CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Ohio Medicaid

DRUG NAME	Leqvio (inclisiran)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Leqvio, approved by the FDA in 2021, is a small interfering RNA (siRNA) directed to proprotein convertase subtilisin kexin type 9 (PCSK9) messenger RNA (mRNA) indicated as an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults with hypercholesterolemia, adults and pediatric patients aged 12 years and older with heterozygous familial hypercholesterolemia (HeFH), and pediatric patients aged 12 years and older with homozygous familial hypercholesterolemia (HoFH).
Leqvio is a first-in-class siRNA that targets PCSK9 to inhibit its production in the liver, prolonging LDL receptor activity. Following induction, it is administered every 6 months by a healthcare professional, which may be beneficial for adherence in comparison to the PCSK9 monoclonal antibody (mAb) drugs.

Leqvio (inclisiran) will be considered for coverage when the following criteria are met:

Hypercholesterolemia

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Member has one of the following:
   a) Diagnosis of ASCVD (e.g., acute coronary syndromes (ACS), myocardial infarction (MI), stroke, angina, or peripheral arterial disease [PAD])
   b) ASCVD risk factor such as metabolic syndrome, chronic kidney disease, diabetes, or coronary artery calcium (CAC) score >300; AND
3. Member has a lipid panel within the past 90 days showing an LDL of at least 100 OR an LDL >55 with ASCVD and intolerance to Repatha or Praluent; AND
4. Member's LDL elevation is despite at least a 3-month adherent trial of high intensity or max tolerated statin therapy in combination with ezetimibe (unless there is documentation of clearly established statin intolerance or statin contraindication—see note*); AND
5. Leqvio will be taken as an adjunct to diet, exercise, and maximum tolerated statin therapy; AND
6. Medication will NOT be used in combination with any other drug that targets PCSK9.
7. **Dosage allowed/Quantity limit:** 284 mg as a single subQ injection initially, again at 3 months, and every 6 months thereafter.
   (QL: 2 syringes per 84 days for the first fill, then 1 syringe per 180 days thereafter; 1 syringe = 1.5 mL)

**Note: If not on statin therapy, member must have documented contraindication to all statin drugs or documentation of intolerance to at least 2 different statins, including low/moderate intensity or alternate dosing such as every other day.*

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Documentation in chart notes must demonstrate clinically meaningful LDL reduction compared to pre-treatment baseline.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Heterozygous Familial Hypercholesterolemia (HeFH)

For **initial** authorization:
1. Member is at least 12 years of age; AND
2. Medication must be prescribed by or in consultation with cardiologist, endocrinologist, or lipid specialist; AND
3. Member has a diagnosis of HeFH as documented by one of the following:
   a) Genetic testing (presence of LDL-R, ApoB, or PCSK9 mutation)
   b) Dutch Lipid Network score greater than 8 points
   c) "Definite" per Simon Broome criteria (i.e., LDL > 190 at baseline AND tendon xanthoma OR LDL-R, ApoB, or PCSK9 mutation); AND
4. Member has a lipid panel within the past 90 days showing LDL of 100 or greater; AND
5. Member's LDL is elevated despite at least a 3-month adherent trial of high intensity or max tolerated statin therapy in combination with ezetimibe (unless there is documentation of clearly established statin intolerance or statin contraindication—see note*); AND
6. Leqvio will be taken as an adjunct to diet, exercise, and maximum tolerated statin therapy; AND
7. Medication will NOT be used in combination with any other drug that targets PCSK9.
8. **Dosage allowed/Quantity limit:** 284 mg as a single subQ injection initially, again at 3 months, and every 6 months thereafter.
   (QL: 2 syringes per 84 days for the first fill, then 1 syringe per 180 days thereafter; 1 syringe = 1.5 mL)

**Note: If not on statin therapy, member must have documented contraindication to all statin drugs or documentation of intolerance to at least 2 different statins, including low/moderate intensity or alternate dosing such as every other day.*

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Documentation in chart notes must demonstrate clinically meaningful LDL reduction compared to pre-treatment baseline.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Homozygous Familial Hypercholesterolemia (HoFH)

For **initial** authorization:
1. Member is 12 to less than 18 years of age; AND
2. Medication must be prescribed by or in consultation with a lipid specialist, cardiologist, or endocrinologist; AND
3. Member has a diagnosis of homozygous familial hypercholesterolemia (HoFH) confirmed by one of the following:
   a) Genetic testing confirmation of two mutant alleles in the LDLR, Apo-B, PCSK9, or LDLRAP1 gene locus; OR
   b) LDL-C > 400 mg/dL before any treatment AND at least one of the following:
      i) Xanthoma before 10 years of age; and/or

ii) Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents; AND
4. Chart notes must include documentation of baseline LDL-C level, taken within the past 90 days; AND
5. Member is unable to achieve LDL-C goal (see Note) after an 8-week trial of a high-intensity/max-tolerated statin in combination with ezetimibe (unless there is documentation of clearly established statin intolerance or statin contraindication—see note*); AND
6. Levqio will be used as an adjunct to other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis), unless contraindicated or intolerant; AND
7. Prescriber attests that the member will follow a diet and exercise regimen; AND
8. Medication will NOT be used in combination with any other drug that targets PCSK9.
9. **Dosage allowed/Quantity limit:** 284 mg as a single subQ injection initially, again at 3 months, and every 6 months thereafter.
(QL: 2 syringes per 84 days for the first fill, then 1 syringe per 180 days thereafter; 1 syringe = 1.5 mL)

NOTE: The LDL-C goals for adults are <70 mg/dL or <55 mg/dL with additional ASCVD risk factors, or <115 mg/dL for children.

*NOTE: *If not on statin therapy, member must have documented contraindication to all statin drugs or documentation of intolerance to at least 2 different statins, including low/moderate intensity or alternate dosing such as every other day*.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Documentation in chart notes must demonstrate clinically meaningful LDL reduction compared to pre-treatment baseline.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Leqvio (inclisiran) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
01/24/2022	New policy created for Leqvio.
07/28/2023	Updated policy for label expansion to include primary hyperlipidemia/primary prevention (increased risk for ASCVD) rather than just the original ASCVD/secondary prevention population. Updated concomitant exclusion terminology to say PCSK9 mAB instead of PCSK9 inhibitor. Added detail to statin intolerance note regarding low/moderate intensity and alternate dosing. Changed LDL cutoff to 90 days instead of 30. Differentiated LDL cutoff of 55 for "very high risk" population. Added references. Added Simon Broome as option to meet diagnosis for HeFH.
05/03/2024	Added QL.
10/14/2025	Updated references. Changed "Primary Hyperlipidemia" header to "Hypercholesterolemia." Removed criteria option for LDL of 55 cut-off (AACE 2025); updated examples of ASCVD risk factors. Combined criteria for LDL goal and statin/ezetimibe trials. Added "exercise" to match label indication wording.
03/26/2026	Updated references. Changed "will not be concomitantly taking a PCSK9 mAb" to "will not be used in combination with any other drug that targets PCSK9." Added HoFH indication (label update).

	Hypercholesterolemia: Changed LDL cutoff from 70 to 100 and added LDL 55 cutoff with stipulations (Blumenthal 2026, sections 4.2.4.3 and 4.2.6). Updated ASCVD definition (Blumenthal 2026). HeFH: Updated age limit per label expansion. Added “exercise” per label. ODM approved on 07/16/2026.

References:

1. Leqvio [prescribing information]. Novartis Pharmaceuticals Corporation; 2026.
2. Raal FJ, Kallend D, Ray KK, et al. Inclisiran for the Treatment of Heterozygous Familial Hypercholesterolemia. *N Engl J Med*. 2020;382(16):1520-1530. doi:10.1056/NEJMoa1913805
3. Ray KK, Wright RS, Kallend D, et al. Two Phase 3 Trials of Inclisiran in Patients with Elevated LDL Cholesterol. *N Engl J Med*. 2020;382(16):1507-1519. doi:10.1056/NEJMoa1912387
4. McGowan MP, Hosseini Dehkordi SH, Moriarty PM, Duell PB. Diagnosis and Treatment of Heterozygous Familial Hypercholesterolemia. *J Am Heart Assoc*. 2019;8(24):e013225. doi:10.1161/JAHA.119.013225
5. Writing Committee, Lloyd-Jones DM, Morris PB, et al. 2022 ACC Expert Consensus Decision Pathway on the Role of Nonstatin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk: A Report of the American College of Cardiology Solution Set Oversight Committee [published correction appears in J Am Coll Cardiol. 2023 Jan 3;81(1):104]. *J Am Coll Cardiol*. 2022;80(14):1366-1418. doi:10.1016/j.jacc.2022.07.006
6. Albosta MS, Grant JK, Taub P, Blumenthal RS, Martin SS, Michos ED. Inclisiran: A New Strategy for LDL-C Lowering and Prevention of Atherosclerotic Cardiovascular Disease. *Vasc Health Risk Manag*. 2023;19:421-431. Published 2023 Jul 6. doi:10.2147/VHRM.S338424
7. Patel SB, Wyne KL, Afreen S, et al. American Association of Clinical Endocrinology Clinical Practice Guideline on Pharmacologic Management of Adults With Dyslipidemia. *Endocr Pract*. 2025;31(2):236-262. doi:10.1016/j.eprac.2024.09.016
8. Patel SB, Belalcazar LM, Afreen S, et al. American Association of Clinical Endocrinology Consensus Statement: Algorithm for Management of Adults with Dyslipidemia - 2025 Update. *Endocr Pract*. 2025;31(10):1207-1238. doi:10.1016/j.eprac.2025.07.014
9. Cuchel M, Raal FJ, Hegele RA, et al. 2023 Update on European Atherosclerosis Society Consensus Statement on Homozygous Familial Hypercholesterolaemia: new treatments and clinical guidance. *Eur Heart J*. 2023;44(25):2277-2291. doi:10.1093/eurheartj/ehad197
10. Blumenthal RS, Morris PB, Gaudino M, et al. 2026 ACC/AHA/AACVPR/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Dyslipidemia: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol*. Published online March 13, 2026. doi:10.1016/j.jacc.2025.11.016
11. Ohio Administrative Code. (2022, February 23). 5160-1-01 (C) Medicaid medical necessity: definitions and principles. Retrieved February 22 2023 from codes.ohio.gov.
12. Ohio Administrative Code. (2022, July 18). 5160-26-03 Managed care: covered services. Retrieved February 22, 2023 from codes.ohio.gov.
13. Ohio Administrative Code. (2020, January 1). 5160-9-03 Pharmacy services: covered drugs and associated limitations. Retrieved February 22, 2023 from codes.ohio.gov.

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