Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	October 8, 2015

PRALUENT® (alirocumab)

LENGTH OF AUTHORIZATION: Initial Review: 3 months Continuation of therapy: 6 months

CLINICAL NOTES: Alirocumab is a PCSK9 (Proprotein Convertase Subtilisin Kexin Type 9) inhibitor antibody indicated as adjunct to maximally tolerated statin therapy and diet for the treatment of adults with clinical atherosclerotic cardiovascular disease or heterozygous familial hypercholesterolemia, that require additional lowering of LDL cholesterol.

INITIAL THERAPY

- Age ≥ 18 years
- Diagnosis of atherosclerotic cardiovascular disease (ASCVD) or 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)
- Prior treatment history with highest available dose or maximally-tolerated dose of high intensity statin (i.e. atorvastatin or rosuvastatin) **AND** Zetia 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 rechallenged 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 Zetia 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
- Patient has not had a prior trial and failure of an alternative PCSK9 inhibitor
- Request is being made for the lowest approved alirocumab dose (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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CONTINUATION OF THERAPY

- Lipid panel showing a further reduction in LDL-C compared to the labs prior to initiating alirocumab
- Continued adherence to maximally-tolerated statin dose established prior to the original alirocumab approval

DOSING & ADMINISTRATION:

- Recommended dose is 75mg subcutaneously once every 2 weeks. The dosage may be increased to the maximum dosage of 150mg administered every 2 weeks if the LDL cholesterol response is inadequate.