AETNA BETTER HEALTH® Coverage Policy/Guideline			
Name:	Leqvio	Page:	1 of 4
Effective Date:	6/6/2025	Last Review Date:	10/10/2023
Applies to:	☐Illinois ☒Maryland ☐Texas	☐Florida ☒Florida Kids ☐Virginia	☒New Jersey ☒Pennsylvania Kids ☒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:

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 ≥ 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 ≥ 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 ≥ 190 mg/dL in the absence of a secondary cause.
2. Member meets ONE of the following:
   i. Current LDL-C level ≥ 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 ≥ 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

- 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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