OPTIMA HEALTH COMMUNITY CARE

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 1-800-319-5003. 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) ***(Non-Preferred)*** ***Medicaid***

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

Drug Form/Strength: _____

Dosage Schedule: _____ **Length of Therapy**: _____

Quantity Limit: 2 pens/syringes per month

CLINICAL CRITERIA*: *The following criteria must be met to qualify or authorization process will be delayed.

Initial Criteria Approval – Three (3) months

- ❑ Patient is ≥ 18 years of age; **AND**
- ❑ Prescribed by or in consultation with a specialist (including cardiologists, lipidologists, or endocrinologists); **AND**
- ❑ Diagnosis of atherosclerotic cardiovascular disease (ASCVD); **AND**
- ❑ Heterozygous familial hypercholesterolemia (HeFH) as confirmed by genotyping or by clinical criteria ("definite FH" using either the Simon Broome or WHO/Dutch Lipid Network criteria); **AND**
- ❑ Prior treatment history with highest available dose or maximally-tolerated dose of high intensity statin (atorvastatin or rosuvastatin) AND ezetimibe for at least three continuous months with 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)
- ❑ If the patient is not able to use a maximum dose of atorvastatin or rosuvastatin due to muscle symptoms, documentation of a causal relationship must be established between statin use and muscle symptoms. Documentation must demonstrate that the patient experienced pain, tenderness, stiffness, cramping, weakness, and/or fatigue and all of the following:
  - ❑ Muscle symptoms resolve after discontinuation of statin; **AND**
  - ❑ Muscle symptoms occurred when re-challenged at a lower dose of the same statin; **AND**
  - ❑ Muscle symptoms occurred after switching to an alternative statin; **AND**
  - ❑ Documentation ruling out 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); **OR**
  - ❑ The patient has been diagnosed with statin-induced rhabdomyolysis
- ❑ The diagnosis should be supported by acute neuromuscular illness or dark urine AND an acute elevation in creatine kinase (usually >5,000 IU/L or five times the upper limit of normal)
- ❑ If the patient failed 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), adherence to maximally-tolerated statin and ezetimibe has been verified using pharmacy claims data and the patient is determined to be compliant for at least three consecutive months prior to the lipid panel demonstrating suboptimal reduction
- ❑ Maximally-tolerated statin will continue to be used in conjunction with alirocumab; **AND**
- ❑ Patient has not had a prior trial and failure of an alternative PCSK9 inhibitor; **AND**
- ❑ Request is being made for the lowest approved alirocumab does (75 mg every 2 weeks) to adequately treat the patient. Requests for an escalated dose (150 mg every 2 weeks) must contain a lipid panel documenting suboptimal reduction in LDL-C after at least 4 weeks (2 doses) of alirocumab at the lower (75 mg every 2 weeks) dose.

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Renewal Criteria Approval – Six (6) months (may be requested by PCP)

- ❑ Lipid panel showing a further reduction in LDL-C compared to the labs prior to initiating alirocumab; **AND**
- ❑ Continued adherence to maximally-tolerated statin dose established prior to the original alirocumab 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 #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

DEA OR NPI #: _____

REVISED/UPDATED: ~~6/29/2017;~~ **8/31/2017**