AETNA BETTER HEALTH® Coverage Policy/Guideline					
Name:	Juxtapid			Page:	1 of 4
Effective Date:	5/23/2025			Last Review Date:	4/2025
Applies to:	☒Illinois ☐New Jersey ☒Pennsylvania Kids	☐Florida ☒Maryland ☐Virginia		☒Florida Kids ☒Michigan ☐Arizona	

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Juxtapid under the patient's prescription drug benefit.

Description:

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

Juxtapid is 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 (APOB), and non-high-density lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH).

Limitations of Use

- The safety and effectiveness of Juxtapid have not been established in patients with hypercholesterolemia who do not have HoFH, including those with heterozygous familial hypercholesterolemia (HeFH).
- The effect of Juxtapid on cardiovascular morbidity and mortality has not been determined.

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Juxtapid

Policy/Guideline:

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Both initial and continuation requests:

- Genetic testing or medical records confirming the diagnosis of HoFH.
- LDL-C level dated within the six months preceding the authorization request.
- With clinical atherosclerotic cardiovascular disease (ASCVD): Chart notes confirming clinical ASCVD (if applicable) (see Appendix).

- Chart notes, medical record documentation, or claims history confirming the member is currently on lipid-lowering therapy.

Coverage Criteria

Homozygous familial hypercholesterolemia (HoFH)[1-4]

Authorization of 6 months may be granted for treatment of homozygous familial hypercholesterolemia when all of the following criteria are met:

- Member has a documented diagnosis of homozygous familial hypercholesterolemia confirmed by any of the following criteria:
  - Variant in two low-density lipoprotein receptor (LDLR) alleles.
  - Presence of homozygous or compound heterozygous variants in apolipoprotein B (APOB) or proprotein convertase subtilisin-kexin type 9 (PCSK9) gene.
  - Member has compound heterozygosity or homozygosity for variants in the gene encoding low-density lipoprotein receptor adaptor protein 1 (LDLRAP1).
  - Member has an untreated LDL-C of > 400 mg/dL and has either of the following:
    - Presence of cutaneous or tendinous xanthomas before the age of 10 years.
    - An untreated LDL-C level of ≥ 190 mg/dL in both parents.
- Prior to initiation of treatment with the requested medication, member meets/has met either of the following criteria:
  - Member has a treated LDL-C level ≥ 70 mg/dL.
  - Member has a treated LDL-C level ≥ 55 mg/dL and meets either of the following criteria:
    - Member has a history of a clinical ASCVD event (see Appendix).
    - Member has major ASCVD risk factors (e.g., 65 years of age or older, familial hypercholesterolemia, diabetes, chronic kidney disease, history of congestive heart failure).
- Prior to initiation of treatment with the requested medication, member is/was receiving stable treatment with at least three lipid-lowering therapies (e.g., statins, ezetimibe, PCSK9 directed therapy) at maximally tolerated dose.
- Member will continue to receive concomitant lipid-lowering therapy.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members (including new members) who meet all of the following criteria:

- Member meets all requirements in the coverage criteria.
- Member has had at least 20% reduction of LDL-C from baseline.
- Member is currently receiving concomitant lipid-lowering therapy.

Appendix

Clinical ASCVD[4-7]

- Acute coronary syndromes
- Myocardial infarction
- Stable or unstable angina
- Coronary or other arterial revascularization procedure (e.g., percutaneous coronary intervention [PCI], coronary artery bypass graft [CABG] surgery)
- Stroke of presumed atherosclerotic origin
- Transient ischemic attack (TIA)
- Non-cardiac peripheral arterial disease (PAD) of presumed atherosclerotic origin (e.g., carotid artery stenosis, lower extremity PAD)
- Obstructive coronary artery disease (defined as ≥ 50% stenosis on cardiac computed tomography angiogram or catheterization)
- Coronary artery calcium (CAC) Score ≥ 300

Approval Duration and Quantity Restrictions:

Approval:

- Initial: 6 months; renewal: 12 months

Quantity Level Limits:

- Juxtapid 5 mg Capsule: 28 per 28 days
- Juxtapid 10 mg Capsule: 28 per 28 days
- Juxtapid 20 mg Capsule: 56 per 28 days
- Juxtapid 30 mg Capsule: 56 per 28 days

References:

1. Juxtapid [package insert]. Parma, Italy: Chiesi Farmaceutici S.p.A.; January 2024.
2. Cuchel M, Raal FJ, Hegele RA, et al. Update on European atherosclerosis society consensus statement on homozygous familial hypercholesterolaemia: new treatments and clinical guidance. Eur Heart J. 2023;44(25):2277-2291.

3. Lloyd-Jones DM, Morris PB, Ballantyne CM, et al. 2022 ACC Expert consensus decision pathway on the role of nonstatin therapies for LDL-cholesterol lowering in the management of atherosclerotic cardiovascular disease risk: A report of the American college of cardiologic solution set oversight committee. J Am Coll Cardiol. 2022;80(14):1366–1418.
4. 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. Circulation. 2019;139:e1082– e1143.
5. Jacobson TA, Ito MK, Maki KC, et al. National Lipid Association recommendations for patient-centered management of dyslipidemia: part 1 — full report. J Clin Lipidol. 2015;9:129–169.
6. Min JK, Labounty TM, Gomez MJ, et al. Incremental prognostic value of coronary computed tomographic angiography over coronary artery calcium score for risk prediction of major adverse cardiac events in asymptomatic diabetic individuals. Atherosclerosis. 2014;232(2):298-304.
7. Budoff MJ, Kinninger A, Gransar H, et al. When does a calcium score equate to secondary prevention?: Insights from the multinational CONFIRM registry. JACC Cardiovasc Imaging. 2023;16(9):1181-1189.