



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Leqvio

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Effective Date: 11/13/2023

Last Review Date: 10/10/2023

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

FDA-Approved Indications

Leqvio is indicated as an adjunct to diet and statin therapy for the treatment of adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce low-density lipoprotein cholesterol (LDL-C).

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Leqvio

Policy/Guideline:

I. Documentation

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

- A. Current LDL-C level for both initial and continuation requests. The level must be dated within six months preceding the authorization request.
- B. For members with clinical atherosclerotic cardiovascular disease (ASCVD), chart notes confirming clinical ASCVD (See Appendix A).
- C. For members without clinical atherosclerotic cardiovascular disease (ASCVD), untreated (before any lipid lowering therapy) LDL-C level).
- D. If member has contraindication or intolerance to statins, chart notes confirming the contraindication or intolerance (See Appendix B and C).

II. Criteria for Initial Approval:

The patient is unable to take Repatha, the preferred formulary alternative, due to a trial and inadequate treatment response or intolerance, or a contraindication.

Primary hyperlipidemia

Authorization may be granted for treatment of primary hyperlipidemia when ONE of the following criteria are met:

- A. Member meets ALL the following:



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1. Member has a history of clinical atherosclerotic cardiovascular disease (ASCVD) (See Appendix A).
2. Member meets ONE of the following:
 - i. Current LDL-C level \geq 70 mg/dL after 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.
 - ii. Current LDL-C level \geq 70 mg/dL with a contraindication or intolerance to statins (See Appendix B and C).
3. Member will continue to receive concomitant statin therapy if no contraindication or intolerance (See Appendix B and C).

B. Member meets ALL the following:

1. Member had an untreated (before any lipid-lowering therapy) LDL-C level \geq 190 mg/dL in the absence of a secondary cause.
2. Member meets ONE of the following:
 - i. Current LDL-C level \geq 100 mg/dL after 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.
 - ii. Current LDL-C level \geq 100 mg/dL with a contraindication or intolerance to statins (See Appendix B and C).

III. Criteria for Continuation of Therapy

Authorization may be granted for continued treatment when ALL the following criteria are met:

1. Member has achieved or maintained an LDL-C reduction (e.g., LDL-C is now at goal, robust lowering of LDL-C).
2. Member will continue to receive concomitant statin therapy if no contraindication or intolerance (See Appendix B and C).

Approval Duration and Quantity Restrictions:

Initial Approval: 6 months

Renewal Approval: 12 months

Quantity Level Limit: Reference Formulary for drug specific quantity level limits

IV. APPENDICES

APPENDIX A. Clinical ASCVD



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- 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
- Non-cardiac peripheral arterial disease (PAD) of presumed atherosclerotic origin (e.g., carotid artery stenosis, lower extremity PAD)
- Obstructive coronary artery disease (defined as fifty percent or greater stenosis on cardiac computed tomography angiogram or catheterization)
- Coronary Artery Calcium Score ≥ 1000

APPENDIX B. Statin-associated muscle symptoms (SAMS) and statin re-challenge

- Score of 7 or higher on the Statin-Associated Muscle Symptom Clinical Index
- Statin-associated elevation in creatine kinase level ≥ 10 times upper limit of normal

NOTE: Statin re-challenge is NOT required for members who have experienced an elevation of CK level ≥ 10 times ULN after receiving lipid-lowering therapy with a statin

APPENDIX C. Contraindications to statins

- 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

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11. 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. *J Am Coll Cardiol.* 2022 Oct, 80 (14) 1366–1418.