AETNA BETTER HEALTH® Coverage Policy/Guideline			
Name:	Leqvio	Page:	1 of 4
Effective Date:	6/6/2025	Last Review Date:	4/2025
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:

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:

A. Initial requests:
   1. With clinical atherosclerotic cardiovascular disease (ASCVD): Chart notes confirming clinical ASCVD (see Appendix A).
   2. Without ASCVD: Untreated (before any lipid lowering therapy) LDL-C level.

B. Both initial and continuation requests:
   1. LDL-C level must be dated within six months preceding the authorization request.
   2. If member has contraindication or intolerance to statins, chart notes or medical record documentation confirming the contraindication or intolerance (see Appendix B).

II. Criteria for Initial Approval:

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:

A. Member meets all of the following criteria:
   1. Member has a history of clinical atherosclerotic cardiovascular disease (ASCVD) (see Appendix A).
   2. Member meets either of the following criteria:
      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).
   3. Member will continue to receive concomitant statin therapy if no contraindication or intolerance (see Appendix B).

B. Member meets all of the following criteria:
   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 either of the following criteria:
      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).
   3. Member will continue to receive concomitant statin therapy if no contraindication or intolerance (see Appendix B).

III. Criteria for 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:

A. Member has achieved or maintained an LDL-C reduction (e.g., LDL-C is now at goal, robust lowering of LDL-C).
B. 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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11. 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.