UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Juxtapid

Program	Prior Authorization
Medication	Juxtapid® (lomitapide)
Markets in Scope	Arizona, California, Colorado Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	3/2013
Pharmacy and Therapeutics Approval Date	9/2020
Effective Date	11/2020

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.

Juxtapid has a black box warning for risk of hepatotoxicity and requires an experienced clinician to carefully monitor the patient. Please see full prescribing information for additional details.

2. Coverage Criteria:

A. <u>Initial Authorization</u>

1. **Juxtapid** will be approved based on **<u>all</u>** of the following criteria:

   a. Diagnosis of homozygous familial hypercholesterolemia (HoFH) as confirmed by **<u>both</u>** of the following:*

      (1) **<u>One</u>** of the following:

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

      -AND-

      (2) **<u>One</u>** 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. History of intolerance, failure or contraindication to Repatha (evolocumab)

-AND-

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

*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 12 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.

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. References:

1. Juxtapid [package insert]. Cambridge, MA: Aegerion Pharmaceuticals;December 2019.
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 - Juxtapid® (lomitapide)
Change Control	
Date	Change
3/2013	New guideline
3/2014	Updated criteria to require patient to be both on a low-fat diet and receiving other lipid-lowering therapy (e.g., statin, LDL apheresis) Reformatted policy to align with UHC standard format

10/2015	Updated initial authorization criteria to require all of the following:
	• Submission of medical records documenting diagnosis of HoFH as confirmed by one of the following:
	  ○ Both of the following:
	  ▪ Untreated LDL-C > 500 mg/dL, or treated LDL-C > 300 mg/dL, AND
	  ▪ Xanthoma before 10 years of age, or evidence of HeFH in both parents
	• Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe, LDL apheresis)
	• Used as adjunct to low-fat diet and exercise regimen
	• Prescribed by cardiologist, endocrinologist, or lipid specialist
	• History of failure, contraindication, or intolerance to Repatha (evolocumab)
	• Not used in combination with Kynamro (mipomersen)
	• Not used in combination with another PCSK9 inhibitor
	Updated reauthorization criteria to require all of the following:
	• Patient is continuing a low-fat diet and exercise regimen
	• Patient continues to receive other lipid-lowering therapy
	• Documentation of a sustained LDL-C reduction from pre-treatment baseline while on Juxtapid therapy
	• Prescribed by cardiologist, endocrinologist, or lipid specialist
	• Not used in combination with another PCSK9 inhibitor
	Not used in combination with Kynamro (mipomersen)

9/2016	Updated policy template and references
3/2017	Changed initial authorization duration to 12 months.
9/2017	Annual review. Removed requirement of medical record submission for diagnosis documentation.
9/2018	Annual review. Updated references.

9/2019	Removed criteria regarding combination therapy with Kynamro since it is no longer on the market.
9/2020	Annual review with no changes to coverage criteria. Updated reference. Added Additional Clinical Rules section.