



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Leqvio

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Effective Date: 10/10/2025

Last Review Date: 9/2025

Applies to:	<input checked="" type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input type="checkbox"/> New Jersey
	<input type="checkbox"/> Maryland	<input type="checkbox"/> Florida Kids	<input type="checkbox"/> Pennsylvania Kids
	<input type="checkbox"/> Texas	<input type="checkbox"/> Virginia	<input type="checkbox"/> Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Leqvio under the patient's prescription drug benefit.

Description:

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 are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Leqvio

Policy/Guideline:

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

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.



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Coverage Criteria

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

Authorization of 12 months may be granted for treatment of hypercholesterolemia when either 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

Authorization of 12 months may be granted for continued treatment in members (including new members) when the member has achieved or maintained an LDL-C reduction (e.g., LDL-C is now at goal, robust lowering of LDL-C).



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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 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

Approval Duration and Quantity Restrictions:

Initial Approval: 12 months

Renewal Approval: 12 months

Quantity Level Limit:

- Leqvio (inclisiran) 284 mg/1.5 mL (189 mg/mL) single-dose prefilled syringe:
 - 1 syringe per 180 days
 - Exception limit: 2 syringes per 270 days

References:

1. Leqvio [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2025.



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2. Raal FJ, Kallend D, Ray KK, et al. Inclisiran for the Treatment of Heterozygous Familial Hypercholesterolemia. *N Engl J Med.* 2020;382(16):1520-1530.
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10. Budoff MJ, Kinnering 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.
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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.