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:	March 6, 2013 December 19, 2016, June 21, 2021

JUXTAPID® (lomitapide)

LENGTH OF AUTHORIZATION: Up to 6 months

REVIEW CRITERIA:

- Patient must be ≥18 years 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 documented 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.
- Must be prescribed by a certified REMS provider demonstrated with supporting documentation (signed attestation).
    - http://www.juxtapidremsprogram.com/

CONTINUATION OF THERAPY:

- Initial criteria met.
- Lipid panel showing improvement from baseline labs.
- Continued utilization of maximally tolerated combination lipid lowering therapy (e.g., statin, ezetimibe).

DOSING & ADMINISTRATION:

- Recommended to initiate treatment at 5 mg once daily. Increase to 10 mg daily after at least 2 weeks; and then, at a minimum of 4-week intervals, to 20 mg, 40 mg, and up to the maximum recommended dose of 60 mg daily.
- Available as 5 mg, 10 mg, 20 mg, and 30 mg capsule.