AvMed

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-877-535-1391**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Leqvio® (inclisiran) **(J1306) (Medical)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Recommended Dosage: SUBQ: Initial: 284 mg as a single injection, again at 3 months, and then every 6 months thereafter

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 12 months

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Section I. Universal Criteria: Applicable for **ALL** Diagnoses

- ❑ Must be prescribed by or in consultation with a Cardiologist, Endocrinologist or Lipid Specialist
- ❑ Medication will be used as adjunct to low-fat diet and exercise
- ❑ Provider has **COMPLETED** Sections II, IIIa or IIIb and IV below

Section II. Diagnoses: (select one below)

❑ Diagnosis: Hypercholesterolemia

NOTE: This is not associated with atherosclerotic cardiovascular disease (ASCVD), heterozygous familial hypercholesterolemia (HeFH), or homozygous familial hypercholesterolemia (HoFH) and may be referred to as combined hyperlipidemia, hypercholesterolemia (pure, primary), dyslipidemia, or increased/elevated low-density lipoprotein cholesterol (LDL-C) levels.

- ❑ Member is 18 years of age or older
- ❑ Member meets **ONE** of the following:
  - ❑ Member has a baseline low-density lipoprotein cholesterol (LDL-C) ≥ 190 mg/dL
  - ❑ Member has an estimated 10-year risk for ASCVD greater than 7.5% and a baseline LDL-C between 70 to 189 mg/dL
  - ❑ Member is an adult with diabetes mellitus with LDL-C ≥ 70 mg/dL
- ❑ Provider has completed sections IIIa or IIIb and IV

❑ Diagnosis: Atherosclerotic Cardiovascular Disease

- ❑ Member is 18 years of age or older and has Atherosclerotic Cardiovascular Disease (ASCVD) confirmed by at least **ONE** of the following:
  - ❑ History of acute coronary syndrome
  - ❑ Previous myocardial infarction
  - ❑ Stable or unstable angina
  - ❑ Peripheral arterial disease
  - ❑ Coronary artery disease
  - ❑ Member has undergone coronary or other arterial revascularization procedure in the past
  - ❑ History of non-hemorrhagic stroke
  - ❑ History of Transient ischemic attack
- ❑ Provider has completed sections IIIa or IIIb and IV

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❑ Diagnosis: Heterozygous familial hypercholesterolemia (HeFH)

- ❑ Member is 12 years of age or older and has heterozygous familial hypercholesterolemia (HeFH) as confirmed by the following:
  - ❑ Member meets **ONE** of the following:
    - ❑ Member has an untreated low-density lipoprotein cholesterol (LDL-C) ≥ 190 mg/dL or ≥ 160 mg/dL for pediatric members (prior to treatment with antihyperlipidemic therapy)
    - ❑ Member has genetic confirmation of heterozygous familial hypercholesterolemia by mutations in the low-density lipoprotein receptor, apolipoprotein B, proprotein convertase subtilisin kexin type 9, or low-density lipoprotein receptor adaptor protein 1 gene
    - ❑ Member has been diagnosed with heterozygous familial hypercholesterolemia by meeting **ONE** of the following diagnostic criteria thresholds:
      - ❑ Member's Dutch Lipid Network criteria score is > 5
      - ❑ Member's Simone Broome criteria meets the threshold for "definite" or "possible (or probable)" familial hypercholesterolemia
- ❑ Provider has completed sections IIIa or IIIb and IV

❑ Diagnosis: Homozygous familial hypercholesterolemia (HoFH)

- ❑ Member is between the ages of 12 to below 18 years old and has homozygous familial hypercholesterolemia (HoFH) as confirmed by the following:
  - ❑ Member meets **ONE** of the following:
    - ❑ Member has genetic confirmation of two mutant alleles at the low-density lipoprotein receptor, apolipoprotein B, proprotein convertase subtilisin kexin type 9 (PCSK9), or low-density lipoprotein receptor adaptor protein 1 gene locus **AND** does **NOT** have null/null variant in LDLR
    - ❑ Member has an untreated low-density lipoprotein cholesterol (LDL-C) level > 400 mg/dL **AND** meets **ONE** of the following:
      - ❑ Member has had clinical manifestations of homozygous familial hypercholesterolemia before the age of 10 (e.g., xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas, or xanthelasma)
      - ❑ Members parents both have had untreated LDL-C levels or total cholesterol levels consistent with heterozygous familial hypercholesterolemia (i.e., both parents have had an untreated LDL-C level ≥ 190 mg/dL and/or an untreated total cholesterol level > 250 mg/dL
    - ❑ Member has a treated LDL-C level ≥ 300 mg/dL **AND** meets **ONE** of the following:
      - ❑ Member has had clinical manifestations of homozygous familial hypercholesterolemia before the age of 10 (e.g., xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas, or xanthelasma)
      - ❑ Member's parents both have had untreated LDL-C levels or total cholesterol levels consistent with heterozygous familial hypercholesterolemia (i.e., both parents have had an untreated LDL-C level ≥ 190 mg/dL and/or an untreated total cholesterol level > 250 mg/Dl

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- ❑ Provider has completed sections IIIa or IIIb and IV

Section IIIa. FOR ALL DIAGNOSES: Skip to Section IIb **IF** member is unable to tolerate statin therapy

- ❑ Member has tried **ONE** of the following statin therapies as a single-entity or combination product for at least 8 consecutive weeks:
  - ❑ High intensity statin therapy with atorvastatin (generic Lipitor) ≥ 40 mg daily
  - ❑ High intensity statin therapy rosuvastatin (generic Crestor) ≥ 20 mg daily
  - ❑ Moderate-intensity statin therapy (member unable to tolerate high intensity therapy)
  - ❑ Low intensity statin therapy (member unable to tolerate moderate intensity therapy
- ❑ Member must meet **ONE** of the following:
  - ❑ Member's LDL-C after 8-week trial of maximally tolerated statin therapy remains ≥ 70 mg/dL
  - ❑ Member's LDL-C after 8-week trial of maximally tolerated statin therapy remains ≥ 55 mg/dL in those with a diagnosis of ASCVD
  - ❑ Member's LDL-C after 8-week trial of maximally tolerated statin therapy remains ≥ 130 mg/dL in children with a diagnosis of HeFH or HoFH
- ❑ Please provide member's LDL levels below **(submit lab results)**:

  LDL baseline: _____**LDL post-treatment:** _____

Section IIIb. FOR ALL DIAGNOSES: Contraindication to statin therapy

- Select below if the member is unable to tolerate low, moderate, and high intensity statin therapy as evidenced by intolerable and persistent symptoms to **TWO** different statins (i.e., more than 2 weeks); Please provide previously attempted statin name, strength & therapy initiation date below:

  Drug Name: _____ **Strength:** _____ **Date started:** _____

  Drug Name: _____ **Strength:** _____ **Date started:** _____

  - ❑ Member is unable to tolerate statin therapy due to the occurrence of at least **ONE** of the following symptoms:
    - ❑ Myalgia (muscle symptoms without CK elevations)
    - ❑ Myositis (muscle symptoms with CK elevations < 10 times upper limit of normal)
    - ❑ Member has experienced rhabdomyolysis or muscle symptoms with CK elevations > 10 times upper limit of normal
    - ❑ Member has a labeled contraindication to **ALL** statins as documented in medical records
  - ❑ Re-initiation of statin therapy has been attempted and failed
  - ❑ Please provide member's LDL levels below **(submit lab results)**:

    LDL baseline: _____ **LDL post-treatment:** _____

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Section IV. Prerequisite Therapy:

- ❑ Member must meet **ONE** of the following:
  - ❑ Member has tried and failed at least 90 days of therapy with Repatha® **(verified by claims, chart notes, and/or labs)**
  - ❑ Member has a contraindication or intolerance to Repatha® **(verified by chart notes and/or labs)**

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member has experienced a positive clinical response to Leqvio therapy (e.g., decreasing low-density lipoprotein cholesterol (LDL-C), total cholesterol, non-high-density lipoprotein (non-HDL-C), or apolipoprotein B levels) and continues to have need of requested medication
- ❑ Please provide member's LDL levels below **(submit lab results)**:

  LDL baseline: _____**LDL post-treatment:** _____

Medication being provided by (check applicable box(es) below):

❑ **Physician's office** **OR** ❑ **Specialty Pharmacy – Proprium Rx**

For urgent reviews: Practitioner should call AvMed Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.*

***Approved by Pharmacy and Therapeutics Committee**: ~~3/17/2022; 11/17/2023; 9/26/2024; 5/28/2026;~~ **7/23/2026**
REVISED/UPDATED/REFORMATTED: ~~5/4/2022; 6/15/2022; 6/16/2022; 12/11/2023; 10/15/2024; 6/15/2026;~~ **8/28/2026**