



coordinated care™

Antihyperlipidemics – Apolipoprotein B Synthesis Inhibitors: lomitapide mesylate

WA.PHAR.38 Antihyperlipidemics APOB Synthesis Inhibitors JUXTAPID

Related medical policies:

- Antihyperlipidemics - Apolipoprotein B Synthesis Inhibitors: Mipomersen sodium (KYNAMRO®)
- Antihyperlipidemics – Proprotein Converterase Subtilisin Kexin type 9 (PCSK-9) Inhibitors

Background:

Apolipoprotein B (ApoB) is a protein that in humans is encoded by the APOB gene. ApoB 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
Lomitapide mesylate (JUXTAPID®)	May be considered medically necessary when: Used for the treatment of homozygous familial hypercholesterolemia (HoFH)

Clinical policy:

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

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

Dosage and quantity limits

Drug Name	Dose and Quantity Limits
Juxtapid 5mg capsule	#1 capsule per day; #28 capsules per 28-days
Juxtapid 10mg capsule	#1 capsule per day; #28 capsules per 28-days
Juxtapid 20mg capsule	#1 capsule per day; #28 capsules per 28-days
Juxtapid 30mg capsule	#1 capsule per day; #28 capsules per 28-days
Juxtapid 40mg capsule	#1 capsule per day; #28 capsules per 28-days
Juxtapid 60mg capsule	#1 capsule per day; #28 capsules per 28-days

References

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