Prior Authorization Approval Criteria
Juxtapid (lomitapide)

Generic name: lomitapide
Brand name: Juxtapid
Medication class: Microsomal triglyceride transfer protein inhibitor
FDA-approved uses: as an adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available, to reduce low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high-density lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH)

Criteria for approval (bullet points below are all inclusive unless otherwise noted):
• Must be clinically diagnosed with homozygous familial hypercholesterolemia (HoFH) and have elevated LDL levels.
• Must be used as an adjunct to a low fat diet and other lipid lowering treatments, including LDL apheresis.
• Tried and failed maximum dose of atorvastatin or rosuvastatin or intolerant to either medication.
• Must have tried LDL apheresis without complete results.
• Tried and failed a statin in combination with other lipid lowering therapies such as ezetimibe, bile acid sequestrants, or niacin.

Criteria for continuation of therapy:
• Patient’s therapy has been re-evaluated within the last 12 months, unless a re-evaluation is not clinically appropriate for the patient’s condition at this time.
• Patient is tolerating treatment and there continues to be a medical need for the medication
• Patient has disease stabilization or improvement in disease (as defined by standard parameters for the patient’s condition)

Caution:
• May cause elevations in transaminases; monitoring recommended
• Hepatic steatosis, with or without concomitant increases in transaminases, may occur
• Severe GI adverse reactions have been reported
• Avoid concomitant use with grapefruit juice and LDL-lowering agents

Contraindication:
• Pregnancy
• Concomitant use with strong or moderate CYP3A4 inhibitors.
• Moderate or severe hepatic impairment or active liver disease including unexplained persistent abnormal liver function tests.

Special considerations:
• Prescribers must be certified to prescribe.
• Because of the risk of hepatotoxicity, Juxtapid is available only through a Risk Evaluation and Mitigation Strategy (REMS) program called the Juxtapid REMS Program. Measure ALT, AST, alkaline phosphatase, and total bilirubin at baseline, before initiation of treatment, and discontinue for clinically significant liver toxicity.
Approval Duration:
- Indefinite

Benefit Type:
- Pharmacy

Adopted: 06/12/13
Revised: 12/14/16, 3/8/17
Reviewed:
3/8/17-no change