Praluent (alirocumab)
Prior Authorization Request Form

Caterpillar Prescription Drug Benefit
Phone: 877-228-7909 Fax: 800-424-7640

MEMBER'S LAST NAME: _____ **MEMBER'S FIRST NAME:** _____

Instructions: Please fill out all applicable sections completely and legibly. Attach any additional documentation that is important for the review (e.g., chart notes or lab data, to support the authorization request). Information contained in this form is Protected Health Information under HIPAA.

☐ **URGENT**

MEMBER INFORMATION	
LAST NAME:	**FIRST NAME:**
PHONE NUMBER:	**DATE OF BIRTH:**
STREET ADDRESS:	
CITY:	**STATE:** **ZIP CODE:**
PATIENT INSURANCE ID NUMBER:	

☐ **MALE** ☐ **FEMALE** **HEIGHT (IN/CM):** _____ **WEIGHT (LB/KG):** _____ **ALLERGIES:** _____

IF YOU ARE NOT THE PATIENT OR THE PRESCRIBER, YOU WILL NEED TO SUBMIT A PHI DISCLOSURE AUTHORIZATION FORM WITH THIS REQUEST WHICH CAN BE FOUND AT THE FOLLOWING LINK: PRIMETHERAPEUTICS.COM/NOPP

PATIENT'S AUTHORIZED REPRESENTATIVE (IF APPLICABLE): _____
AUTHORIZED REPRESENTATIVE'S PHONE NUMBER: _____

PRESCRIBER INFORMATION	
LAST NAME:	**FIRST NAME:**
PRESCRIBER SPECIALTY:	**EMAIL ADDRESS:**
NPI NUMBER:	**DEA NUMBER:**
PHONE NUMBER:	**FAX NUMBER:**
STREET ADDRESS:	
CITY:	**STATE:** **ZIP CODE:**
REQUESTOR (if different than prescriber)**:**	**OFFICE CONTACT PERSON:**

MEDICATION OR MEDICAL DISPENSING INFORMATION			
MEDICATION NAME:			
DOSE/STRENGTH:	**FREQUENCY:**	**LENGTH OF THERAPY/REFILLS:**	**QUANTITY:**
☐ **NEW THERAPY** ☐ **RENEWAL**		**IF RENEWAL:** DATE THERAPY INITIATED:	
DURATION OF THERAPY (SPECIFIC DATES):			

Continued on next page.

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1. HAS THE PATIENT TRIED ANY OTHER MEDICATIONS FOR THIS CONDITION? ☐ YES (if yes, complete below) ☐ NO		
MEDICATION/THERAPY (SPECIFY DRUG NAME AND DOSAGE)**:**	**DURATION OF THERAPY** (SPECIFY DATES)**:**	**RESPONSE/REASON FOR FAILURE/ALLERGY:**

2. LIST DIAGNOSES:	**ICD-10:**
□ Clinical atherosclerotic cardiovascular disease □ Heterozygous familial hypercholesterolemia (HeFH) □ Homozygous familial hypercholesterolemia(HoFH) □ Primary hyperlipidemia □ Other diagnosis: _____ICD-10 Code(s): _____	

3. REQUIRED CLINICAL INFORMATION: PLEASE PROVIDE ALL RELEVANT CLINICAL INFORMATION TO SUPPORT A PRIOR AUTHORIZATION.

For <u>all diagnoses</u>, <u>for initial and renewal requests,answer the following</u>:
Will drug be used as part of a clinical trial? □ Yes □ No

Will Praluent be used as an adjunct to a low-fat diet and exercise? □ Yes □ No

Is Praluent prescribed by, or in consultation with, a cardiologist or endocrinologist? □ Yes □ No

Will Praluent be used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor or Juxtapid (lomitapide)? □ Yes □ No

Has the patient had a trial with a maximally tolerated dose of a statin, AND failed to come to their LDL goal? □ Yes □ No
Has the patient had a trial with ezetimibe(Zetia), AND failed to come to their LDL goal? □ Yes □ No

Will Statin therapy at a maximally tolerated daily dose be continued with PCSK9 therapy ? □ Yes □ No *<u>Please provide documentation.</u>*
Does patient have an absolute contraindication to statin therapy? □ Yes □ No *<u>Please provide documentation.</u>*

Will ezetimibe, bempedoic acid or a bile-acid sequestrant therapy be continued with PCSK9 therapy? □ Yes □ No *<u>Please provide documentation.</u>*
Does patient have an absolute contraindication to other lipid-lowering agents? □ Yes □ No *<u>Please provide documentation.</u>*

***<u>If the patient is not able to use a maximum dose of a statin due to muscle symptoms, a causal relationship must be established between statin use and muscle symptoms such as</u>*:**
Does the patient have evidence of pain, tenderness, stiffness, cramping, weakness, and/or fatigue <u>and all of the following?</u> □ Yes □ No *<u>Please provide documentation.</u>*
Does patient have muscle symptoms that resolve after discontinuation of statin? □ Yes □ No *<u>Please provide documentation.</u>*

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Does patient have muscle symptoms occurring when re-challenged at a lower dose of the same statin? □ Yes □ No ***Please provide documentation.***

Did muscle symptoms occur after switching to an alternative statin? □ Yes □ No ***Please provide documentation.***

Has 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) have been ruled out? □ Yes □ No ***Please provide documentation.***

Has The patient been diagnosed with rhabdomyolysis associated with statin use? □ Yes □ No ***Please provide documentation.***
Did the patient experience acute neuromuscular illness or dark urine and an acute elevation in creatine kinase? □ Yes □ No ***Please provide documentation.***

Does the patient have atherosclerotic cardiovascular disease (ASCVD) (i.e., myocardial infarction, non-hemorrhagic stroke, or peripheral arterial disease) or ASCVD risk that requires additional lowering of LDL-C? □ Yes □ No

Does patient have at least one of the following major risk factors*: Please provide documentation.*

- □ **Diabetes mellitus, type 1 or 2**
- □ **Age 65 years or older**
- □ **MI or non-hemorrhagic stroke (TIAs don't qualify) in the past 6 months**
- □ **Current daily cigarette smoker**
- □ **History of more than one MI**
- □ **History of more than one non-hemorrhagic stroke (TIAs don't qualify)**
- □ **History of one MI plus one non-hemorrhagic stroke (TIAs don't qualify)**
- □ **History of one MI plus history of symptomatic peripheral arterial disease as defined above**
- □ **History of one non-hemorrhagic stroke (TIAs don't qualify) plus history of symptomatic peripheral arterial disease as defined above**

IF PATIENT DOES NOT HAVE ANY OF THE ABOVE, does patient have at least 2 of the following minor risk factors below: ***Please provide documentation***

- □ **History of non-MI related coronary revascularization**
- □ **Residual coronary artery disease with >40% stenosis in at least 2 large vessels**
- □ **Metabolic syndrome (as defined by Alberti et al., Circulation, 2009; 120:1640-1645,**
- □ **Most recent HDL-C < 40 mg/dL (men) and < 50 mg/dL (women), in the absence of metabolic syndrome or in the presence of metabolic syndrome when 3 of its four non-HDL criteria are met (as per Alberti et al., 2009)**
- □ **Most recent hsCRP (high-sensitivity C-reactive protein) > 2.0 mg/L**
- □ **Most recent LDL-C > 130 mg/dL or non-HDL-C > 160 mg/dL**
- □ **Most recent fasting LDL-C > 70 mg/dL or non-HDL-C > 100mg/dL after > 2 weeks stable lipid lowering therapy**
- □ **Most recent fasting triglycerides < 400 mg/dL**

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Is patient classified as very high risk ASCVD, defined as extensive burden of or active ASCVD, or ASCVD with extremely high burden of adverse poorly controlled cardiometabolic risk factors requiring LDL-C ≤ 70 mg/dL? □ Yes □ No *Please provide documentation.*

Is patient classified as high risk ASCVD, defined as less extensive ASCVD and poorly controlled cardiometabolic risk factors requiring LDL-C ≤100 mg/dL? □ Yes □ No *Please provide documentation.*

Is patient classified as Intermediate risk ASCVD with LDL-C ≥ 130 mg/dL; with poorly controlled risk factors? □ Yes □ No *Please provide documentation.*

Is patient classified as Very High Risk ASCVD with recent acute coronary syndrome(ACS) including MI and/or unstable angina and/or hospitalized for ACS to 12 months post-index ACS event requiring LDL-C ≤ 55 mg/dL? □ Yes □ No *Please provide documentation.*

Does patient demonstrate or has current evidence of any of the following? □ Yes □ No *Please provide documentation.*
□ Diabetes mellitus
□ Polyvascular disease (vascular disease in ≥2 arterial beds)
□ Symptomatic peripheral arterial disease
□ Recurrent MI
□ MI in the past two years
□ Previous coronary artery bypass graft surgery
□ Heterozygous familial hypercholesterolemia

For diagnosis of primary hyperlipidemia, please answer the following:
Does patient have a fasting LDL-C greater than or equal to 75mg/dL? □ Yes □ No *Please provide documentation.*

Does patient have a diagnosis of coronary heart disease(CHD) or is patient a risk equivalent for CHD? □ Yes □ No *Please provide documentation.*

Has patient had previous background lipid-lowering therapy in which patient requires a LDL-C less than 100mg/dL? □ Yes □ No *Please provide documentation.*

If patient does not have coronary heart disease(CHD) or is not a risk a CHD risk equivalent, has the patient had background lipid-lowering therapy requiring a LDL-C less than 130mg/dL? □ Yes □ No *Please provide documentation.*

Does patient have a triglyceride level less than or equal to 400mg/dL? □ Yes □ No *Please provide documentation.*

Is patient NYHA class II, III or IV? □ Yes □ No *Please provide documentation.*

Is patient's last known left ventricular ejection fracture less than 30%? □ Yes □ No

Is patient a Type I diabetic? □ Yes □ No

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Is patient a poorly controlled Type II diabetic with a HgA1c greater than or equal to 7%? □ Yes □ No

Does patient have uncontrolled hypertension with a blood pressure greater than or equal to 140/90mmHg?□ Yes □ No

For <u>heterozygous familial hypercholesterolemia (HeFH),</u> also answer the following:
Has there been genetic confirmation of the diagnosis through a mutation identified in the LDL receptor, ApoB or PCSK9? □ Yes □ No

If Yes, does the patient have an untreated/ pre-treatment LDL-C greater than 190 mg/dL? □ Yes □ No

Is there documented evidence of tendinous xanthomas in the patient and/or first-degree relative, and/or second-degree relative? □ Yes □ No

If Yes, is the individual with tendinous xanthomas 18 years of age or older with an untreated/pre-treatment LDL-C greater than 190 mg/mL? □ Yes □ No

Was the patient assessed w ith the Dutch Lipid Clinic Netw ork diagnostic criteria and found to have a cumulative score greater than or equal to 9 points (i.e., definite FH)? □ Yes □ No (If Yes, please submit calculation with final score)

For <u>homozygous familial hypercholesterolemia (HoFH):</u>
Does patient have one of the following?: *Please submit genetic/laboratory reports(and/or chart documents).*
□ Documented homozygous or compound heterozygous mutations in both low-density lipoprotein receptor (LDLR) alleles.
□ Presence of homozygous or compound heterozygous mutations in apolipoprotein B (APOB), proprotein convertase subtilisin/kexin type 9 (PCSK9), or low-density lipoprotein receptor adaptor protein 1 (LDLRAP1) alleles
□ Presence of double heterozygous mutations, (i.e., mutations on different genes in the LDLR, APOB, or PCSK9 alleles).
□ Untreated total cholesterol >500 mg/dl (12.93 mmol/l) and triglycerides <300 mg/dl (3.39 mmol/l) AND EITHER (a) OR (b): (a) both biological parents have a history of total cholesterol >250 mg/dl (6.46 mmol/l), OR (b) patient is documented to have had cutaneous or tendinous xanthoma(s) before 10 years of age.

Does patient have documented evidence of a null mutation in both LDLR alleles? □ Yes □ No *Please submit genetic/laboratory reports(and/or chart documents).*

Does the patient have a low-density lipoprotein cholesterol (LDL C) level greater than or equal to 70 mg/dl (1.81 mmol/l)? □ Yes □ No *Please submit lab reports.*

<u>Additional Renewal Criteria</u>:
Does patient have a sustained reduction in LDL-C levels from pre-treatment baseline? □ Yes □ No

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Are there any other comments, diagnoses, symptoms, medications tried or failed, and/or any other information the physician feels is important to this review?

_____

_____

Please note: Not all drugs/diagnosis are covered on all plans. This request may be denied unless all required information is received.

ATTESTATION: I attest the information provided is true and accurate to the best of my knowledge. I understand that the Health Plan, insurer, Medical Group or its designees may perform a routine audit and request the medical information necessary to verify the accuracy of the information reported on this form.

Prescriber Signature or Electronic I.D. Verification: _____ **Date:** _____

FAX THIS FORM TO: 800-424-7640

MAIL REQUESTS TO: Prime Therapeutics Management Prior Authorization Program
Attn: CP – 4201
P.O. Box 64811
St. Paul, MN 55164-0811