

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:	June 21, 2021

EVKEEZATM (evinacumab)

LENGTH OF AUTHORIZATION: Up to one year

<u>REVIEW CRITERIA</u>:

- Patient must be ≥ 12 old.
- Patient must have a diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) confirmed by documented functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL receptor functionality or skin fibroblast LDL receptor activity <20% normal, or a history of an untreated LDL-C concentration >500 mg/dL and triglycerides <300 mg/dL and both parents with a history of 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 HoFH.

AND

Patient has demonstrated statin intolerability as defined by statin-related rhabdomyolysis or skeletal related muscle symptoms.

CONTINUATION OF THERAPY:

- Initial criteria met.
- Documentation of improvement of LDL-C compared to baseline labs.
- Continued utilization of maximally tolerated combination lipid lowering therapy (e.g., statin, ezetimibe).

DOSING AND ADMINISTRATION:

- Administer 15 mg/kg intravenous (IV) infusion once monthly.
- Available as 345 mg/2.3 mL (150 mg/mL) and 1,200 mg/8 mL (150 mg/mL) solution in single-dose vials.