Prior Authorization Approval Criteria
Kynamro (mipomersen)

Generic name: Mipomersen
Brand name: Kynamro
Medication class: Antisense oligonucleotide

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 intolerant to atorvastatin.
- Tried and failed maximum dose of rosuvastatin or intolerant to rosuvastatin.
- 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:

- Injection site reactions may occur and typically consist of one or more of the following: erythema, pain, tenderness, pruritus and local swelling.
- Flu-like symptoms, which typically occur within 2 days after an injection, may occur and include one or more of the following: influenza-like illness, pyrexia, chills, myalgia, arthralgia, malaise or fatigue.
- Monitor for elevations in transaminases.
- Increases in hepatic fat, with or without increases in transaminases, have been reported and may increase risk for advanced liver disease, including steatohepatitis and cirrhosis.

Contraindication:

- Moderate or severe hepatic impairment, or active liver disease, including unexplained persistent abnormal liver function tests.
- Known sensitivity to product components.

Special considerations:

- Prescribers must be certified to prescribe.
• Because of the risk of hepatotoxicity, Kynarmo is available only through a Risk Evaluation and Mitigation Strategy (REMS) program called the Kynarmo REMS Program.
• Pregnancy category B

Approval Duration:
• Indefinite

Benefit Type:
• Pharmacy

Adopted: 12/11/13
Revised: 12/14/16, 3/8/17
Reviewed:
3/8/17-no change