Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Leqvio® (inclisiran)

Effective: January 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Public Plans Products

☒ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☒ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☒ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☒ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Overall, in the United States, almost 1 in 10 people are estimated to have some form of atherosclerotic cardiovascular disease (ASCVD), and ASCVD remains the leading cause of death. An estimated ~62.6 million American adults have elevated low-density lipoprotein cholesterol (LDL-C) and are eligible to use statins. Approximately 27.4 million U.S. adults with elevated LDL-C levels are taking a statin. Approximately 19.4 million patients with elevated LDL-C levels currently taking statins are not able to get to their LDL-C goal. Another 9.5 million people are not able to tolerate statins. Leqvio is approved for use 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).

Inclisiran is a double-stranded small interfering ribonucleic acid (siRNA), conjugated on the sense strand with triantennary N-Acetylgalactosamine (GalNAc) to facilitate uptake by hepatocytes. In hepatocytes, inclisiran utilizes the ribonucleic acid (RNA) interference mechanism and directs catalytic breakdown of messenger RNA for proprotein convertase subtilisin/kexin type 9 (PCSK9). This increases LDL-C receptor recycling and expression on the hepatocyte cell surface, which increases LDL-C uptake and lowers LDL-C levels in the circulation.

Leqvio is a first-in-class small interfering RNA (siRNA) with a new mechanism of action that lowers LDL-C (also known as bad cholesterol) with 2 doses per year. The initial dose of Leqvio is 284 mg, administered as a subcutaneous injection by a healthcare provider, then again at 3 months, and then every 6 months.

The FDA based its approval on results from the ORION clinical research program, which included three Phase 3 trials in more than 3400 patients with ASCVD or HeFH who had elevated LDL-C while on a maximally tolerated dose of statin therapy. In the trials, Leqvio demonstrated effective and sustained LDL-C reduction of up to 52% at Month 17 versus placebo. Leqvio was well tolerated in the studies, with a safety profile comparable to placebo.

Food and Drug Administration (FDA) Approved Indications:

Leqvio (inclisiran) is a small interfering RNA (siRNA) directed to PCSK9 (proprotein convertase subtilisin kexin type 9) mRNA 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

The effect of Leqvio on cardiovascular morbidity and mortality has not been determined.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Leqvio when **ALL** of the following clinical criteria is met:

1. Documented diagnosis of primary hyperlipidemia, including heterozygous familial hypercholesterolemia or to reduce low-density lipoprotein cholesterol

AND

2. Documentation of **one (1)** of the following:
    a. Member is receiving statin therapy
    b. Member is statin intolerant

AND

3. The Member is 18 years of age or older

Limitations

- None

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J1306	Injection, inclisiran, 1 mg

References:

1. Leqvio (inclisiran). East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2024.
2. Raal F, et al. Inclisiran for the treatment of heterozygous familial hypercholesterolemia. N Engl J Med. 2020;382(16):1520–1530.

Approval And Revision History

April 19, 2023: year: Reviewed by the Medical Policy Approval Committee (MPAC).

May 9, 2023: Reviewed by Pharmacy and Therapeutics Committee (P&T).

Subsequent endorsement date(s) and changes made:

- Originally approved September 13, 2022, by P&T and September 21, 2022 by MPAC committees effective January 1, 2023.
- Administrative update: April 2023 added Medical Benefit Drugs to title and updated MATogether and RITogether fax numbers to 617-673-0939.
- May 17, 2023: Annual review, no change, effective July 1, 2023.
- August 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024.
- November 2023: Administrative Update in support of calendar year 2024 Medicare Advantage and PDP Final Rule.
- November 12, 2024: Removed the Limitations “The Plan may authorize coverage of Leqvio for up to 12 months if criteria are met.” and “Any indications other than FDA-approved indications are considered experimental or investigational and will not be approved by the Plan.” Updated diagnosis requirements to be in line with package labeling. Added the requirement that the member is receiving statin therapy or is statin intolerant (eff 2/1/25).
- December 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 2/1/25).
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- December 9, 2025: No changes (eff 1/1/26)
- December 2025: Joint Medical Policy and Health Care Services UM Committee review (effective 1/1/26)

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guidelines not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when

applicable, and adherence to plan policies, plan procedures, and claims editing logic.