| AETNA BETTER HEALTH®<br>Coverage Policy/Guideline | | | |
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| Name: | Leqvio | Page: | 1 of 4 |
| Effective Date: | 7/14/2025 | Last Review Date: | 10/10/2023; 6/2025 |
| Applies to: | ☐Illinois<br>☒Maryland<br>☐Texas | ☐Florida<br>☒Florida Kids<br>☐Virginia | ☒New Jersey<br>☒Pennsylvania Kids<br>☒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 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:

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.

Both initial and continuation requests:

- LDL-C level must be dated within six months preceding the authorization request.
- If member has contraindication or intolerance to statins, chart notes or medical documentation confirming the contraindication or intolerance (see Appendix B).

### 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 including heterozygous familial hypercholesterolemia (HeFH)

Authorization of 12 months may be granted for treatment of primary hyperlipidemia 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 will continue to receive concomitant statin therapy if no contraindication or intolerance (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).
  - Member will continue to receive concomitant statin therapy if no contraindication or intolerance (see Appendix B).

### III. Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members (including new members) who meet both of the following criteria:

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

### 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

### 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 (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 fifty percent or greater stenosis on cardiac computed tomography angiogram or catheterization)
- Coronary Artery Calcium (CAC) Score ≥ 300

APPENDIX B. Contraindications to statin therapy

- 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 of 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

## References:

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12. 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.