Draft Revised Policy: Do Not Implement

Inclisiran (Leqvio®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:

POLICY

INDICATIONS

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.

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) (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 record documentation confirming the contraindication or intolerance (See Appendix B).

COVERAGE 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:

- Member meets all of the following criteria:
  - Member has a history of clinical ~~atherosclerotic cardiovascular disease~~ ~~(~~ASCVD~~)~~ (See Appendix A).
  - Member meets either of the following criteria:

- Member has a 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.~~
- 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).
- ~~Current LDL-C level ≥ 70 mg/dL with a contraindication or intolerance to statins (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 meets one of the following:~~
  - ~~Current LDL-C level ≥ 100 mg/dL after~~ 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.
  - ~~Current LDL-C level ≥ 100 mg/dL~~ Member has ~~with~~ a contraindication or intolerance to statin~~s~~ 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).

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).

APPENDIX~~CES~~

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 ≥ 50 ~~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

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

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EFFECTIVE DATE

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