

**Prior Authorization (PA) Form**

**PROPROTEIN CONVERTASE SUBTILISIN KEXIN TYPE 9 (PCSK9)**

If the following information is not complete, correct, or legible, the PA process can be delayed.

Please use one form per member.

**MEMBER INFORMATION**

Last Name:

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First Name:

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Medicaid ID Number:

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Date of Birth:

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Gender:  Male  Female

Is Member Over 18 Years of Age?  Yes  No

**PRESCRIBER INFORMATION**

Last Name:

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First Name:

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NPI Number:

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Phone Number:

			-				-				
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Fax Number:

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Specialty: Is the drug prescribed by or in consultation with a specialist?

Cardiologists  Lipidologists  Endocrinologists  Other: \_\_\_\_\_

**DRUG INFORMATION**

Drug Name/Form: \_\_\_\_\_

Strength: \_\_\_\_\_

Dosing Frequency: \_\_\_\_\_

Length of Therapy: \_\_\_\_\_

Quantity per Day: \_\_\_\_\_

(Form continued on next page.)

Member's Last Name:

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Member's First Name:

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**CRITERIA**

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1. Indications the drug is being prescribed for?
  - Homozygous familial hypercholesterolemia (HoFH)
  - Heterozygous familial hypercholesterolemia (HeFH)
  - Clinical atherosclerotic cardiovascular disease (ASCVD) or history of a cardiovascular event without homozygous/heterozygous familial hypercholesterolemia
  - Other
  
2. Has the member been able to achieve target LDL-C levels using other lipid-lowering interventions?
  - Yes  No
  
3. Has the member had prior treatment history with highest available dose or maximally-tolerated dose of high intensity statin (atorvastatin or rosuvastatin) AND ezetimibe for at least three continuous months with failure to reach target LDL-C **and** is in one of the 3 groups identified by NLA; extremely high risk ASCVD members with LDL-C  $\geq 70$  mg/dL, very high risk ASCVD members with LDL-C  $\geq 100$  mg/dL, and high risk members with LDL-C  $\geq 130$  mg/dL.
  - Yes  No
  
4. Is this request for a new start or continuation of Praluent/Repatha therapy?
  - Yes  No
    - a. If New start, skip to diagnosis section  New Start  Continuation
  
5. Was Praluent/Repatha previously authorized for this member and they are stable on the medication? If No, skip to diagnosis section.
  - Yes  No
  
6. How long has the member been receiving treatment with Praluent/Repatha?
  - a. 3 to 5 months (or first renewal request after initial authorization)
  - b. 6 months or more (or second and subsequent renewal requests)
  
7. Has the member achieved an at least 30% reduction in LDL-C since the beginning of treatment with Praluent/Repatha? **ACTION REQUIRED: If Yes, please attach clinical notes and laboratory results that support an at least 30% reduction in LDL-C after initiation of Praluent/Repatha therapy.**
  - Yes  No
  
8. Does the member continue to receive benefit from Praluent/Repatha treatment as measured by either of the following: 1) continued decrease in LDL-C levels, or 2) maintenance of optimum LDL-C levels? **ACTION REQUIRED: If yes, please attach clinical notes and laboratory results that support continued benefit of Praluent/Repatha therapy.**
  - Yes  No

(Form continued on next page.)

Member's Last Name:

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Member's First Name:

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9. The member is not able to use a maximum dose of atorvastatin or rosuvastatin due to muscle symptoms, documentation of a causal relationship must be established between statin use and muscle symptoms. Documentation must demonstrate that the member experienced pain, tenderness, stiffness, cramping, weakness, and/or fatigue and all of the following:
- a. Muscle symptoms resolved after discontinuation of statin; AND
  - b. Muscle symptoms occurred when re-challenged at a lower dose of the same statin; AND
  - c. Muscle symptoms occurred after switching to an alternative statin; AND
  - d. Documentation ruling out non-statin causes of muscle symptoms (e.g., hypothyroidism, reduced renal function, reduced hepatic function, rheumatologic disorders, such as polymyalgia rheumatica, steroid myopathy, vitamin D deficiency, or primary muscle disease); OR
  - e. The member has been diagnosed with statin-induced rhabdomyolysis

Yes  No

If yes to any, give details: \_\_\_\_\_

**DIAGNOSIS AND LAB VALUES FOR HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA(HOFH)**

10. Has genetic testing confirmed the presence of 2 mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus? **ACTION REQUIRED: If yes, please attach a copy of genetic testing result.**

Yes  No

11. Has the diagnosis of HoFH been confirmed by ANY of the following? **ACTION REQUIRED: Please indicate below and provide a copy of the laboratory report with LDL-C level at time of diagnosis and other documentation supporting the presence of xanthoma or family history of HoFH (e.g., chart notes, medical records).**

- Untreated LDL-C > 500 mg/dL AND cutaneous or tendon xanthoma before age 10 years
- Untreated LDL-C > 500 mg/dL AND untreated elevated LDL-C levels consistent with heterozygous familial hypercholesterolemia in both parents
- Treated LDL-C ≥ 300 mg/dL AND cutaneous or tendon xanthoma before age 10 years
- Treated LDL-C ≥ 300 mg/dL AND untreated elevated LDL-C levels consistent with heterozygous familial hypercholesterolemia in both parents
- No/none of the above

(Form continued on next page.)

PROPROTEIN CONVERTASE SUBTILISIN KEXIN TYPE 9 (PCSK9)

Member's Last Name:

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Member's First Name:

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12. Does the member have a history of clinical atherosclerotic cardiovascular disease (ASCVD) or a cardiovascular event listed below?

- Yes     No
- Acute coronary syndromes     Myocardial infarction     Stable or unstable angina
- Stroke of presumed atherosclerotic origin     Transient ischemic attack (TIA)
- Coronary or other arterial revascularization procedure (e.g., PTCA, CABG)
- Peripheral arterial disease of presumed atherosclerotic origin
- Findings from CT angiogram or catheterization consistent with clinical ASCVD

13. What is the member's pre-treatment LDL-C level (i.e., prior to starting PCSK9 inhibitor therapy)?  
\_\_\_\_\_ mg/dL.

14. Is age  $\geq$  13 years if diagnosed with homozygous familial hypercholesterolemia (HoFH)?  
 Yes     No

**DIAGNOSIS AND LAB VALUES FOR HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA(HEFH)**

15. Does the member have a **definite** diagnosis of heterozygous familial hypercholesterolemia (HeFH) as defined by the Dutch Lipid Clinic Network criteria (total score greater than 8)? **ACTION REQUIRED: If yes, please provide a copy of the lab report with LDL-C level at time of diagnosis and other documentation supporting clinical/family history and/or physical findings (e.g., chart notes, medical records).**

Yes     No

16. Does the member have a definite diagnosis of HeFH as defined by Simon Broome diagnostic criteria?

Yes     No

\_\_\_\_\_  
**Prescriber Signature (Required)**

\_\_\_\_\_  
**Date**

By signature, the Physician confirms the above information is accurate and verifiable by member records.

**Please include ALL requested information; Incomplete forms will delay the PA process.**

Submission of documentation does NOT guarantee coverage.

The completed form may be **FAXED TO 1-844-512-7020.**