

Market Applicability/Effective Date														
Market	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

Juxtapid (lomitapide)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Juxtapid (lomitapide)	1 capsule per day

APPROVAL CRITERIA

Requests for Juxtapid (lomitapide) may be approved based on the following criteria:

- I. Individual is 18 years of age or older and has a clinical diagnosis of Homozygous Familial Hypercholesterolemia (HoFH), based on the presence of the following:
 - a. Genetic confirmation of two mutant alleles at the LDL receptor, ApoB, PCSK9 or ARH adaptor protein gene locus; **OR**
 - b. An untreated LDL-cholesterol concentration > 500 mg/dL (13 mmol/L); **OR**
 - c. Treated LDL-cholesterol ≥ 300 mg/dL (7.76 mmol/L) **AND** one of the following:
 - i. Cutaneous or tendonous xanthoma before age of 10 years; **OR**
 - ii. Untreated LDL cholesterol levels consistent with heterozygous FH in both parents (> 190 mg/dL)

AND

- II. Individual has had an adequate trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and titration of Repatha or Repatha Pushtronex and achieved suboptimal lipid lowering response, despite at least 90 days of compliant therapy.

Juxtapid (lomitapide) may **not** be approved for the following:

- I. Concurrent use with PCSK-9 Inhibitors; **OR**
- II. Individual with moderate or severe hepatic impairment (Child-Pugh B or C) or active liver disease.

Note: Juxtapid is a pregnancy category X. Juxtapid (lomitapide) has a black box warning for risk of hepatotoxicity. Juxtapid can cause elevations in transaminases. Juxtapid also increases hepatic fat (hepatic steatosis) with or without concomitant increases in transaminases.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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Because of the risk of hepatotoxicity, Juxtapid is only available through a restricted program, Juxtapid REMS.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2016. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2016; Updated periodically.

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