



## Praluent

### HMSA - Prior Authorization Request

CVS Caremark administers the prescription benefit plan for the patient identified. This patient's benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of the prescribed medication is necessary. **Please respond below and fax this form to CVS Caremark toll-free at 1-866-237-5512.** If you have questions regarding the prior authorization, please contact CVS Caremark at **1-808-254-4414**. For inquiries or questions related to the patient's eligibility, drug copay or medication delivery; please contact the Specialty Customer Care Team: CaremarkConnect® 1-800-237-2767.

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**Patient's Name:** \_\_\_\_\_ **Date:** \_\_\_\_\_  
**Patient's ID:** \_\_\_\_\_ **Patient's Date of Birth:** \_\_\_\_\_  
**Patient's Phone Number:** \_\_\_\_\_  
**Physician's Name:** \_\_\_\_\_  
**Specialty:** \_\_\_\_\_ **NPI#:** \_\_\_\_\_  
**Physician Office Telephone:** \_\_\_\_\_ **Physician Office Fax:** \_\_\_\_\_

*Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.*

#### Additional Demographic Information:

*Patient Weight:* \_\_\_\_\_ kg  
*Patient Height:* \_\_\_\_\_ ft \_\_\_\_\_ inches

#### **Indicate where the drug is being dispensed:**

- Office  Outpatient Hospital  Ambulatory Surgical  Inpatient Hospital
- Off Campus Outpatient Hospital  Urgent Care  Emergency Room  Birthing Center
- Military Facility  Skilled Nursing Facility  Nursing Facility  Hospice
- Inpatient Psychiatric  Psychiatric Residential Treatment  End Stage Renal Facility
- Psychiatric Facility  Pharmacy  Other

#### **Indicate where the drug is being administered:**

- Ambulatory surgical  Home  Inpatient hospital  Office
- Outpatient Hospital  Pharmacy

**Send completed form to: CVS Caremark Specialty Programs. Fax: 1-866-237-5512**

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**Exception Criteria Questions:**

- A. Is the product being requested for any of the following indications?
- Prevention of cardiovascular events
  - Primary hyperlipidemia (including heterozygous familial hypercholesterolemia)
  - Homozygous Familial Hypercholesterolemia
- Yes  No *If No, skip to Criteria Questions*
- B. The preferred product for your patient's health plan is Repatha.  
Can the patient's treatment be switched to the preferred product?
- Yes *Please obtain Form for preferred product and submit for corresponding PA.*  
 No
- C. Has the patient experienced a documented inadequate response or intolerable adverse event to Repatha and the provider does not expect the same event to occur with the requested drug? ***ACTION REQUIRED: If 'Yes', please attach supporting chart note(s).***  Yes  No

**Criteria Questions:**

1. What is the ICD-10 code? \_\_\_\_\_
2. What is the current LDL-C level? \_\_\_\_\_mg/dl
3. What is the diagnosis?  
 Prior history of clinical atherosclerotic cardiovascular disease (ASCVD)  
 Primary hyperlipidemia including heterozygous familial hypercholesterolemia (HeFH)  
 Homozygous familial hypercholesterolemia (HoFH)
4. Is this request for continuation of therapy with a PCSK9 inhibitor?  
 Yes  No *If No, and ASCVD, skip to #6; if No and HeFH or HoFH skip to #7*
5. Has the patient achieved or maintained an LDL-C reduction (e.g., LDL-C is now at goal, robust reduction in LDL-C) as the result of PCSK9 inhibitor therapy?  Yes  No *No further questions*
6. Which of the manifestations of clinical atherosclerotic cardiovascular disease (ASCVD) has the patient experienced? *Any answer, skip to #9*  
 Acute coronary syndrome(s)  
 Myocardial infarction  
 Stable or unstable angina  
 Coronary or other arterial revascularization procedure (e.g., percutaneous coronary angioplasty [PTCA], coronary artery bypass graft [CABG] surgery)  
 Stroke of presumed atherosclerotic origin  
 Transient ischemic attack (TIA)  
 Non-cardiac peripheral arterial disease of presumed atherosclerotic origin (e.g., carotid artery stenosis, lower extremity PAD)  
 Other
7. What is the patient's untreated (before any lipid-lowering therapy) LDL-C level?  
Untreated (before any lipid-lowering therapy) LDL-C level \_\_\_\_\_
8. Are there any secondary causes that could explain the elevated untreated LDL-C?  Yes  No
9. Is the patient receiving a high-intensity statin dose daily, such as rosuvastatin (Crestor) 20 mg daily or atorvastatin (Lipitor) 40 mg daily?  Yes  No *If No, skip to #12*
10. Has the patient received this dose for at least 3 months?  Yes  No *If No, skip to #12*
11. Has the patient received the high-intensity statin dose for at least 3 months in combination with ezetimibe?  
 Yes  No *No Further Questions*

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12. Was the patient unable to tolerate a high-intensity statin due to adverse effects?  Yes  No *If No, skip to #16*
13. Is the patient receiving a moderate-intensity statin dose daily, such as atorvastatin (Lipitor) 20 mg or equivalent?  Yes  No *If No, skip to #16*
14. Has the patient received this dose for at least 3 months?  Yes  No *If no, skip to #16*
15. Has the patient received the moderate-intensity statin dose for at least 3 months in combination with ezetimibe?  Yes  No *No Further Questions*
16. Did the patient score a 7 or higher on the Statin-Associated Muscle Symptom Clinical Index (SAMS-CI)?  
\*\*See appendix\*\*  Yes  No *If Yes, no further questions*
17. Did the patient experience a statin-associated increase in creatine kinase (CK) level to greater than or equal to 10 times the upper limit of normal (ULN) during previous treatment with a statin?  
 Yes  No *If Yes, no further questions*
18. Does the patient have any of the following contraindications to statins?  
 Active liver disease, including unexplained persistent elevations in hepatic transaminase levels (e.g., ALT greater than or equal to 3 times upper limit of normal)  
 Currently pregnant  
 May become pregnant  
 Nursing mother  
 None of the above

***I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by CVS Caremark or the benefit plan sponsor.***

X \_\_\_\_\_  
**Prescriber or Authorized Signature**

\_\_\_\_\_  
**Date (mm/dd/yy)**

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## Statin-Associated Muscle Symptom Clinical Index (SAMS-CI)

### Instructions:

- Use with patients who have had muscle symptoms that were **new or increased** after starting a statin regimen.
- A **statin regimen** includes any statin at any dose or frequency, including a statin the patient has used previously, at the same or a different dose.
- **Muscle symptoms** may include aches, cramps, heaviness, discomfort, weakness, or stiffness.
- Interpret overall score in light of **other possible causes** of the muscle symptoms, such as:
 

Recent physical exertion	Hypothyroidism	Concurrent illness
Changes in exercise patterns	Drug interaction with statin	Underlying muscle disease
- **See reverse** for Frequently Asked Questions

**How many** statin regimens has the patient had that involved new or increased muscle symptoms?

One

Two or more

Complete the questions on the left side of this page.

Complete the questions on the right side of this page.

### Regarding this statin regimen:

#### A. Location and pattern of muscle symptoms

(If more than one category applies, record the highest number.)

**Enter score:**

Symmetric, hip flexors or thighs	3
Symmetric, calves	2
Symmetric, proximal upper extremity	2
Asymmetric, intermittent, or not specific to any area	1

#### B. Timing of muscle symptom onset in relation to starting statin regimen

<4 weeks	3
4–12 weeks	2
>12 weeks	1

#### C. Timing of muscle symptom improvement after withdrawal of statin (If patient is still taking statin, stop regimen and monitor symptoms.)

<2 weeks	2
2–4 weeks	1
No improvement after 4 weeks	0

### Rechallenge the patient with a statin regimen, (even if same statin compound or regimen as above) then complete final question:

#### D. Timing of recurrence of similar muscle symptoms in relation to starting second regimen

<4 weeks	3
4–12 weeks	1
>12 weeks or similar symptoms did not reoccur	0

**Total:**

All four scores above must be entered before totaling

### Regarding the statin regimen before the most recent regimen:

#### A. Location and pattern of muscle symptoms

(If more than one category applies, record the highest number.)

**Enter score:**

Symmetric, hip flexors or thighs	3
Symmetric, calves	2
Symmetric, proximal upper extremity	2
Asymmetric, intermittent, or not specific to any area	1

#### B. Timing of muscle symptom onset in relation to starting statin regimen

<4 weeks	3
4–12 weeks	2
>12 weeks	1

#### C. Timing of muscle symptom improvement after withdrawal of statin

<2 weeks	2
2–4 weeks	1
No improvement after 4 weeks	0

### Regarding the most recent statin regimen:

(even if same statin compound as above)

#### D. Timing of recurrence of similar muscle symptoms in relation to starting regimen

<4 weeks	3
4–12 weeks	1
>12 weeks or similar symptoms did not reoccur	0

**Total:**

All four scores above must be entered before totaling

	Total score:	2–6	7–8	9–11
<b>Interpretation</b>	Likelihood that the patient's muscle symptoms are due to statin use:	Unlikely	Possible	Probable

10 Oct 2016. Based on Rosenson et al. An assessment by the Statin Muscle Safety Task Force: 2014 update. *J Clin Lipidol.* 2014 May–Jun;8(3 Suppl):S58–71.

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