

## PHARMACY POLICY STATEMENT

### Common Ground Healthcare Cooperative (CGHC)

<b>DRUG NAME</b>	<b>Juxtapid (Iomitapide)</b>
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Juxtapid, approved by the FDA in 2012, 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 (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 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 > 400 mg/dL before any lipid-lowering drug treatment AND at least one of the following:
    - i) Cutaneous or tendon xanthoma before 10 years of age; and/or
    - ii) Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents; AND
4. Chart notes must include documentation of baseline LDL-C above goal within the past 90 days; AND
5. Member is unable to achieve LDL-C goal (see Note) after 8-week trials with ALL of the following:
  - a) High-intensity /max-tolerated statin in combination with ezetimibe (unless there is documentation of clearly established statin intolerance or statin contraindication—see note\*); and
  - b) PCSK9 inhibitor (e.g., Repatha or Praluent; prior authorization required) unless there is evidence of no LDL receptor function (receptor-negative type HoFH); AND
6. Juxtapid will be used as an adjunct to other lipid-lowering treatments (e.g., statins, ezetimibe, PCSK9 inhibitor, LDL apheresis, etc.), unless contraindicated or intolerant; AND
7. Prescriber attests that the member will be on a low-fat diet during treatment; AND
8. Member does NOT have moderate to severe hepatic impairment; AND
9. Juxtapid is not being concomitantly initiated with Evkeeza.
10. **Dosage allowed/Quantity limit:** Start 5 mg once daily and titrate up to 60 mg once daily per prescribing information.

(QL: 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 for adults are <70 mg/dL or <55 mg/dL with additional ASCVD risk factors.

*\*NOTE: If not on statin therapy, member must have documented contraindication to all statin drugs or documentation of intolerance to at least 2 different statins, including low/moderate intensity or alternate dosing such as every other day.*

***If all the above requirements are met, the medication will be approved for 6 months.***

For **reauthorization**:

1. Chart notes/labs show at least 15% LDL-C reduction since starting Juxtapid.

***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.
05/25/2023	Added references. Changed “baseline cholesterol” to “baseline LDL-C above goal.” Added receptor-negative as exception to PCSK9 requirement. Simplified statement regarding Evkeeza (does not prohibit using them together, but they may not be started at the same time).
05/07/2024	Updated references. Removed LDL cutoff for HeFH in parents. Changed LDL cutoffs of 500 or 300 to 400; specified at least 15% LDL reduction for reauth; changed LDL goals of 100 or 70 to 70 or 55; changed statin/ezetimibe and PCSK9 trials from 90 days to 8 weeks (EAS/Cuchel 2023). Added note about statin intolerance. Added that the member does not have moderate to severe hepatic impairment (contraindication).

References:

1. Juxtapid [Package insert]. Cambridge, MA: Aegerion Pharmaceuticals, Inc; 2020.
2. 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.
3. Robinson JG. Management of familial hypercholesterolemia: a review of the recommendations from the National Lipid Association Expert Panel on Familial Hypercholesterolemia. *J Manag Care Pharm.* 2013;19(2):139-149. doi:10.18553/jmcp.2013.19.2.139

4. Gidding SS, Champagne MA, de Ferranti SD, et al. The Agenda for Familial Hypercholesterolemia: A Scientific Statement From the American Heart Association [published correction appears in *Circulation*. 2015 Dec 22;132(25):e397]. *Circulation*. 2015;132(22):2167-2192. doi:10.1161/CIR.0000000000000297
5. France M, Rees A, Datta D, et al. HEART UK statement on the management of homozygous familial hypercholesterolaemia in the United Kingdom. *Atherosclerosis*. 2016;255:128-139. doi:10.1016/j.atherosclerosis.2016.10.017
6. Mach F, Baigent C, Catapano AL, et al. 2019 ESC/EAS Guidelines for the management of dyslipidaemias: lipid modification to reduce cardiovascular risk [published correction appears in *Eur Heart J*. 2020 Nov 21;41(44):4255]. *Eur Heart J*. 2020;41(1):111-188. doi:10.1093/eurheartj/ehz455
7. Watts GF, Gidding SS, Hegele RA, et al. International Atherosclerosis Society guidance for implementing best practice in the care of familial hypercholesterolaemia. *Nat Rev Cardiol*. 2023;20(12):845-869. doi:10.1038/s41569-023-00892-0
8. Cuchel M, Raal FJ, Hegele RA, et al. 2023 Update on European Atherosclerosis Society Consensus Statement on Homozygous Familial Hypercholesterolaemia: new treatments and clinical guidance. *Eur Heart J*. 2023;44(25):2277-2291. doi:10.1093/eurheartj/ehad197

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