

AvMed

PHARMACY 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 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Lerochol® (lerodalcibep-liga)

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: _____

Quantity Limit: 300 mg/1.2 mL prefilled syringe – one syringe per month

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

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 (if applicable) below

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Section II. Diagnosis: (select one below)

☐ Diagnosis: Hypercholesterolemia

- ☐ 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
 - ☐ Member 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
- ☐ Member does **NOT** have homozygous familial hypercholesterolemia (HoFH)
- ☐ Provider has completed sections IIIa or IIIb and IV (if applicable)

☐ Diagnosis: Heterozygous familial hypercholesterolemia (HeFH)

- ☐ Member is 18 years of age or older
- ☐ Member has heterozygous familial hypercholesterolemia (HeFH) as confirmed by **ONE** of the following:
 - ☐ Member has an untreated low-density lipoprotein cholesterol (LDL-C) ≥ 190 mg/dL (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

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- ☐ Member does **NOT** have homozygous familial hypercholesterolemia (HoFH)
- ☐ Provider has completed sections IIIa or IIIb and IV (if applicable)

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
- ☐ Please provide member's LDL levels below (**submit current 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 current lab results**):

LDL baseline: _____ LDL post-treatment: _____

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Section IV. FOR ALL DIAGNOSES:

- ☐ 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 Lerochol therapy (e.g., decreasing low-density lipoprotein cholesterol (LDL-C), total cholesterol, non-high-density lipoprotein (non-HDL-C)) and continues to have need of requested medication
- ☐ Please provide member's LDL levels below (submit current lab results):

LDL baseline: _____ LDL post-treatment: _____

Medication being provided by Specialty Pharmacy – Proprium Rx

Not all drugs may be covered under every Plan

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

*****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.****