PHARMACY POLICY STATEMENT
TRICARE

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, including heterozygous familial hypercholesterolemia (HeFH).
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:

Heterozygous Familial Hypercholesterolemia (HeFH)

For **initial** authorization:
1. Member is at least 18 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 and maximum tolerated statin therapy; AND
7. Member will NOT be concomitantly taking a PCSK9 mAb (e.g., Repatha, Praluent).
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.

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., coronary heart disease [CHD], cardiovascular disease [CVD], 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 70 mg/dL or greater 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
4. Leqvio will be taken as an adjunct to diet, exercise, and maximum tolerated statin therapy; AND
5. Member will NOT be concomitantly taking a PCSK9 mAb (e.g., Repatha, Praluent).
6. **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.

TRICARE Prime® Demo by CareSource Military & Veterans™ 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.

References:

1. Leqvio [prescribing information]. Novartis Pharmaceuticals Corporation; 2025.
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. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC Guideline on the Management of Blood Cholesterol. *JACC*. 2018;73(24)doi:10.1016/j.jacc.2018.11.002.
6. 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
7. 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
8. 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
9. 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

Effective date: 04/01/2026
Revised date: 10/14/2025