

PHARMACY POLICY STATEMENT

Marketplace

DRUG NAME	Leqvio (inclisiran)
BILLING CODE	J3490
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office
STATUS	Prior Authorization Required

Leqvio was approved by the FDA in December 2021 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). Leqvio is a first-in-class small interfering RNA (siRNA) that lowers LDL by acting against PCSK9 messenger RNA (mRNA). Following induction, it is administered every 6 months by a healthcare professional, which may be beneficial for adherence.

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 Criteria score greater than 8 points
4. Member has a lipid panel within the past 30 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 inhibitor.
8. **Dosage allowed/Quantity limit:** 284 mg as a single subQ injection initially, again at 3 months, and every 6 months thereafter.

**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.*

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.

Atherosclerotic Cardiovascular Disease (ASCVD)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Member has a history of ASCVD (coronary heart disease [CHD], cardiovascular disease [CVD], or peripheral arterial disease [PAD]); AND
3. Member has a lipid panel within the past 30 days showing LDL of 70 or greater; AND
4. 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
5. Leqvio will be taken as an adjunct to diet and maximum tolerated statin therapy; AND
6. Member will NOT be concomitantly taking a PCSK9 inhibitor.
7. **Dosage allowed/Quantity limit:** 284 mg as a single subQ injection initially, again at 3 months, and every 6 months thereafter.

**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.*

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.

References:

1. Leqvio [prescribing information]. Novartis Pharmaceuticals Corporation; 2021.
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.

Effective date: 07/01/2022

Revised date: 01/24/2022