content validation and inter-rater reliability. *Cardiovasc Drugs Ther*. 2017;31:179-186.
8. Warden BA, Guyton JR, Kovacs AC, et al. Assessment and management of statin-associated muscle symptoms (SAMS): A clinical perspective from the National Lipid Association. *J Clin Lipidol*. 2023;17(1):19-39.
9. Lloyd-Jones DM, Morris PB, Ballantyne CM. et al. 2022 ACC Expert consensus decision pathway on the role of nonstatin therapies for LDL-cholesterol lowering in the management of atherosclerotic cardiovascular disease risk: A report of the American college of cardiology solution set oversight committee. *J Am Coll Cardiol*. 2022;80(14):1366–1418.
10. Budoff MJ, Kinninger A, Gransar H, et al. When does a calcium score equate to secondary prevention?: Insights from the multinational CONFIRM registry. *JACC Cardiovasc Imaging*. 2023;16(9):1181-1189.
11. American Diabetes Association Professional Practice Committee. Cardiovascular disease and risk management: standards of care in diabetes – 2024. *Diabetes Care*. 2024;47(Suppl 1):S179-S218.
12. Rao SV, O’Donoghue ML, Ruel M, et al. 2025 ACC/AHA/ACEP/NAEMSP/SCAI guideline for the management of patients with acute coronary syndromes: a report of the American College of Cardiology/American Heart Association Joint Committee on clinical practice guidelines. *Circulation*. 2025;151(13):e771-e862.

CPT Codes / HCPCS Codes / ICD-10 Codes

Code	Description
Other CPT codes related to the Med B drug criteria:	

96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
HCPCS codes covered if selection criteria are met:	
J1306	Injection, inclisiran, 1 mg
ICD-10 codes covered if selection criteria are met:	
E78.00	Pure hypercholesterolemia, unspecified
E78.010	Homozygous familial hypercholesterolemia [HoFH]
E78.011	Heterozygous familial hypercholesterolemia [HeFH]
E78.019	Familial hypercholesterolemia, unspecified
E78.6	Lipoprotein deficiency

Revision History

Date	Version	Update	Revisions
01/01/2024	2023a	New Criteria	Policy effective.
06/27/2024	2024	Annual Review	Medicare Utilization Management Committee approved.
12/01/2024	2024a	Criteria Change	Initial authorization duration of approval changed from 6 months to 12 months. In clinical atherosclerotic cardiovascular disease (ASCVD) appendix coronary artery calcium (CAC) score for ASCVD equivalent risk lowered from greater than or equal to 1000 to greater than or equal to 300. Contraindications to statin therapy appendix related to creatine kinase (CK) elevation updated to: presence of statin-associated muscle symptoms with elevation in CK level > 3 times upper limit of normal (ULN) or statin-associated elevation in CK level greater than or equal to 10 times ULN.
07/01/2025	2025	Criteria Change	For members with clinical atherosclerotic cardiovascular disease (ASCVD), the current LDL-C (low-density lipoprotein-cholesterol) criteria added coverage for LDL-C greater than or equal to 55 mg/dL if the member has multiple high-risk conditions (e.g., 65 years of age or older, familial hypercholesterolemia, diabetes, chronic kidney disease, history of congestive heart failure) per the 2024 ADA guidelines on CVD update, further supported by the 2022 ACC Expert consensus decision pathway on the role of non-statin therapies.



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12/01/2025	2025a	Criteria Change	Relabeled coverage diagnosis of "primary hyperlipidemia including heterozygous familial cholesterolemia (HeFH)" to "hypercholesterolemia including HeFH" per FDA label update. Removed requirement to continue to receive concomitant statin therapy due to label update.
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See Evidence of Coverage for a complete description of plan benefits, exclusions, limitations and conditions of coverage. Plan features and availability may vary by service area.