Juxtapid (lomitapide)

Coverage Criteria:

Reserved for requests meeting all three criteria listed below:

1. Juxtapid is reserved for FDA-approved indications
   a. Homozygous Familial Hypercholesterolemia

2. Juxtapid is reserved for prescribing by Cardiology, Endocrinology, Lipidology, advanced practice providers within these specialties, and other providers in consultation with these specialists.

3. Patient has had a trial and failure of (or medical contraindications to) Evkeeza.

4. Juxtapid is reserved for patients with (a) therapeutic failure on standard therapy or (b) intolerance/ contraindications to standard therapy.

   Standard therapy includes a high intensity statin (atorvastatin 40-80mg daily or rosuvastatin (20-40mg daily), Repatha, and ezetimibe (Zetia).*
   * A trial with Zetia is required unless patients are unlikely to reach goals (LDL cholesterol while taking high-intensity statins and Repatha >= 100 mg/ dL for secondary prevention, or >= 130 mg/ dL for primary prevention).

   a. Therapeutic failure on standard therapy is defined as an inability to achieve and maintain an LDL cholesterol level below 70 mg/dL for secondary prevention, or 100 mg/dL for primary prevention.

      Patients must have documented adherence >= 80%, based on three or more prescriptions fills over six or more months.
      Current cholesterol lab values and cholesterol treatment history must be submitted.

   b. Intolerance to statin therapy is defined as increased LFTs (an ALT >= 3x ULN), or intolerable myalgia or myopathy.

      One retrial of high-intensity statins over three or more months is required.
      Some patients not tolerating atorvastatin may be able to tolerate rosuvastatin.
      A second re-trial with lower doses or alternative statins over three or more months is required.
      Contraindications to high-intensity statin therapy are defined as rhabdomyolysis or myositis (creatine kinase level >= 10x ULN).

A therapeutic failure on lower doses or alternative statins is defined as an inability to achieve and maintain goals (LDL cholesterol level below 70 mg/dL for secondary prevention, or 100 mg/dL for primary prevention). A trial with Zetia is also required unless patients are unlikely to reach goals (LDL cholesterol >= 100 mg/ dL for secondary prevention, or >= 130 mg/ dL for primary prevention).

Juxtapid is limited to the FDA-approved dose.
Initial authorizations are for a period of 3 months. Reauthorizations are given annually for patients with a clinically significant response to treatment (LDL reductions >= 35%).