

Juxtapid® (lomitapide) Effective 02/01/2022

Plan	□ MassHealth UPPL ⊠Commercial/Exchange	Program Type	Prior Authorization Output the limit
Benefit	Pharmacy BenefitMedical Benefit (NLX)		☑ Quantity Limit □ Step Therapy
Specialty Limitations	This medication has been designated as a limited distribution specialty product and must be filled at a contracted specialty pharmacy; dispensing is available through Dohmen Life Science Services.		
Contact Information	All Plans	cialty Medications Phone: 866-814-5506	Fax: 866-249-6155
	MassHealth	pecialty Medications Phone: 877-433-7643	Fax: 866-255-7569
	Commercial Exchange	Phone: 800-294-5979 Phone: 855-582-2022	Fax: 888-836-0730 Fax: 855-245-2134
	Medical Specialty Medications (NLX)All PlansPhone: 844-345-2803Fax: 844-851-0882		
Exceptions	N/A		

Overview

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) with homozygous familial hypercholesterolemia (HoFH).

Coverage Guidelines

Authorization may be granted for members new to the plan who are currently receiving treatment with Juxtapid, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted for members when ALL the following criteria are met:

- 1. Member has a diagnosis of homozygous familial hypercholesterolemia (HoFH)
- 2. Member is \geq 18 years of age
- 3. Member is adherent to a low-fat diet (< 20% of energy supplied by dietary fat intake) and will be taking a dietary supplement to prevent nutritional deficiencies
- 4. Member has had a documented side-effect, allergy, inadequate response, treatment failure, or contraindication to treatment with a high potency HMG Co-A reductase inhibitor (e.g. statin), including atorvastatin or rosuvastatin used in combination with ezetimibe, a fibric acid derivative, and/or cholestyramine
- 5. Member has had an inadequate response, treatment failure, or has a contraindication to lipid apheresis therapy
- 6. Member has had an inadequate response, treatment failure, or has a contraindication to Kynamro**

* Note: Needle phobia is not considered an adequate justification for not utilizing Kynamro®

Mass General Brigham Health Plan includes Mass General Brigham Health Plan, Inc. and Mass General Brigham Health Insurance Company.

Limitations

- 1. Initial authorizations will be approved for 3 months.
- 2. Reauthorizations will be approved for 12 months.
- 3. The following quantity limits apply:

 Juxtapid
 30 capsules per 30 days

References

- Lloyd-Jones DM, Morris PB, Ballantyne CM, et al; Writing Committee. 2016 ACC expert consensus decision pathway on the role of non-statin therapies for LDL-cholesterol lowering in the management of atherosclerotic cardiovascular disease risk: a report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents. J Am Coll Cardiol. 2016;68(1):92-125.[PubMed 27046161]Farnier M, Bruckert E. Severe familial hypercholesterolemia:
- 2. Yusuf S, Bosch J, Dagenais G, et al. Cholesterol Lowering in Intermediate-Risk Persons without Cardiovascular Disease. N Engl J Med 2016; 374:2021
- 3. Juxtapid (lomitapide) [prescribing information]. Cambridge, MA: Aegerion Pharmaceuticals, Inc; September 2020.
- 4. Kynamro (mipomersen) [prescribing information]. Cambridge, MA: Genzyme Corporation; March 2019
- 5. Mortensen MB, Nordestgaard BG. Elevated LDL cholesterol and increased risk of myocardial infarction and atherosclerotic cardiovascular disease in individuals aged 70-100 years: a contemporary primary prevention cohort. Lancet 2020; 396:1644.
- 6. National Heart Lung and Blood Institute. Clinical Practice Guidelines and Reports under Development. Available at:
- 7. http://www.nhlbi.nih.gov/guidelines/indevelop.htm . Accessed December 28, 2012.
- Jellinger PS, Handelsman Y, Rosenblit PD, et al. American Association of Clinical Endocrinologists and American College of Endocrinology guidelines for management of dyslipidemia and prevention of cardiovascular disease. Endocr Pract. 2017;23(suppl 2):1-87.[PubMed 28437620]10.4158/EP171764.APPGL.
- Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol 2019; 73: e285

Review History

06/01/2018 - Implemented

02/26/2018 – Reviewed

11/26/2018 - Reviewed

01/22/2020 – Added started and stabilized criteria and removed PCSK9 inhibitor trial

09/22/2021 – Reviewed at September P&T; removed diagnosis and age requirement for new members currently on Juxtapid; references updated. Effective 02/01/2022.

09/21/2022 – Reviewed at Sept P&T; no clinical changes; Separated out Comm/Exch vs. MH.