# PHARMACY PRE-AUTHORIZATION CRITERIA

## DRUG (S)

<table>
<thead>
<tr>
<th>Juxtapid (lomitapide)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kynamro (mipomersen)</td>
</tr>
</tbody>
</table>

## POLICY #

23107

## INDICATIONS

Juxtapid is indicated as an adjunct to a low-fat diet and other lipid-lowering treatments, including low-density lipoprotein (LDL) apheresis where available, to reduce LDL cholesterol, total cholesterol, apolipoprotein B (apo B), and non–high-density lipoprotein cholesterol (non–HDL-C) in patients with homozygous familial hypercholesterolemia.

Kynamro is indicated in homozygous familial Hypercholesterolemia 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.

## CRITERIA

ConnectiCare will consider Juxtapid and Kynamro to be medically necessary in patients who meet all of the following criteria:

- Medication is being prescribed by a cardiologist, lipidologist, or endocrinologist
- Member must be 18 years of age or older
- Member must have a diagnosis of definite homozygous familial hypercholesterolemia as defined by at least one of the following:
  - Genetic confirmation of 2 mutant alleles at the LDL receptor, ApoB, PCSK9, or ARH adaptor protein gene locus
  - OR
  - An untreated LDL-C > 500 mg/dL or treated LDL-C > 300 mg/dL, or treated non-HDL cholesterol > 330 mg/dL

  **With at least one of the following:**
  - Cutaneous or tendonous xanthoma before age 10 years
  - OR
  - Elevated LDL cholesterol levels before lipid lowering therapy consistent with heterozygous familial hypercholesterolemia in both parents (untreated total cholesterol > 290 mg/dL (7.5 mmol/L) or untreated LDL-C > 190 mg/dL

  **AND**
  - Member must have had 90 days of consecutive therapy in the past 12 months, intolerance or contraindication to a high intensity HMG CoA reductase inhibitor (statin) at the maximum approved or tolerated dose per the package insert (high intensity statins include atorvastatin 80 mg and Crestor 40 mg) and Zetia

  **AND**
  - Member has had an inadequate response or contraindication to Repatha
# Pharmacy Pre-Authorization Criteria

## Drug(s)

| Juxtapid (lomitapide)  
| Kynamro (mipomersen) |

## Limitations

- Initial approval will be for 8 weeks. Further approval will require evidence of at least a 30% reduction in baseline LDL level.
- Juxtapid will be allowed at a quantity of 30 capsules per month.
- Kynamro may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

## References

7. Facts & Comparisons, Online

## P&T Review History

2/13, 10/13, 10/14, 11/15, 8/16, 8/17, 7/18

## Revision Record

8/16