Alaska Medicaid

JUXTAPID™(lomitapide) OR KYNAMRO®(mipomersen sodium)

Juxtapid available 5mg 10mg, and 20mg capsules
Kynamro available 200mg/ml solution

INDICATIONS and USAGE:

JUXTAPID: JUXTAPID is indicated 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).

Limitations of Use

- The safety and effectiveness of JUXTAPID have not been established in patients with hypercholesterolemia who do not have HoFH.
- The effect of JUXTAPID on cardiovascular morbidity and mortality has not been determined.

KYNAMRO: KYNAMRO™ is 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).

Limitations of Use

- The safety and effectiveness of KYNAMRO have not been established in patients with hypercholesterolemia who do not have HoFH.
- The effect of KYNAMRO on cardiovascular morbidity and mortality has not been determined.
- The safety and effectiveness of KYNAMRO as an adjunct to LDL apheresis have not been established; therefore, the use of KYNAMRO as an adjunct to LDL apheresis is not recommended.

Criteria for Approval:

1. Confirmed diagnosis of homozygous familial hypercholesterolemia (HoFH); **AND**
    a. **Submit** clinical or laboratory confirmed diagnosis of HoFH
2. **Box Warnings** discussed with recipient and all relevant lab work is being monitored; **AND**
3. Submit current lipid-lowering treatments; **AND**
4. For female recipients, obtain a negative pregnancy test of reproductive potential; **AND**
5. Medical records documenting that prior to the initiation of therapy, the recipient is on a low-fat diet supplying < 20% of energy from fat; **AND**
6. Recipient is 18 years of age or older

Length of Authorization:

Initial authorization will be limited to 6 months. For continuation of therapy, submit medical records, documenting tolerance, progress notes, and effectiveness of therapy (May be approved up to 12 months).

Dispensing Limit:

The dispensing limit is a 30 day supply of medication with the following **Quantity Limit:**

JUXTAPID:

- 5mg or 10mg – one (1) capsule per day
- 20mg – up to three (3) capsules per day

KYNAMRO:

- Four(4) vials or prefilled syringes per month

Reminder: You are encouraged to report negative side effects of prescription drugs to the FDA. Visit http://www.fda.gov/Safety/MedWatch/default.htm or call 1-800-FDA-1088

References:

JUXTAPID™ package insert is available at: < http://www.juxtapid.com/ >
Accessed 10/14/13

KYNAMRO® package insert is available at: < http://www.kynamro.com/families.aspx >
Accessed 10/14/13