RxAdvance

Clinical Policy Title:	lomitapide
Policy Number:	RxA.604
Drug(s) Applied:	Juxtapid®
Original Policy Date:	03/06/2020
Last Review Date:	8/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Homozygous Familial Hypercholesterolemia (HoFH) (must meet all):

1. Diagnosis of HoFH defined as one of the following (a or b):
   a. Genetic mutation indicating HoFH (e.g., mutations in low density lipoprotein receptor [LDLR] gene, proprotein convertase subtilisin kexin 9 [PCSK9] gene, apo B gene, low density lipoprotein receptor adaptor protein 1[LDLRAP1] gene);
   b. Treated LDL-C ≥ 300 mg/dL and meets one of the following (i or ii);
      i. Tendinous or cutaneous xanthoma prior to age 10 years;
      ii. Evidence of HeFH in both parents (e.g., documented history of elevated LDL- C ≥ 190 mg/dL prior to lipid-lowering therapy) and/or an untreated total cholesterol level > 250 mg/dl;
2. Untreated LDL-C ≥ 500 mg/dL, and member has one of the following (i or ii):
      i. Tendinous or cutaneous xanthoma prior to age 10 years;
      ii. Evidence of HeFH in both parents (e.g., documented history of elevated LDL- C ≥ 190 mg/dL prior to lipid-lowering therapy) and/or an untreated total cholesterol level > 250 mg/dl;
3. Documentation of recent (within the last 60 days) LDL-C ≥ 70 mg/dL;
4. For members on statin therapy, both of the following (a and b):
   a. Juxtapid® is prescribed in conjunction with a statin at the maximally tolerated dose;
   b. Member has been adherent for at least the last 4 months to maximally tolerated doses of one of the following statin regimens (i, ii, or iii):
      i. A high intensity statin;
      ii. A moderate intensity statin and member has one of the following (a or b);
         a) Intolerance to two high intensity statins;
         b) A statin risk factor;
      iii. A low intensity statin and member has one of the following (a or b):
         a) Intolerance to one high and one moderate intensity statins;
         b) A statin risk factor and history of intolerance to two moderate intensity statins;
5. For members not on statin therapy, member meets one of the following (a or b):
   a. Statin therapy is contraindicated;
   b. For members who are statin intolerant, member has tried at least two statins, 1 of which must be hydrophilic statins (pravastatin, fluvastatin, or rosuvastatin), and member meets one of the following (i or ii):
      i. Member has documented statin risk factors;

ii. Member is statin intolerant due to statin-associated muscle symptoms (SAMS) and meets both of the following (a and b):
   a) Documentation of intolerable SAMS persisting at least two weeks, which disappeared with discontinuing the statin therapy and recurred with a statin re-challenge;
   b) Documentation of re-challenge with titration from lowest possible dose and/or intermittent dosing frequency (e.g., 1 to 3 times weekly);

6. Member has been adherent to ezetimibe therapy used concomitantly with a statin at the maximally tolerated dose for at least the last 4 months, unless contraindicated or member has a history of ezetimibe intolerance (e.g., associated diarrhea or upper respiratory tract infection);
7. Trial and failure of Repatha® or Praluent, unless contraindicated or clinically significant adverse effects are experienced;
   *Prior authorization may be required for Repatha or Praluent.
8. Treatment plan does not include coadministration with Repatha®, or Praluent®.

Approval duration
All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. Homozygous Familial Hypercholesterolemia (HoFH) (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration
All Lines of Business (except Medicare): 12 months

References

1. Stone NJ, Robinson JG, Lichtenstein AH, et al. 2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation. 2014 June 24; 129[suppl 2]: S1-S45. Available at: https://www.ahajournals.org/doi/pdf/10.1161/01.cir.0000437738.63853.7a . Accessed August 28, 2024.
2. Jacobson TA, et al. National Lipid Association recommendations for patient-centered management of dyslipidemia: part 1 – full report. Journal of Clinical Lipidology. March- April 2015; 9(2): 129-169. http://dx.doi.org/10.1016/j.jacl.2015.02.003. Available at: https://pubmed.ncbi.nlm.nih.gov/25911072/ . Accessed August 28, 2024.
3. Familial hypercholesterolemia: screening, diagnosis and management of pediatric and adult patients: clinical guidance from the National Lipid Association Expert Panel on Familial Hypercholesterolemia. Journal of Clinical Lipidology. June 2011; 5(3S): 1-15. Available at: https://www.lipid.org/sites/default/files/articles/familial_hypercholesterolemia_1.pdf . Accessed August 28, 2024.
4. Fitchett DH, Hegele RA, Verma S. Statin intolerance. Circulation 2015;131:e389-391. Available at: https://doi.org/10.1161/CIRCULATIONAHA.114.013189. Accessed August 28, 2024.
5. Lloyd-Jones DM, Morris PB, Minissian MB, et al. 2017 Focused update of the 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. J Am Coll Cardiol 2017; 70(14):1785-1822. Available at: http://dx.doi.org/10.1016/j.jacc.2017.07.745. Accessed August 28, 2024.
6. Grundy SM, Stone NJ, Bailey AL, et all. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA guideline on the management of blood cholesterol: executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol 2019; 73(24):

3168–3209. doi:10.1016/j.jacc.2018.11.002. Available at: https://www.jacc.org/doi/abs/10.1016/j.jacc.2018.11.002 Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	03/2019	03/06/2020
Policy was reviewed: 1. Policy title table was updated: Line of business policy applies was updated to All lines of business. 2. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance…”. 3. References were updated.	10/30/2020	12/07/2020
Policy was reviewed: 1. Continued Therapy Approval II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 2. References were reviewed and updated.	10/14/2021	12/07/2021
Policy was reviewed: 1. Initial Approval Criteria I.A.10: Updated to remove Kynamro® since it has been withdrawn from the market. 2. References were reviewed and updated.	09/01/2022	10/19/2022
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated.	8/28/2024	9/13/2024