CareSource

PHARMACY POLICY STATEMENT **Marketplace**	
DRUG NAME	Juxtapid (lomitapide)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative products include Repatha and Praluent QUANTITY LIMIT— 30 capsules per 30 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Juxtapid (lomitapide) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HoFH)

For **initial** authorization:

1. Member is 18 years old or older; AND
2. Medication must be prescribed by or in consultation with a cardiologist or a lipid specialist; AND
3. Member has a diagnosis of homozygous familial hypercholesterolemia (HoFH) confirmed by **one** of the following:
   a) Genetic testing confirmation of two mutant alleles in the LDLR, Apo-B, PCSK9, or LDLRAP1 gene locus; OR
   b) LDL-C > 500 mg/dL before any treatment or LDL-C > 300 mg/dL if treated with a lipid-lowering drug AND **one** of the following:
      i) Xanthoma before 10 years of age; OR
      ii) Evidence of heterozygous familial hypercholesterolemia (HeFH) (i.e., total cholesterol > 250 mg/dL) in both parents; AND
4. Chart notes must include documentation of baseline cholesterol lab levels, taken within the past 90 days prior to therapy; AND
5. Member is unable to achieve LDL-C goal (see Note) after trials with **both** of the following:
   a) 90-day trial of a high-intensity statin (i.e., rosuvastatin ≥ 20mg, atorvastatin ≥ 40mg for 18 years or older, ≥ 20mg for under 18 years old) together with ezetimibe. If intolerance occurs, a second attempt must be initiated with a moderate or low-intensity statin + ezetimibe;
   b) 90-day trial with Repatha or Praluent (prior authorization required); AND
6. Juxtapid will be used as an adjunct to other lipid-lowering treatments (e.g., statins, ezetimibe, LDL apheresis, etc.), unless contraindicated or intolerant; AND
7. If request is for adding Juxtapid to current Evkeeza therapy, must have a 6 month trial and failure of Juxtapid with maximized statin, ezetimibe, or PCSK9 (without Evkeeza) AND a strong clinical reason why Juxtapid must be used together with Evkeeza; AND
8. Prescriber attests that the member will be on a low-fat diet during treatment.
9. **Dosage allowed:** up to 60 mg daily or 1 capsule by mouth daily.

NOTE: The LDL-C goals are <100 mg/dL for adults 18 years or older, < 135 mg/dL for children, and < 70 mg/dL for adults with clinical ASCVD.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes along with recent labs have been provided showing a meaningful reduction of cholesterol levels (LDL-C, total cholesterol, apolipoprotein B, etc.) from baseline OR all cholesterol levels are at goal.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Juxtapid (lomitapide) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
07/22/2020	New policy for Juxtapid created.
04/05/2021	Added Praluent to list of alternative products. Changed trials to include Praluent in addition to Repatha and increased trial length to 90 days. Added a trial requirement for concomitant request of Juxtapid and Evkeeza. Updated genetic testing requirement to ask for specific alleles (previously not specified). Updated atorvastatin high-intensity requirement to reflect pediatric vs. adult dosing.

References:

1. Juxtapid [Package insert]. Cambridge, MA: Aegerion Pharmaceuticals, Inc; December 2012.
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(32):2146-2157.
3. Alonso R, Cuevas A, Mata P. Lomitapide: a review of its clinical use, efficacy, and tolerability. *Core Evid*. 2019;14:19-30. Published 2019 Jul 1.

Effective date: 01/01/2022
Revised date: 04/05/2021