Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

KYNAMRO® (mipomersen sodium) PA CRITERIA:

Kynamro (mipomersen sodium) is an oligonucleotide inhibitor of apolipoprotein B-100 synthesis indicated as an adjunct to lipid-lowering medications and diet to reduce low density lipoprotein-cholesterol (LDL-C), apolipoprotein B (apo B), total cholesterol (TC), and non-high density lipoprotein-cholesterol (non HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH). The safety and efficacy of Kynamro have not been established in patients with hypercholesterolemia who do not have HoFH.

Kynamro must be prescribed by, or in consultation with a cardiologist, endocrinologist, or lipid specialist and submits upon request, the following clinical documentation:

Initial Authorization: 6 months

- Age ≥ 18 years; ***AND***
- 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 plus ONE of the following:
        - Cutaneous or tendon xanthoma before age of 10 years
        - Untreated LDL-C levels consistent with heterozygous familial hypercholesterolemia in both parents
            - LDL > than 190 mg/dL or TC > 310mg/dL
            - Premature ASCVD (before age 55 men; before age 60 women)
            - Sudden premature cardiac death
            - Tendon xanthoma

    AND

- Must meet prior authorization criteria for and failed or had clinically significant adverse effects to Repatha (evolocumab) 420mg (unless contraindicated)

Kynamro will NOT be approved for the following:

1. Concurrent use with PCSK-9 Inhibitors
2. Concurrent use with Juxtapid (lomitapide)
3. Use of Kynamro as an adjunct to LDL ***apheresis is not*** recommended as safety and effectiveness have not been established.

<u>Reauthorization</u>: 12 months

Authorization for continued use shall be reviewed at least every 12 months to confirm all of the following criteria are met:

- Beneficiary's response to therapy compared to baseline is positive and this response is maintained upon subsequent reauthorizations. (Submission of medical records with chart notes, laboratory values upon request documenting maintenance of LDL-C reduction while on Kynamro therapy.); ***AND***
- Beneficiary does not have any contraindications to therapy; ***AND***
- If appropriate, beneficiary continues to receive other lipid-lowering therapy (e.g., statin, etc.); ***AND***
- Physician attests that beneficiary is adherent to and will continue a low-fat diet and exercise regimen

Contraindication:

- Beneficiary does not have moderate or severe hepatic impairment (ie, Child-Pugh category B or C) or active liver disease including unexplained persistent elevations of serum transaminases.

General Information:

- Safety and effectiveness of Kynamro have not been established in patients with hypercholesterolemia who do not have HoFH.
- Safety and effectiveness have not been studied for patients < 18 years of age.
- Effect on cardiovascular morbidity and mortality has not been determined.
- Kynamro is not recommended for use with LDL apheresis.
- Kynamro has a "Black Box" warning for risk of hepatotoxicity. Kynamro can cause elevations in transaminases. Kynamro also increases hepatic fat (hepatic steatosis) with or without concomitant increases in transaminases.
- Kynamro should be discontinued for clinically significant liver toxicity.
- Because of the risk of hepatotoxicity, availability is only through a Risk Evaluation and Mitigation Strategy (REMS) program.

Dosing:

- The recommended dose of Kynamro is 200 mg SQ once weekly.
- Kynamro is intended for subcutaneous use only. Do not administer IM or IV.
- The injection should be given on the same day every week, but if a dose is missed, the injection should be given at least 3 days from the next weekly dose.

Product Availability:

- Pre-filled syringe: 1 ml of 200 mg/ml solution
- Dosing Regimen: 200 mg SC once per week