Antihyperlipidemics– Apolipoprotein B Synthesis Inhibitors: lomitapide mesylate

WA.PHAR.38 Antihyperlipidemics– Apolipoprotein B Synthesis Inhibitors: lomitapide mesylate Effective: November 3, 2018

Related medical policies:

- **Antihyperlipidemics – Proprotein Converatase Subtilisin Kexin type 9 (PCSK-9) Inhibitors**

Note:

- *For non-preferred agents in this class/category, patients must have had an inadequate response or have had a documented intolerance due to severe adverse reaction or contraindication to at least TWO* preferred agents.*
  **If there is only one preferred agent in the class/category documentation of inadequate response to ONE preferred agent is needed*
- *If a new-to-market drug falls into an existing class/category, the drug will be considered non-preferred and subject to this class/category prior authorization (PA) criteria*

Background:

Lomitapide is a microsomal triglyceride transfer protein inhibitor 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-HDLC) in patients with homozygous familial hypercholesterolemia (HoFH).

Medical necessity

Drug	Medical Necessity
Lomitapide mesylate (JUXTAPID®)	May be considered medically necessary when: Used for the treatment of homozygous familial hypercholesterolemia (HoFH) following a trial of a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor

Clinical policy:

Drug	Clinical Criteria (Initial Approval)
Lomitapide mesylate (JUXTAPID®)	1. Homozygous familial hypercholesterolemia (HoFH) confirmed by **one** of the following: a. Genetic confirmation of two mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus. b. Documented DNA test for functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL receptor functionality c. 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: i. Cutaneous or tendon xanthoma before age 10 years ii. Evidence of heterozygous familial hypercholesterolemia in both parents

	2. History of failure after 3 months of **two** PCSK9 inhibitors with different active ingredients without decrease of LDL to patient specific goal, unless contraindication or intolerance due to severe adverse side effects. 3. Greater than or equal to (≥) 18 years of age 4. 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)
	1. Continued clinical benefit (e.g. LDL reduction over baseline) 2. 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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History

Date	Action and Summary of Changes
12/6/2018	Removal of Kynamro from related policies
11/02/2018	Trial of PCSK-9 added
04/18/2018	New Policy