

# SENTARA HEALTH PLANS

## 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 1-800-750-9692.** 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)

<input type="checkbox"/> Praluent <sup>®</sup> (alirocumab)	<input type="checkbox"/> Repatha <sup>®</sup> (evolocumab)
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**MEMBER & PRESCRIBER INFORMATION:** Authorization may be delayed if incomplete.

Member Name: \_\_\_\_\_

Member Sentara #: \_\_\_\_\_ 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)  $\geq 190$  mg/dL
    - Member's LDL-C after 8-week trial of maximally tolerated statin therapy remains  $\geq 70$  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)  $\geq 190$  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  $\geq 190$  mg/dL and/or an untreated total cholesterol level  $> 250$  mg/dL)
    - ❑ Member has a treated LDL-C level  $\geq 300$  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  $\geq 190$  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)  $\geq 40$  mg daily
  - High intensity statin therapy rosuvastatin (generic Crestor)  $\geq 20$  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  $\geq 70$  mg/dL
  - Member's LDL-C after 8-week trial of maximally tolerated statin therapy remains  $\geq 55$  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.\****