

## PHARMACY POLICY STATEMENT

### Marketplace

<b>DRUG NAME</b>	<b>Juxtapid (Iomitapide)</b>
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Juxtapid 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). Juxtapid was approved by the FDA in 2012.

Juxtapid (Iomitapide) will be considered for coverage when the following criteria are met:

### Homozygous Familial Hypercholesterolemia (HoFH)

For **initial** authorization:

1. Member is at least 18 years of age; 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/Quantity limit:** Up to 60 mg once daily. See package insert for titration. (Max 60 capsules per 30 days [for the 20 mg or 30 mg capsules]; 30 capsules per 30 days for the 5 mg or 10 mg capsules)

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 all the above requirements are met, 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 all the above requirements are met, the medication will be approved for an additional 12 months.***

**CareSource considers Juxtapid (Iomitapide) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.**

DATE	ACTION/DESCRIPTION
7/22/2020	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.
02/22/2022	Policy for Juxtapid transferred to new template. Corrected the quantity limit from 30/30 to 60/30; highest capsule strength is 30mg.

References:

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

Effective date: 07/01/2022

Revised date: 02/22/2022