JUXTAPID (lomitapide mesylate) & KYNAMRO (mipomersen sodium)
Pharmacy Coverage Policy

CRITERIA FOR COVERAGE/NONCOVERAGE

JUXTAPID (lomitapide mesylate) and KYNAMRO (mipomersen sodium) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

- Patient has a diagnosis of homozygous familial hypercholesterolemia (HoFH) as evidence by one of the following:
  - Genetic confirmation of 2 mutant alleles at the LDL receptor, ApoB, PCSK9, or autosomal recessive hypercholesterolemia (ARH) adaptor protein gene locus OR
  - Untreated/pre-treatment LDL >500 mg/dL with at least one of the following:
    - Cutaneous or tendonous xanthoma before age 10 years
    - History of early vascular disease (men <55 years of age, women <60 years of age) on both sides of the family if parental LDL levels are unknown
    - Elevated LDL cholesterol levels before lipid-lowering therapy consistent with heterozygous FH in both parents where LDL levels are known:
      - LDL cholesterol >250 mg/dL in a patient aged 30 or more;
      - LDL cholesterol >220 mg/dL for patients aged 20 to 29;
      - LDL cholesterol >190 mg/dL in patients under age 20;

AND
- Juxtapid or Kynamro will be used as adjunct to a low-fat diet and other lipid-lowering treatments

AND
- Patient does not have any of the following contraindications to therapy:
  - Pregnancy (Juxtapid only)
  - Concomitant use with strong or moderate CYP3A4 inhibitors (Juxtapid only)
  - Moderate or severe hepatic impairment or active liver disease including unexplained persistent abnormal liver function tests

AND
- Patient has tried and had an inadequate response to the maximum tolerated dose of a high potency statin (e.g. atorvastatin, rosuvastatin), unless all statins are contraindicated
Quantity Limits:
Juxtapid will be subject to the following quantity limits:
- 5 mg tablets: 1 tablet/day
- 10 mg tablets: 1 tablet/day
- 20 mg tablets: 3 tablets/day
- 30 mg tablets: 1 tablets/day
- 40 mg, 60 mg tablets: 1 tablet/day

Kynamro will be subject to the following quantity limits:
- 200mg/mL vials: 1 vial/week

Initial Authorization Duration: 6 months

Reauthorization Criteria and Duration:
Authorization for continued use shall be reviewed at least every 12 months to confirm all of the following criteria are met:
- Patient has responded to therapy (i.e. decreased LDL levels) from baseline AND
- Patient does not have any contraindications to therapy