

## PHARMACY POLICY STATEMENT

### Georgia Medicaid

DRUG NAME	Juxtapid (Iomitapide)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative product includes Repatha QUANTITY LIMIT— 30 capsules per 30 days
LIST OF DIAGNOSES CONSIDERED <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

Juxtapid (Iomitapide) 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; OR
  - b) LDL-C >500 mg/dL before any treatment or LDL-C >300 mg/dL if treated with a lipid-lowering drug (not including PCSK9) AND **one** of the following:
    - i) Xanthoma before 10 years of age;
    - ii) Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents; AND
4. Chart notes must include documentation of baseline cholesterol lab levels, taken within the past 90 days prior to starting Juxtapid; 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) together with ezetimibe. If intolerance occurs, a second attempt must be initiated with a moderate or low-intensity statin + ezetimibe;
  - b) 8-week trial with Repatha (prior authorization required); AND
6. Juxtapid will be used as an adjunct to other lipid-lowering therapies (i.e., statin, ezetimibe, LDL apheresis, etc.); AND
7. Prescriber attests that the member will be on a low-fat diet during treatment.
8. **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.

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: 12/01/2020

Revised date: 07/22/2020