

PROTEIN CONVERTASE SUBTILISIN/KEXIN TYPE 9 (PCSK9) INHIBITORS PRIOR AUTHORIZATION REQUEST PRESCRIBER FAX FORM

Only the prescriber may complete this form. This form is for prospective, concurrent, and retrospective reviews.

The following documentation is **REQUIRED**. Incomplete forms will be returned for additional information. For formulary information please visit www.myprime.com. Start saving time today by filling out this form electronically. Visit covermymeds.com to begin using this free service.

What is the priority level of this request?

- Standard review
- Expedited/Urgent review – prescriber certifies that waiting for a standard review could seriously harm the patient's life, health or ability to regain maximum function

Today's Date: _____

PATIENT AND INSURANCE INFORMATION

Date of Service (if differs from Today's Date): _____

Patient Name (First):	Last:	M:	DOB (mm/dd/yyyy):
Patient Address:	City, State, Zip:	Patient Telephone:	
Member ID Number:	Group Number:		

PRESCRIBER/CLINIC INFORMATION

Prescriber Name:	Prescriber NPI#:	Specialty:	Contact Name:
Clinic Name:	Clinic Address:		
City, State, Zip:	Phone #:	Secure Fax #:	

PLEASE ATTACH ANY ADDITIONAL INFORMATION THAT SHOULD BE CONSIDERED WITH THIS REQUEST

Medication Requested:	Strength:
Dosing Schedule:	Quantity per Month:

For all requests:

1. Is the patient currently treated with the requested agent? Yes No
 If yes, is the patient currently stable on the requested agent? **Please note, chart notes are required**..... Yes No
2. Will the patient be using the requested agent in combination with another PCSK9 agent for the requested indication? Yes No
3. Is the patient currently adherent to high-intensity statin (i.e., rosuvastatin greater than or equal to 20 mg daily, atorvastatin greater than or equal to 40 mg daily)? Yes No

If no, answer the following:

Has the patient been determined to be statin intolerant by meeting one of the following criteria:

- Has the patient experienced statin-related rhabdomyolysis? Yes No
- Has the patient experienced skeletal-related muscle symptoms (e.g., myopathy [muscle weakness] or myalgia [muscle aches, soreness, stiffness, or tenderness]) and BOTH of the following:
 - The skeletal-related muscle symptoms (e.g., myopathy or myalgia) occurred while receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination products) AND
 - When receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination products), the skeletal-related muscle symptoms (e.g., myopathy, myalgia) resolved upon discontinuation of each respective statin therapy (atorvastatin and rosuvastatin)? Yes No
- Did the patient experience elevations in hepatic transaminase while receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination products)? Yes No
- Does the patient have an FDA labeled contraindication to atorvastatin and rosuvastatin? Yes No
- Does the patient have a hypersensitivity to atorvastatin and rosuvastatin? Yes No

If yes, answer the following:

- Has the patient been adherent to high-intensity statin therapy for greater than or equal to 8 continuous weeks? Yes No
- Does the patient's LDL-C level after this treatment regimen remains greater than or equal to 70 mg/dL? ... Yes No
- Has the patient achieved a 50% reduction in LDL-C from baseline after this treatment regimen? Yes No
- If the patient has ASCVD, does the patient's non HDL-C level after this treatment regimen remain greater than or equal to 100 mg/dL? Yes No
- If the patient has ASCVD, is the patient at very high risk and the patient's LDL-C level after this treatment regimen remains greater than or equal to 55 mg/dL? Yes No

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Patient Name (First):	Last:	M:	DOB (mm/dd/yyyy):
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4. Does the patient have any FDA labeled contraindications to the requested agent? Yes No
 If yes, please specify FDA labeled contraindications: _____
5. Was the agent prescribed by, or in consultation with, a cardiologist, an endocrinologist, and/or a physician who focuses in the treatment of cardiovascular (CV) risk management and/or lipid disorders? Yes No
6. Is the patient's age within FDA labeling for the requested indication for the requested agent? Yes No
 If no, is the patient's age within FDA labeling for the requested indication for the requested agent? Yes No
7. Is the requested quantity (dose) greater than the maximum FDA labeled dose for the requested indication? Yes No
 If no, can the requested quantity (dose) be achieved with a lower quantity of a higher strength? Yes No
 If no, please explain: _____

Please select the patient's diagnosis (or % ASCVD risk) and answer any corresponding questions.

Homozygous familial hypercholesterolemia (HoFH)

8. Has the patient had genetic confirmation of two mutant alleles at the *LDLR*, *Apo-B*, *PCSK9*, or *LDLRAP1* gene? Yes No
9. Does the patient have a history of untreated LDL-C greater than 500 mg/dL (greater than 13 mmol/L) or treated LDL-C greater than or equal to 300 mg/dL (greater than or equal to 7.76 mmol/L)? Yes No
10. Does the patient have clinical manifestations of HoFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas, or xanthelasma)? Yes No

Heterozygous familial hypercholesterolemia (HeFH)

11. Has the patient had genetic confirmation of one mutant allele at the *LDLR*, *Apo-B*, *PCSK9*, or *LDLRAP1* gene? Yes No
12. Does the patient have a history of LDL-C greater than 190 mg/dL (greater than 4.9 mmol/L) (pretreatment)? Yes No
13. Does the patient have clinical manifestations of HeFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthoma, or xanthelasma)? Yes No
14. Does the patient have a Dutch Lipid Clinic Network Criteria score of greater than 5? Yes No
15. Does the patient have "definite" or "possible" familial hypercholesterolemia as defined by the Simon Broome criteria? Yes No
16. Does the patient have a treated low-density lipoprotein cholesterol (LDL-C) level greater than or equal to 100 mg/dL after treatment with antihyperlipidemic agents but prior to PCSK9 inhibitor therapy? Yes No

Clinical atherosclerotic cardiovascular disease (ASCVD)

17. Does the patient have one of the following: 1) acute coronary syndrome, 2) history of myocardial infarction, 3) stable or unstable angina, 4) coronary or other arterial revascularization, 5) history of stroke, 6) history of transient ischemic attack, or 7) peripheral arterial disease, including aortic aneurysm, presumed to be of atherosclerotic origin? ... Yes No

Primary hyperlipidemia

18. Does the patient have a coronary artery calcium or calcification (CAC) score greater than or equal to 300 Agatston units? Yes No
19. Does the patient have an LDL-C level greater than or equal to 220 mg/dL (greater than or equal to 5.7 mmol/L) while receiving maximally tolerated statin and ezetimibe therapy? Yes No

A greater than or equal to 40% 10-year ASCVD risk

20. Does the patient have an LDL-C of greater than or equal to 70 mg/dL while on maximally tolerated statin therapy? Yes No
21. Does the patient have extensive or active burden of ASCVD (i.e., polyvascular ASCVD, which affects all 3 vascular beds-coronary, cerebrovascular, and peripheral arterial; clinical peripheral arterial disease in addition to coronary and/or cerebrovascular disease; a clinical ASCVD event with multivessel coronary artery disease defined as greater than or equal to 40% stenosis in greater than or equal to 2 large vessels; or recurrent myocardial infarction within 2 years of the initial event) in the presence of adverse or poorly controlled cardiometabolic risk factors? Yes No
22. Does the patient have extremely high-risk elevations in cardiometabolic factors with less-extensive ASCVD (i.e., diabetes, LDL-C of greater than or equal to 100 mg/dL, less than high-intensity statin therapy, chronic kidney disease, poorly controlled hypertension, high-sensitivity C-reactive protein >3 mg/L, or metabolic syndrome, usually occurring with other extremely high-risk or very-high-risk characteristics), usually with other adverse or poorly controlled cardiometabolic risk factors present? Yes No
23. Does the patient have ASCVD and LDL-C greater than or equal to 220 mg/dL with greater than or equal to 45% 10- year ASCVD risk despite statin therapy? Yes No

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A 30-39% 10-year ASCVD risk

24. Does the patient have LDL-C greater than or equal to 100 mg/dL while on maximally tolerated statin therapy? Yes No

25. Does the patient have less-extensive clinical ASCVD (i.e., no polyvascular ASCVD, no clinical peripheral arterial disease, a prior ASCVD event greater than or equal to 2 years prior, and no coronary artery bypass grafting)? Yes No

26. Does the patient have adverse or poorly controlled cardiometabolic risk factor(s) including age greater than or equal to 65 years, current smoking, chronic kidney disease, lipoprotein(a) greater than or equal to 37 nmol/L, high-sensitivity C-reactive protein 1-3 mg/L, metabolic syndrome with a history of myocardial infarction, ischemic stroke, or symptomatic peripheral arterial disease, usually in the presence of other adverse or poorly controlled cardiometabolic risk factors? Yes No

A 20-29% 10-year ASCVD risk

27. Does the patient have an LDL-C of greater than or equal to 130 mg/dL while on maximally tolerated statins? Yes No

28. Does the patient have less extensive ASCVD and well-controlled cardiometabolic risk factors (i.e., no diabetes, nonsmoker, on high-intensity statin with LDL-C less than 100 mg/dL, blood pressure less than 140/90 mm Hg, and C-reactive protein less than 1 mg/dL)? Yes No

29. Is the use for primary prevention with LDL-C greater than or equal to 220 mg/dL? Yes No

30. Does the patient have no clinical ASCVD or CAC less than 100 Agatston units? Yes No

31. Does the patient have poorly controlled cardiometabolic risk factors? Yes No

Other (ICD code and description): _____

For Praluent requests (chart notes are required to support the answers):

32. Has the patient tried and had an inadequate response to Repatha? Yes No

33. Was Repatha, discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? Yes No

34. Does the patient have an intolerance or hypersensitivity to Repatha? Yes No

35. Does the patient have an FDA labeled contraindication to Repatha? Yes No

36. Is Repatha expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient's adherence of care; OR worsen a comorbid condition; OR decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm?..... Yes No

37. Is Repatha not in the best interest of the patient based on medical necessity? Yes No

38. Has the patient tried another prescription drug in the same pharmacologic class or with the same mechanism of action as Repatha and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? Yes No

For renewal requests:

39. Has the patient shown clinical benefit with a PCSK9? Yes No

40. Is the patient currently adherent to therapy with a PCSK9?..... Yes No

Please fax or mail this form to:
 Prime Therapeutics LLC
 Clinical Review Department
 2900 Ames Crossing Road
 Eagan, MN 55121

TOLL FREE

Phone: **Fax: 877.243.6930**

BCBSIL: 800.285.9426
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BCBSNM: 800.544.1378
BCBSOK: 800.991.5643
BCBSTX: 800.289.1525

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