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 22, 2015 July 16, 2018, June 21, 2021, December 8, 2021

REPATHA® (evolocumab)

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

REVIEW CRITERIA:

- Patient must be ≥ 18 years old with the diagnosis of Atherosclerotic Cardiovascular Disease (ASCVD).

OR

- Patient must be ≥ 10 years old with the diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH) as confirmed by genotyping or by clinical criteria ("definite FH" using either the Simon Broome, WHO/Dutch Lipid Network criteria, or MEDPED).

OR

- Patient must be ≥ 10 years old with the 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. (Baseline lipid panel demonstrating failure to reach target LDL-C must be provided).

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.

OR

- Adult patient age ≥ 18 years old, for the prevention of cardiovascular events, (myocardial infarction, stroke, and coronary revascularization) with established cardiovascular disease:
  - LDL-C ≥ 70mg/dL and/or non-HDL-C ≥ 100mg/dL.

  AND

  - Prior treatment history with highest available dose or maximally tolerated dose of high intensity statin (e.g., atorvastatin or rosuvastatin).

  AND

  - Other cardiovascular medication(s) currently in the regimen (e.g., anti-platelet, beta blocker, angiotensin converting enzyme inhibitor, or angiotensin receptor blocker).

CONTINUATION OF THERAPY:

- Initial criteria met.
- Lipid panel showing a further reduction in LDL-C compared to the labs prior to initiating evolocumab.

- Continued utilization of maximally tolerated combination lipid lowering therapy established prior to initiating evolocumab.

DOSING & ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as 140 mg/mL solution single-dose prefilled syringe, 140 mg/mL solution single-dose prefilled SureClick® Autoinjector, and 420 mg/3.5 mL solution single-dose Pushtronex® system.