

OPTIMA HEALTH PLAN

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. Incomplete form will delay authorization process.

Drug Requested: Praluent® (alirocumab) Injection

DRUG INFORMATION: Complete all information below or authorization process will be delayed.

Drug Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code, if applicable: _____

CLINICAL CRITERIA: ALL information below must be checked to ensure authorization process will NOT be delayed. Chart notes and any lab results MUST be submitted with this request to include a baseline lipid panel AND panel post statin therapy.

Initial Criteria - approval is for 3 months.

- Must be prescribed or in consultation with one of the following:

<input type="checkbox"/> Cardiologist	<input type="checkbox"/> Endocrinologist	<input type="checkbox"/> Lipid Specialist
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AND

- Adjunct to low-fat diet and exercise

Diagnoses: (select one below)

- Atherosclerotic Cardiovascular Disease:** Select if the patient has Atherosclerotic cardiovascular disease (ASCVD) confirmed by the following:

- Acute Coronary Syndrome
- History of myocardial infarction
- Stable or unstable angina
- Peripheral arterial disease presumed to be of atherosclerotic origin
- Coronary or arterial revascularization
- Stroke
- Transient ischemic attack

Please note: Chart documentation of the above is required to be submitted along with this request form.

- Heterozygous familial hypercholesterolemia (HeFH):** Select if the patient has heterozygous familial hypercholesterolemia (HeFH) as confirmed by the following:

- Untreated/pre-treatment LDL cholesterol (LDL-C) \geq 190mg/dL in an adult or \geq 155mg/dL in a child less than 16 years of age

AND (ONE of the following)

- Family history of myocardial infarction in first-degree relative less than 60 years of age
- Family history of myocardial infarction in second-degree relative less than 50 years of age
- Submission of medical records (e.g., chart notes, laboratory values) documenting LDL-C $>$ 190mg/dL in first or second degree relative

OR (ONE of the following)

Select if there is submission of medical records (e.g., chart notes, laboratory values) documenting the following:

- Genetic confirmation of functional mutation in the LDL receptor, Apo-B, or PCSK9 gene adaptor protein 1 (i.e., LDLRAP1 or ARH)
- Tendinous xanthomata

Please note: Chart documentation of the above is required to be submitted along with this request form.

- Other diagnosis: _____
ICD-10 Code(s) plus description: _____

Other diagnosis: _____

ICD-10 Code(s) plus description: _____

FOR ALL DIAGNOSIS: Skip to Section B IF patient is unable to tolerate statin therapy. *Chart notes or labs are REQUIRED for review*

A. Please select which statin therapy the patient has received for at least 12 consecutive weeks and will continue to receive at the maximally tolerated dose:

- High-intensity statin therapy
- Moderate-intensity statin therapy (patient unable to tolerate high intensity therapy)
- Low intensity statin therapy (patient unable to tolerate moderate intensity therapy)

Select **ONE** of the following LDL-C values while on maximally tolerated lipid-lowering therapy within the last 120 days:

- LDL-C greater than or equal to 100 mg/dL with ASCVD
- LDL-C greater than or equal to 130 mg/dL without ASCVD
- LDL-C between 70 and 99 mg/dL with ASCVD **AND** 12 consecutive weeks of ezetimibe (Zetia®) therapy as an adjunct to maximally tolerated statin therapy
- LDL-C between 100 mg/dL and 129 mg/dL without ASCVD **AND** 12 consecutive weeks of ezetimibe (Zetia®) therapy as an adjunct to maximally tolerated statin therapy

*Please document: the LDL levels below (Labs **MUST** be attached or authorization will be delayed)*

LDL baseline: _____ LDL post-treatment: _____

B. Select below if the patient is unable to tolerate low, moderate, and high intensity statin therapy as evidenced by one of the following intolerable and persistent symptoms to **TWO** different statins (i.e., more than 2 weeks): documentation **MUST** be provided and claims will be verified.

Drug Name: _____ Strength: _____ Date started: _____

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- Myalgia (muscle symptoms without CK elevations)

OR

- Myositis (muscle symptoms with CK elevations < 10 times upper limit of normal)

AND

- Reinitiating of statin therapy must have been attempted and failed

OR

- Patient has a labeled contraindication to ALL statins as documented in medical records and/or has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations > 10 times upper limit of normal

Renewal criteria – approved for 12 months. Requests must include all of the following information:

- Patient has been compliant on therapy and is continuing a low-fat diet and exercise regimen
- Lipid panel showing further reduction in LDL cholesterol compared to the labs prior to initiating a PCSK9 inhibitor has been submitted:

LDL-C baseline: _____ LDL-C post-Praluent® treatment: _____

- Patient does not have any contraindications to therapy
- Continued adherence to maximally tolerated statin dose established prior to PCSK9 inhibitor approval unless patient has documented inability to take statins
- Patient is continuing a low-fat diet and exercise regimen

Medication being provided by a Specialty Pharmacy - PropriumRx

(signature must be submitted with this form; information on next page)

****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.

Patient Name: _____

Member Optima #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

DEA OR NPI #: _____

***Approved by Pharmacy and Therapeutics Committee:** 9/17/2015

REVISED/UPDATED: 9/28/2015; 10/14/2015; 10/19/2015; 11/4/2015; 11/10/2015; 11/19/2015; 12/29/2015; 12/19/2016; 8/16/2017. **6/28/2018**