Leqvio (inclisiran)
Effective TBD

Plan	☐ MassHealth ☐ MassHealth (PUF) ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit (NLX)		
Specialty Limitations			
Contact Information	**Specialty Medications** All Plans | Phone: 866-814-5506 | Fax: 866-249-6155 **Non-Specialty Medications** MassHealth | Phone: 877-433-7643 | Fax: 866-255-7569 Commercial | Phone: 800-294-5979 | Fax: 888-836-0730 Exchange | Phone: 855-582-2022 | Fax: 855-245-2134 **Medical Specialty Medications (NLX)** All Plans | Phone: 844-345-2803 | Fax: 844-851-0882		
Exceptions	N/A		

Overview
Leqvio is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low-density lipoprotein cholesterol (LDL-C).

Coverage Guidelines
Authorization may be reviewed for members new to AllWays Health Partners who are currently receiving treatment with Leqvio excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

Clinical Atherosclerotic Cardiovascular Disease (ASCVD)

1. Member has a history of clinical ASCVD (see Appendix A)
2. Member meets ONE of the following:
    a. Current LDL-C level ≥70mg/dL after at least three months of treatment with documentation of a high-intensity statin (if member is unable to tolerate a high-intensity statin, a moderate intensity statin will be considered)
    b. Current LDL-C level ≥ 70mg/dL with documented contraindication or intolerance to statins (see Appendix B and C)
3. Member will continue to receive concomitant statin therapy if there are no contraindications or intolerance
4. Member has documented intolerance, adverse event, or contraindication to Praluent.

Heterozygous Familial Hypercholesterolemia (HeFH)

1. Member has a history of HeFH with a diagnosis confirmed by ONE of the following:
    a. Documentation of LDL-receptor mutation, familial defective apo B-100, or a PCSK9 mutation
    b. A documented history of untreated LDL-C of > 190mg/dL and meets at least ONE of the following criteria:
        i. Presence of tendon xanthoma(s) in the member or first/second degree relative
        ii. Family history of myocardial infarction (MI) at < 60 years in first degree relative or < 50 years in second degree relative
        iii. Family history of total cholesterol (TC) > 290mg/dL in a first/second degree relative
2. Member meets ONE of the following:
    a. Current LDL-C level ≥70mg/dL after at least three months of treatment with documentation of a high-intensity statin (if member is unable to tolerate a high-intensity statin, a moderate intensity statin will be considered)
    b. Current LDL-C level ≥ 70mg/dL with documented contraindication or intolerance to statins (see Appendix B and C)
3. Member will continue to receive concomitant statin therapy if there are no contraindications or intolerance
4. Member has documented intolerance, adverse event, or contraindication to Praluent.

Continuation of Therapy

Reauthorization requires physician documentation of continuation of therapy, positive response to therapy, and member has achieved maintained LDL-C reduction (e.g., LDL-C is now at goal, robust lowering of LDL-C). Documentation that member continues to receive statin therapy if there are no contraindications or intolerance.

Limitations

1. Initial approvals will be granted for 6 months.
2. Reauthorizations will be granted for 12 months

Appendix

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 ≥ 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 (SAMS-CI)
- Statin-associated elevation in creatine kinase (CK) level ≥ 10 times upper limit of normal (ULN)

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 (LLT) 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

References

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6. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC guideline on the management of blood cholesterol: report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2018.
7. Min JK, Labounty TM, Gomez MJ, et al. Incremental prognostic value of coronary computed tomographic angiography over coronary artery calcium score for risk prediction of major adverse cardiac events in asymptomatic diabetic individuals. *Atherosclerosis*. 2014;232(2):298-304.
8. Banach M, Rizzo M, Toth PP, et al. Statin intolerance – an attempt at a unified definition. Position paper from an International Lipid Expert Panel. *Arch Med Sci*. 2015;11:1-23.
9. Mesi O, Lin C, Ahmed H, et al. Statin Intolerance and New Lipid-lowering Treatments. Cleve Clin J Med. 2021; 88(7)381-387. DOI: 10.3949/ccjm.88a.20165.
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Review History

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