UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2021 P 2072-9 |
| Program | Prior Authorization/Medical Necessity |
| Medication | Juxtapid® (lomitapide) |
| P&T Approval Date | 10/2015, 9/2016, 9/2017, 9/2018, 9/2019, 9/2020, 7/2021 |
| Effective Date | 10/1/2021;<br>Oxford only: 10/1/2021 |

**1. Background:**

Juxtapid (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-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH). The safety and efficacy of Juxtapid have not been established in patients with hypercholesterolemia who do not have HoFH.

Members currently on Juxtapid, as documented in claims history, will be allowed continued coverage of their current therapy. Members new to therapy will be required to meet the coverage criteria below.

**2. Coverage Criteria[a]:**

**A. Initial Authorization**

**1. Juxtapid** will be approved based on **all** of the following criteria:

a. Diagnosis of homozygous familial hypercholesterolemia (HoFH) as confirmed by **both** of the following:[2]*

(1) **One** of the following:

(a) Pre-treatment LDL-C greater than 500 mg/dL
(b) Treated LDL-C greater than 300 mg/dL

**-AND-**

(2) **One** of the following:

(a) Xanthoma before 10 years of age
(b) Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

**-AND-**

b. Used as an adjunct to a low-fat diet and exercise

**-AND-**

c. Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe, LDL apheresis)

**-AND-**

d. Prescribed by **one** of the following:

(1) Cardiologist
(2) Endocrinologist
(3) Lipid specialist

**-AND-**

e. **One** of the following:

(1) **All** of the following:

(a) History of intolerance, failure or contraindication to Repatha (evolocumab)

**-AND-**

(b) Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor

**-AND-**

(c) History of intolerance, failure or contraindication to Evkeeza (evinacumab)

**-OR-**

(2) Patient is currently on Juxtapid therapy

*Results of prior genetic testing can be submitted as confirmation of diagnosis of HoFH, however please note that UnitedHealthcare commercial plans do not currently cover genetic testing for evidence of an LDL-receptor mutation, familial defective apo B-100 or a PCSK9 mutation.

**Authorization will be issued for 6 months.**

**B. Reauthorization**

**1. Juxtapid** will be approved based on **all** of the following criteria:

a. Patient is continuing a low-fat diet and exercise regimen

**-AND-**

b. Patient continues to receive other lipid-lowering therapy (e.g., statin, LDL apheresis)

**-AND-**

c. Submission of medical records (e.g. chart notes, laboratory values) documenting LDL-C reduction while on Juxtapid therapy

**-AND-**

d. Prescribed by **one** of the following:

(1) Cardiologist
(2) Endocrinologist
(3) Lipid specialist

**-AND-**

e. Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor

**Authorization will be issued for 12 months.**

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

**4. Reference:**


1. Juxtapid [package insert]. Cambridge, MA: Amryt Pharmaceuticals; September 2020.
2. Cuchel M, Bruckert E, Ginsberg HN, et al. Homozygous familial hypercholesterolaemia: new insights and guidance for clinicians to improve detection and clinical management. A position paper from the Consensus Panel on Familial Hypercholesterolaemia of the European Atherosclerosis Society. Eur Heart J. 2014; 35:2146-57.


| Program | Prior Authorization/Medical Necessity - Juxtapid™ (lomitapide) |
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| **Change Control** | |
| 10/2015 | New program. |
| 7/2016 | Added Indiana and West Virginia coverage information. |
| 9/2016 | Annual Review. Updated references. |
| 11/2016 | Administrative change. Added California coverage information. |
| 9/2017 | Annual review. Removed requirement of medical record submission for diagnosis documentation. Updated state mandate verbiage. |
| 9/2018 | Annual review with no changes to coverage criteria. Updated reference. |
| 9/2019 | Annual review. Removed criteria regarding combination therapy with |

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| | Kynamro as Kynamro no longer on market. |
| 9/2020 | Annual review with no changes to coverage criteria. Updated reference. |
| 7/2021 | Added continuation of coverage to background and criteria. Added Evkeeza as step through agent. Updated reference. |