Prior Authorization Criteria

JUXTAPID® (lomitapide) PA CRITERIA:

For use 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)

Juxtapid may be approved based on ALL of the following criteria:

INITIAL AUTHORIZATION: 6 months

☐ Yes ☐ No Age of patient is within the age of the FDA label; AND

☐ Yes ☐ No Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist; AND

☐ Yes ☐ No Diagnosis of Homozygous Familial Hypercholesterolemia (HoFH), based on the presence of the following:

  • Genetic confirmation of two mutant alleles at the LDLR, ApoB, PCSK9, or LDLRAP1 gene locus
    OR
  • Treated LDL-C of > 300 mg/dL OR untreated LDL-C of > 500 mg/dL;

    AND

☐ Yes ☐ No ONE of the following:

  o Cutaneous or tendon xanthoma before age 10 years; OR
  o Evidence of heterozygous familial hypercholesterolemia in both parents such as:

    • LDL > than 190 mg/dL or TC > 310mg/dL
    or
    • Premature ASCVD (before age 55 men; before age 60 women)
    or
    • Sudden premature cardiac death
    or
    • Tendon xanthoma

    AND

☐ Yes ☐ No History of intolerance, failure or contraindication to Repatha (evolocumab); AND

☐ Yes ☐ No Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe, LDL apheresis); AND

☐ Yes ☐ No Not used in combination with a PCSK-9 Inhibitor.
REAUTHORIZATION: 12 months

☐ Yes  ☐ No  Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist; AND

☐ Yes  ☐ No  Patient is adherent to and will continue a low-fat diet and exercise regimen; AND

☐ Yes  ☐ No  Submission of medical records (e.g. chart notes, laboratory values) upon request documenting maintenance of LDL-C reduction while on Juxtapid therapy; AND

☐ Yes  ☐ No  Patient does not have any contraindications to therapy; AND

☐ Yes  ☐ No  Not used in combination with a PCSK9 inhibitor; AND

☐ Yes  ☐ No  If appropriate, beneficiary continues to receive other lipid-lowering therapy (e.g., statin, ezetimibe, LDL apheresis, etc.).

Juxtapid Product Availability:

- Capsules 5mg, 10mg, 20mg, 30mg, 40mg, and 60 mg