

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)**

DRUG INFORMATION: Complete 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 qualify or authorization process will 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.

- Patient has documented trial and failure with Repatha®
- Diagnoses: (select one below)
 - Clinical Atherosclerotic Cardiovascular Disease
 - OR**
 - Heterozygous familial hypercholesterolemia (HeFH)
 - Genetic confirmation of a mutation in the LDL receptor, ApoB-100, or PCSK9, confirmed by clinical criteria (confirmation of FH using either Simon Broome or WHO/Dutch Lipid Network criteria) **OR**
 - Untreated/pre-treatment LDL ≥ 190 mg/dl in adult with presence of tendon xanthomas in patient, first degree relative or second degree relative
- AND**
- Prescribed by, or in consultation with: Cardiologist **OR** Endocrinologist **OR** Lipid Specialist
- Adjunct to low-fat diet and exercise
- No labeled contraindications to PCSK9 therapy

AND two (2) of the following:

<input type="checkbox"/> High-Intensity Statin Candidate	<input type="checkbox"/> Moderate-Intensity Statin Candidate	<input type="checkbox"/> Intolerance to Statins	<input type="checkbox"/> Contraindication to Statins
Patient has received at least 3 months of therapy with: <ul style="list-style-type: none"> ▪ High-intensity statin therapy <li style="text-align: center;">AND ▪ Add-on therapy with ezetimibe (Zetia) or bile acid sequestrants to the maximum tolerable dose of statin <li style="text-align: center;">AND Failure to reach target LDL-C (70 mg/dl for patients with clinical ASCVD and 100 mg/dl for patients with HeFH and no history of clinical ASCVD) <ul style="list-style-type: none"> <li style="text-align: center;">AND Statin therapy will be continued with PCSK9 therapy	Patient has intolerance or contraindications to high-intensity statin therapy <ul style="list-style-type: none"> <li style="text-align: center;">AND Patient has received at least 3 months of therapy with moderate-intensity statin therapy: <ul style="list-style-type: none"> <li style="text-align: center;">AND Add-on therapy with ezetimibe (Zetia) or bile acid sequestrants to the maximum tolerable dose of statin or Vytorin <ul style="list-style-type: none"> <li style="text-align: center;">AND Failure to reach target LDL-C (70 mg/dl for patients with clinical ASCVD and 100 mg/dl for patients with HeFH and no history of clinical ASCVD) <ul style="list-style-type: none"> <li style="text-align: center;">AND Statin therapy will be continued with PCSK9 therapy	Patient experienced one of the following symptoms to at least <u>two</u> different statins <ul style="list-style-type: none"> ▪ Myalgia (muscle symptoms without CK elevations) ▪ Myositis (muscle symptoms with CK elevations < 10 times ULN) <li style="text-align: center;">AND Reinitiating of statin therapy must have been attempted and failed	Patient has a labeled contraindication to all statins as documented in medical records <ul style="list-style-type: none"> <li style="text-align: center;">OR Patient has experienced: <ul style="list-style-type: none"> ▪ Rhabdomyolysis or muscle symptoms with CK elevations ≥ 10 times ULN

(continued on next page)

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
- Patient does not have any contraindications to therapy
- Continued adherence to maximally tolerated statin dose established prior to the initial PCSK9 inhibitor approval

****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 #: _____ Member Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Phone Number: _____ Fax Number: _____

DEA/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; 12/28/2015; 12/19/2016; 9/22/2017