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# Antihyperlipidemics – Apolipoprotein B Synthesis Inhibitors: mipomersen sodium (KYNAMRO®)

## WA.PHAR.37 Antihyperlipidemics APOB Synthesis Inhibitors KYNAMRO

### Related medical policies:

- Antihyperlipidemics – Apolipoprotein B Synthesis Inhibitors: lomitapide mesylate (JUXTAPID®)
- Antihyperlipidemics – Proprotein Converstase Subtilisin Kexin type 9 (PCSK-9) Inhibitors

### Background:

Apolipoprotein B is a protein that in humans is encoded by the APOB gene. Apolipoprotein B is the primary apolipoprotein of chylomicrons, VLDL, IDL, and LDL particles, which is responsible for carrying fat molecules, including cholesterol, around the body to all cells within all tissues. While all the functional roles of ApoB within the LDL particles remains somewhat unclear, it is the primary organizing protein component of the particles and is required for the formation of these particles. What is also clear is that the ApoB on the LDL particle acts as a ligand for LDL receptors, in various cells throughout the body.

### Medical necessity

Drug	Medical Necessity
Mipomersen sodium (KYNAMRO®)	May be considered medically necessary when: Used for the treatment of homozygous familial hypercholesterolemia (HoFH)

### Clinical policy:

Drug	Clinical Criteria (Initial Approval)
Mipomersen sodium (KYNAMRO®)	<ol style="list-style-type: none"> <li>Homozygous familial hypercholesterolemia (HoFH) confirmed by <b>one</b> of the following:               <ol style="list-style-type: none"> <li>Genetic confirmation of two mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus.</li> <li>Documented DNA test for functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL receptor functionality</li> <li>An untreated low density lipoprotein (LDL) cholesterol &gt; 500mg/dL and TG &lt; 300 mg/dL and both parents with documented untreated TC &gt; 250 mg/dL with either:                   <ol style="list-style-type: none"> <li>Cutaneous or tendon xanthoma before age 10 years</li> <li>Evidence of heterozygous familial hypercholesterolemia in both parents</li> </ol> </li> </ol> </li> <li>Greater than or equal to (≥) 18 years of age</li> <li>Prescribed by or in consultation with a provider specializing in lipid management (e.g. cardiologist, lipid specialist, or endocrinologist)</li> </ol>

	<b>Approve for 6 months</b>
	<b>Criteria (Reauthorization)</b>
	<ol style="list-style-type: none"> <li>Continued clinical benefit (e.g. LDL reduction over baseline)</li> <li>Prescribed by or in consultation with a cardiologist or endocrinologist</li> </ol>
	<b>Approve for 12 months</b>

## Dosage and quantity limits

Drug Name	Dose and Quantity Limits
Kynamro 200mg/mL solution	200mg SQ injection once weekly; #4 vials/syringe in 28-days

## References

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- Stein, EA, Dufour, R, Gagne, C, et al. Apolipoprotein B synthesis inhibition with mipomersen in heterozygous familial hypercholesterolemia: results of a randomized, double-blind, placebo-controlled trial to assess efficacy and safety as add-on therapy in patients with coronary artery disease. *Circulation*. 2012;126:2283-92. PMID: 23060426
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- Juxtapid® [Prescribing Information]. Cambridge, MA: Aegerion Pharmaceuticals; May 2016