Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:
Medical Benefit Drugs
Leqvio (inclisiran)

Effective: September 1, 2026

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

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☒ Tufts Health Plan Commercial products; Fax 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ 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

Food and Drug Administration (FDA) Approved Indications:

Leqvio (inclisiran) is a small interfering RNA (siRNA) directed to proprotein convertase subtilisin kexin type 9 (PCSK9) 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)
- pediatric patients aged 12 years and older with homozygous familial hypercholesterolemia (HoFH)

Clinical Guideline Coverage Criteria

The Plan may authorize initial coverage of Leqvio (inclisiran) for Members when **ALL** of the following criteria are met:

Clinical atherosclerotic cardiovascular disease

1. Documentation the Member has a history of clinical atherosclerotic cardiovascular disease or has experienced a cardiovascular event

AND

2. Documentation the Member has a current LDL-C level ≥ 70 mg/dL while on maximally tolerated statin therapy in combination with ezetimibe (unless member has a contraindication or history of intolerance to each such therapy)

AND

3. Documentation of at least one of the following:
   a. Member has a contraindication to statin therapy (e.g., rhabdomyolysis or significant allergic reaction)
   b. Member is statin intolerant to at least two statin medications
   c. Member is receiving maximally tolerated statin therapy

AND

4. Documentation of at least one of the following:
   a. Member is currently on ezetimibe
   b. Member has history of contraindication or intolerance to ezetimibe

AND

5. The member has tried and failed, has a contraindication to, or is not a candidate for a PCSK9 Inhibitor (e.g., Repatha)

Primary Hyperlipidemia or Heterozygous familial hypercholesterolemia

1. Documented diagnosis of primary hyperlipidemia or heterozygous familial hypercholesterolemia (HeFH)

AND

2. Documentation the Member had an untreated (i.e., before any lipid lowering therapy was initiated) LDL-C level ≥ 190 mg/dL

AND

3. Documentation the Member has a current LDL-C level ≥ 100 mg/dL while on maximally tolerated statin therapy in combination with ezetimibe (unless member has a contraindication or history of intolerance to each such therapy)

AND

4. Documentation of at least one of the following:
   a. Member has a contraindication to statin therapy (e.g., rhabdomyolysis or significant allergic reaction)
   b. Member is statin intolerant to at least two statin medications
   c. Member is receiving maximally tolerated statin therapy

AND

5. Documentation of at least one of the following:
   a. Member is currently on ezetimibe
   b. Member has history of contraindication or intolerance to ezetimibe

AND

6. The member has tried and failed, has a contraindication to, or is not a candidate for a PCSK9 Inhibitor (e.g., Repatha)

Homozygous familial hypercholesterolemia

1. Documentation of diagnosis of homozygous familial hypercholesterolemia (HoFH) received by, or in written consultation with (documentation required), a lipid specialist (e.g., cardiologist, endocrinologist, lipid specialist/lipidologist)

AND

2. Confirmed diagnosis of homozygous familial hypercholesterolemia (HoFH) based on both of the following (a and b):
   a. Documentation of one of the following:
      i. Documented genetic mutation at both alleles of at least one of the following genes by an FDA approved generic test: low-density lipoprotein receptor (LDLR), Apolipoprotein B (apo B), or Proprotein convertase subtilisin kexin type 9 (PCSK9)

OR

      ii. Documentation that genetic testing was completed, and results are negative, where the provider attests the member has a mutation that may cause FH but remains unknown.

AND

   b. Recognized diagnostic criteria is met (documentation provided):
      i. Dutch Lipid Clinic criteria

OR

      ii. Simon Broome criteria

AND

3. Member is concurrently taking other lipid-lowering medication(s), or the provider indicates clinical inappropriateness for concurrent use with other lipid-lowering medication(s)

AND

4. Member is 12 to 17 years of age

AND

5. The Member has demonstrated an inadequate response to an appropriate trial with or a contraindication and or intolerance to each of the following classes:
   a. Maximally tolerated statin
   b. PCSK9 Inhibitor
   c. Ezetimibe

AND

6. A baseline LDL-C is provided

Reauthorization Criteria:

The Plan may reauthorize coverage of Leqvio for Members when all the following criteria are met:

1. Documentation the member shows an improvement from baseline in LDL-C.

Limitations

- Initial authorization will be limited to 12 months. Subsequent reauthorization requests may be given in 12-month intervals for Members who are continuing therapy.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J1306	Injection, inclisiran, 1 mg

References:

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4. Food and Drug Administration (FDA). Drugs@FDA. Accessed December 27, 2021. http://www.accessdata.fda.gov/scripts/cder/drugsatfda
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11. National institute of Health and Care Excellence (NICE). Inclisiran for treating primary hypercholesterolaemia or mixed dyslipidaemia (TA733). Published October 6, 2021. Accessed December 27, 2021. https://www.nice.org.uk/guidance/ta733.
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14. Raal FJ, Honarpour N, Blom DJ, et al. Inhibition of PCSK9 with evolocumab in homozygous familial hypercholesterolaemia (TESLA Part B): a randomised, double-blind, placebo-controlled trial. Lancet. 2015a;385(9965):341-350. doi:10.1016/S0140-6736(14)61374-X.
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Approval And Revision History

April 19, 2023: 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
- November 14, 2023: Added coverage for the expanded indication for Leqvio in primary hyperlipidemia (effective 12/1/23).
- November 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024.
- August 13, 2024: Effective January 1, 2025, defined statin intolerance as intolerance to at least two statin medications. Added rhabdomyolysis or significant allergic reaction as examples of contraindications to statin therapy. Added criterion for member to be on maximally tolerated statin therapy in combination with ezetimibe (unless member has a contraindication or history of intolerance to each such therapy). Administrative update to clarify documented diagnosis of primary hyperlipidemia or HeFH.
- August 12, 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- August 11, 2026: Added coverage criteria for Leqvio's supplemental indication in pediatric patients aged 12 years and older with HoFH. Administrative updates: Updated overview with Leqvio's expanded age in patients 12 years of age and older with HeFH. Template updated to remove CareLink from the Medical Necessity Guideline template. Template updated from "Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans" to "Tufts Health Together- MassHealth Accountable Care Partnership Plans."

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is 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.