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

- ❑ For all diagnosis **EXCEPT** major adverse cardiovascular events (MACE) risk reduction: 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

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
    - ❑ 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
  - ❑ Provider has completed sections IIIa or IIIb & IV if applicable

❑ 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 meets **ONE** of the following:
  - ❑ Repatha requests: Member is 10 years of age or older
  - ❑ Praluent requests: Member is 8 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 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:
    - ❑ 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 meets **ONE** of the following:
  - ❑ Repatha requests: Member is 10 years of age or older
  - ❑ Praluent requests: Member is 18 years of age or older
- ❑ Member has homozygous familial hypercholesterolemia (HoFH) as confirmed by **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)
    - ❑ 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 & IV if applicable

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®, or Repatha® is not FDA-approved in the member's age **(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; 5/28/2026;~~ **7/23/2026**
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; 6/15/2026;~~ **8/28/2026**