

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	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)	May be subject to quantity limit

### 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 diagnosis of homozygous familial hypercholesterolemia (HoFH) based on the presence of the following (Cuchel 2014, Singh 2015):
  - A. Genetic confirmation of two mutant alleles at the LDL receptor, apoB, PCSK9 or ARH adaptor protein (LDLRAP1) gene locus; **OR**
  - B. One of the following:
    1. An untreated LDL-cholesterol (LDL-C) concentration greater than 500 mg/dL (13 mmol/L); **OR**
    2. Treated LDL-C greater than or equal to 300 mg/dL (7.76 mmol/L) **AND** one of the following:
      - a. Cutaneous or tendonous xanthoma before age of 10 years; **OR**
      - b. Untreated LDL-C levels consistent with heterozygous familial hypercholesterolemia in both parents (greater than 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 (ACC 2016).

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

- I. Concurrent use with PCSK-9 Inhibitors; **OR**

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- II. Individual with moderate or severe hepatic impairment (Child-Pugh B or C) or active liver disease.

**Note:** 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. Because of the risk of hepatotoxicity, Juxtapid is only available through restricted distribution REMS programs.

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

**Key References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. Cuchel M, Bruckert E, Ginsberg HN, et. al. Homozygous familial hypercholesterolaemia: new insights and guidance for clinicians to improve detection and clinical management. *European Heart Journal*. 2014; 35: 2146–2157.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: July 13, 2018.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.
6. Lloyd-Jones DM, Morris PB, Ballantyne CM, et al. 2016 ACC expert consensus decision pathway on the role of non-statin therapies for LDL-cholesterol lowering in the management of atherosclerotic cardiovascular disease risk: a report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents. *J Am Coll Cardiol*. 2016;68:92–125.
7. Rosenson RS, Durrington P. Familial hypercholesterolemia in adults: Overview. Last updated March 12, 2018. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: July 13, 2018.
8. Rosenson RS, Durrington P. Familial hypercholesterolemia in adults: Treatment. Last updated May 15, 2017. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: July 13, 2018.
9. Singh S, Bittner V. Familial hypercholesterolemia--epidemiology, diagnosis, and screening. *Curr Atheroscler Rep*. 2015; 17(2):482.

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