Division: Pharmacy Policy	Subject: State of Florida's Agency for Health Care Administration's Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	October 8, 2015 June 21, 2021

PRALUENT® (alirocumab)

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

REVIEW CRITERIA:

- Patient must be ≥18 years old.
- Patient must have a 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)

OR

- Patient must have a diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) confirmed by documented DNA test for functional mutation(s) in both low-density lipoprotein (LDL) receptor alleles or alleles known to affect LDL receptor functionality; or a history of an untreated LDL-C concentration > 500 mg/dL and triglycerides < 300 mg/dL and both parents with documented untreated total cholesterol > 250 mg/dL.

AND

- Prior treatment history with highest available dose or maximally tolerated dose for lipid lowering therapy (e.g., statins, ezetimibe) with failure to reach target an LDL-C <70 mg/dL for patients with clinical ASCVD and 100 mg/dL for patients with HeFH or HoFH and no history of clinical ASCVD.

AND

- Patient has demonstrated statin intolerability as defined by statin-related rhabdomyolysis or skeletal related muscle symptoms.
- Patient has not had a prior trial and failure of an alternative PCSK9 inhibitor.

CONTINUATION OF THERAPY:

- Initial criteria met.
- Lipid panel showing a further reduction in LDL-C compared to the labs prior to initiating alirocumab.
- Continued utilization of maximally tolerated combination lipid lowering therapy established prior to initiating alirocumab.

DOSING & ADMINISTRATION:

- ASCVD and HeFH: 75 mg 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.
- HoFH: 150 mg once every 2 weeks administered subcutaneously.
- Available as 75 mg/mL and 150 mg/mL single-dose pre-filled pens.