# 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:** (select drug below)

| | |
|---|---|
| ❑ **Praluent®** (alirocumab) | ❑ **Repatha®** (evolocumab) |

**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 Name/Form/Strength:** _____

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

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

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

| DRUG | QUANTITY LIMIT |
|---|---|
| PRALUENT 150 MG/ML PEN | 2 pens per 28 days |
| PRALUENT 75 MG/ML PEN | 2 pens per 28 days |
| REPATHA 140 MG/ML SURECLICK | 3 auto-injectors per 28 days |
| REPATHA 140 MG/ML SYRINGE | 3 syringes per 28 days |
| REPATHA 420 MG/3.5ML PUSHTRONX | 1 cartridge per 28 days |

**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
- ❑ For all diagnosis **EXCEPT** major adverse cardiovascular events (MACE) risk reduction: Medication will be used as adjunct to low-fat diet
- ❑ Provider has **COMPLETED** Sections II, IIIa or IIIb and IV (if applicable) 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, dyslipidemia, or increased/elevated low-density lipoprotein cholesterol (LDL-C) levels. Criteria is applicable for adults with increased risk of major adverse cardiovascular events (cardiovascular death, myocardial infarction, stroke, unstable angina requiring hospitalization, or coronary revascularization).

- ❑ Member must meet **ALL** the following:
  - ❑ 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's LDL-C after 8-week trial of maximally tolerated statin therapy remains ≥ 70 mg/dL **AND** provider has completed sections IIIa or IIIb
    - ❑ 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

### ❑ 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 & IV if applicable

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## ❑ Diagnosis: Heterozygous familial hypercholesterolemia (HeFH)

- ❑ Member is 10 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 (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:
      - ❑ Provider attests member's Dutch Lipid Network criteria score was > 5
      - ❑ Provider attests that Simone Broome criteria met the threshold for "definite" or "possible (or probable)" familial hypercholesterolemia
- ❑ Provider has completed sections IIIa or IIIb & IV if applicable

## ❑ Diagnosis: Homozygous familial hypercholesterolemia (HoFH)

- ❑ Member is 10 years of age or older 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
    - ❑ Member has an untreated low-density lipoprotein cholesterol (LDL-C) level > 500 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)
      - ❑ 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
- ❑ Provider has completed sections IIIa or IIIb & IV if applicable

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**Section IIIa. FOR ALL DIAGNOSES:** Skip to Section IIIb **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:

  **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:

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

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## Section IV. FOR ALL PRALUENT REQUESTS:

- ❑ 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:** 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.

**Provider please note: a one-time reauthorization is required after initial 12-month approval**

- ❑ Provider attests member has experienced a positive clinical response to PCSK9 therapy (e.g., decreasing low-density lipoprotein cholesterol (LDL-C), total cholesterol, non-high-density lipoprotein (non-HDL-C), or apolipoprotein B levels)

## 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.****



***Approved by Pharmacy and Therapeutics Committee**: ~~9/17/2015; 9/21/2023; 11/16/2023; 9/26/2024;~~ **1/22/2026**
**REVISED/UPDATED/REFORMATTED:** ~~9/28/2015; 10/14/2015; 10/19/2015; 11/4/2015; 11/10/2015; 11/19/2015; 12/29/2015; 12/19/2016; 8/16/2017. 6/28/2018; 10/26/2018; 10/14/2014; 11/8/2021; 11/22/2021; 4/26/2022; 6/13/2022; 6/17/2022; 8/26/2022; 10/17/2023; 12/11/2023; 10/15/2024;~~ **2/11/2026**