LOUISIANA BLUE

lomitapide (Juxtapid®)

Policy # 00243
Original Effective Date: 03/20/2013
Current Effective Date: 01/01/2027

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider the use of lomitapide (Juxtapid®)‡ to reduce low-density lipoprotein cholesterol (LDL-C), in patients with homozygous familial hypercholesterolemia (HoFH) to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility will be considered for lomitapide (Juxtapid) when ALL of the following criteria are met:

Initial

I. Patient is greater than or equal to 2 years of age; AND

II. Patient is adherent to any medications required for therapy prior to receiving authorization for lomitapide (Juxtapid); AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

III. Juxtapid will be used with a maximally tolerated statin [in those who are not considered statin intolerant (see below for statin intolerance)] AND a maximally dosed proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor, such as Repatha®‡ (evolocumab) or Praluent®‡ (alirocumab), unless the patient has two LDL-receptor negative alleles, AND generic ezetimibe 10 mg daily; AND

IV. Patient has a clinical diagnosis of HoFH, based on the presence of the following (Patient must meet A, B, **or** C):
   A. Patient has had genetic confirmation of two (2) mutant alleles at the low-density lipoprotein receptor (LDLR), apolipoprotein B (APOB), PCSK9 or low-density lipoprotein receptor adaptor protein 1 (LDLRAP1) gene locus; OR
   B. Patient has an untreated (i.e., prior to therapy with any antihyperlipidemic agent) LDL-C concentration greater than 400 mg/dL AND meets one of the following criteria (i **or** ii):

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i. Patient had clinical manifestations of HoFH (i.e., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas, or xanthelasma) before the age of 10 years; OR

ii. Both parents of the patient had untreated (i.e., prior to therapy with any antihyperlipidemic agent) LDL-C levels or total cholesterol levels consistent with heterozygous familial hypercholesterolemia (HeFH); OR
(Note: An example of HeFH in both parents would be if both had an untreated LDL-C level greater than or equal to 190 mg/dL and/or an untreated total cholesterol level greater than 250 mg/dL.)
(Note: In digenic form, one parent may have normal LDL-C levels and the other may have LDL-C levels consistent with HoFH.)

C. Patient has a treated (i.e., therapy with at least one antihyperlipidemic agent) LDL-C level greater than or equal to 300 mg/dL AND meets one of the following criteria (i **or** ii):
(Note: Treated refers to after therapy with at least one antihyperlipidemic agent. Some examples of antihyperlipidemic agents include statins [e.g., atorvastatin, rosuvastatin, lovastatin, simvastatin, pravastatin], ezetimibe, PCSK9 inhibitors [i.e., Repatha (evolocumab), Praluent (alirocumab)], and Evkeeza®‡ [evinacumab-dgnb].)

i. Patient had clinical manifestations of HoFH (i.e. cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas, or xanthelasma) before the age of 10 years; OR

ii. Both parents of the patient had untreated (i.e., prior to therapy with any antihyperlipidemic agent) LDL-C levels or total cholesterol levels consistent with heterozygous familial hypercholesterolemia (HeFH); AND
(Note: An example of HeFH in both parents would be if both had an untreated LDL-C greater than or equal to 190 mg/dL and/or an untreated total cholesterol greater than 250 mg/dL.)

V. Patient meets one of the following criteria (A **or** B):

A. Patient meets ALL of the following criteria (i, ii, **and** iii)

i. Patient has tried one high-intensity statin at the maximum daily dose (i.e., generic atorvastatin greater than or equal to 80 mg daily; generic rosuvastatin greater than or equal to 40 mg daily [as a single-entity or as a combination product]) for greater than or equal to 12 continuous weeks OR patient has tried a maximally tolerated stable daily dose of a statin of any intensity for greater than or equal to 12 continuous weeks if proof is given that a high-intensity statin at the maximum daily dose was not well tolerated [as a single-entity or as a combination product]); AND
*(Note that the 12-week timeframe is an additional Company requirement and will be denied as not medically necessary** if not met.)*

ii. Patient has taken the statin along with generic ezetimibe 10 mg daily (as a single entity or as a combination product) for greater than or equal to 12 continuous weeks, unless the patient is statin intolerant (defined below), then generic ezetimibe 10 mg daily without a statin should be taken for greater than or equal to 12 continuous weeks; AND

*(Note that the 12-week timeframe is an additional Company requirement and will be denied as not medically necessary** if not met.)*

iii. Patient's LDL-C level after this treatment regimen remains greater than or equal to 70 mg/dL or greater than or equal to 55-mg/dL based on "high risk" or "very high risk" classifications of the patient; OR

B. Patient has been determined to be statin intolerant by meeting the following criteria (i **and** ii):

i. Patient's LDL-C level remains greater than or equal to 70 mg/dL or greater than or equal to 55 mg/dL based on "high risk" or "very high risk" classifications of the patient due to statin intolerance; AND

ii. Patient meets ALL of the following criteria [1, 2, **and** 3]:

1. Patient was unable to tolerate at least 2 different statins. [The inability to tolerate one statin will be accepted if the patient experienced rhabdomyolysis or clinically significant myonecrosis secondary to a statin. Rhabdomyolysis/myonecrosis is considered to be a muscle breakdown with signs and symptoms such as muscle pain, weakness, tenderness ALONG WITH either: a.) acute renal failure or myoglobinuria AND elevated creatine kinase levels (i.e., greater than or equal to 10 times the upper limit of normal) OR b.) elevated creatine kinase levels (i.e., greater than or equal to 10 times the upper limit of normal) alone]; AND
2. Patient's intolerance was associated with confirmed, intolerable statin-related adverse effects [i.e., skeletal related muscle symptoms (myopathy [muscle weakness] or myalgia [muscle aches, soreness, stiffness, or tenderness])]; AND
3. Patient's symptoms or biomarker changes resolved or showed significant improvement on dose decrease or discontinuation; AND

VI. Patient meets ONE of the following criteria (A, B, **or** C):

A. Patient meets BOTH of the following criteria (i **and** ii):

i. Patient has tried a PCSK9 inhibitor for greater than or equal to 12 continuous weeks at the FDA-approved maximum dose for HoFH; AND
(Note: Examples of PCSK9 inhibitors at their maximum dose include Repatha (evolocumab) 420 mg once every 2 weeks and Praluent (alirocumab) 150 mg once every 2 weeks.)
*(Note that the 12-week timeframe is an additional Company requirement and will be denied as not medically necessary** if not met.)*

ii. Patient's LDL-C level after the maximum PCSK9 inhibitor HoFH dosing regimen remains greater than or equal to 70 mg/dL or greater than or equal to 55 mg/dL based on "high risk" or "very high risk" classifications of the patient; OR

B. Patient is known to have two LDL-receptor negative alleles; OR

C. Patient is 2 to 9 years of age.

Re-authorization: (Patient must meet I **and** II)

I. Patient previously met the initial criteria and received approval for lomitapide (Juxtapid); AND

II. Patient has achieved clinically significant LDL-C lowering AND is adherent to lomitapide (Juxtapid).
*(Note that the re-authorization criteria are additional Company requirements and will be denied as not medically necessary** if not met.)*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of lomitapide (Juxtapid) when the patient has not tried the required prerequisite medications for a timeframe of at least 12 weeks to be **not medically necessary.****

Based on review of available data, the Company considers the use of lomitapide (Juxtapid) when the re-authorization criteria are NOT met to be **not medically necessary.****

Based on review of available data, the Company considers the use of lomitapide (Juxtapid) when the patient is not adherent to their cholesterol-lowering regimen to be **not medically necessary.****

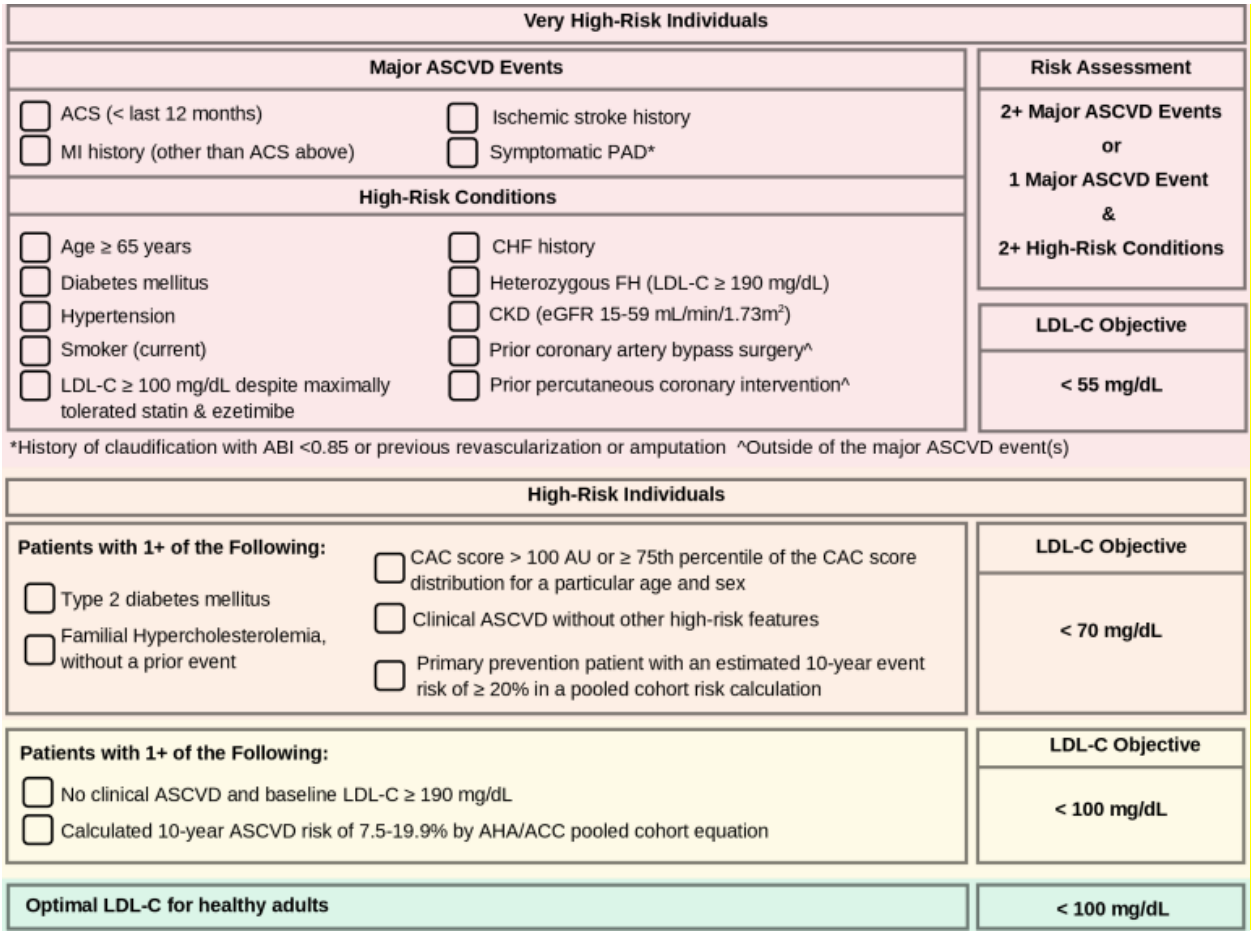
When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of lomitapide (Juxtapid) when patient selection criteria are not met (with the exception of those denoted above as **not medically necessary****) to be **investigational.***

Policy Guidelines

The National Lipid Association sets LDL-C treatment goal levels for patients at various risk stratifications. Those with clinical atherosclerotic cardiovascular disease would fall into the "very high risk" or "high risk" category and would therefore be treated to an LDL-C of less than 55 mg/dL or less than 70 mg/dL depending on patient-specific factors. Patients with familial hypercholesterolemia could fall into either the "very high risk" or "high risk" categories, based on their patient characteristics and would therefore have a treatment goal of less than 55 mg/dL or 70 mg/dL (respectively). Risk stratification (per the National Lipid Association) is as follows:



Very High-Risk Individuals

Major ASCVD Events		Risk Assessment
☐ ACS (< last 12 months)	☐ Ischemic stroke history	2+ Major ASCVD Events or 1 Major ASCVD Event & 2+ High-Risk Conditions
☐ MI history (other than ACS above)	☐ Symptomatic PAD*	

High-Risk Conditions		LDL-C Objective
☐ Age ≥ 65 years	☐ CHF history	< 55 mg/dL
☐ Diabetes mellitus	☐ Heterozygous FH (LDL-C ≥ 190 mg/dL)	
☐ Hypertension	☐ CKD (eGFR 15-59 mL/min/1.73m^2)	
☐ Smoker (current)	☐ Prior coronary artery bypass surgery^	
☐ LDL-C ≥ 100 mg/dL despite maximally tolerated statin & ezetimibe	☐ Prior percutaneous coronary intervention^	

*History of claudification with ABI <0.85 or previous revascularization or amputation ^Outside of the major ASCVD event(s)

High-Risk Individuals

Patients with 1+ of the Following:		LDL-C Objective
☐ Type 2 diabetes mellitus	☐ CAC score > 100 AU or ≥ 75th percentile of the CAC score distribution for a particular age and sex	< 70 mg/dL
☐ Familial Hypercholesterolemia, without a prior event	☐ Clinical ASCVD without other high-risk features	
	☐ Primary prevention patient with an estimated 10-year event risk of ≥ 20% in a pooled cohort risk calculation	

Patients with 1+ of the Following:	LDL-C Objective
☐ No clinical ASCVD and baseline LDL-C ≥ 190 mg/dL	< 100 mg/dL
☐ Calculated 10-year ASCVD risk of 7.5-19.9% by AHA/ACC pooled cohort equation	

Optimal LDL-C for healthy adults	< 100 mg/dL

The above chart comes from the National Lipid Association 2025 LDL-C Management Simplified in Adults guidance. Available at: https://www.lipid.org/resource/ldl-c-management-simplified-in-adults-guidance-from-the-national-lipid-association/

Clinical ASCVD (includes one or more of the following):

I. Myocardial infarction or other acute coronary syndrome
II. Angina (stable or unstable)
III. Coronary or other revascularization procedure
IV. Transient ischemic attack
V. Ischemic stroke
VI. Atherosclerotic peripheral arterial disease (ABI of less than 0.90)
VII. Other documented atherosclerotic diseases such as
    A. Clinically significant coronary atherosclerosis diagnosed by coronary angiography, stress test, stress echocardiography, or myocardial perfusion imaging
    B. Renal atherosclerosis
    C. Aortic aneurysm secondary to atherosclerosis
    D. Carotid plaque (greater than or equal to 50% stenosis)

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Background/Overview

Juxtapid (lomitapide) is a microsomal triglyceride transfer protein inhibitor indicated as an adjunct to a low-fat diet, exercise, and other LDL-C therapies to reduce LDL-C in adult and pediatric patients 2 years of age and older with homozygous familial hypercholesterolemia (HoFH). Lomitapide reduces the assembly and secretion of apolipoprotein B-containing lipoproteins, including very-low-density lipoprotein (VLDL) and chylomicrons. Juxtapid is supplied as oral capsules and is taken once daily, swallowed whole with water, and without food. Recommended starting dosage is 2 mg once daily for patients 2 to 15 years of age and 5 mg once daily for patients 16 years of age and older, with titration based on LDL-C response, safety, and tolerability. Before treatment, patients should begin a low-fat diet supplying less than 20% of energy from fat or less than 30 grams of fat per day, whichever is less. Because Juxtapid reduces absorption of fat-soluble vitamins and fatty acids, daily supplementation with vitamin E, linoleic acid, alpha-linolenic acid, eicosapentaenoic acid, and docosahexaenoic acid is recommended. Juxtapid can cause hepatotoxicity, including elevations in transaminases and hepatic fat accumulation; therefore, liver-related laboratory testing is required before and during treatment, and Juxtapid is available only through the Juxtapid Risk Evaluation and Mitigation Strategy (REMS) Program.

Familial hypercholesterolemia (FH) is a genetic disorder characterized by markedly elevated low-density lipoprotein cholesterol (LDL-C) levels and increased risk for premature atherosclerotic cardiovascular disease (ASCVD). FH is most commonly caused by pathogenic variants in genes involved in LDL receptor-mediated clearance of LDL particles, including the low-density lipoprotein receptor (LDLR) gene, apolipoprotein B (APOB) gene, and proprotein convertase subtilisin/kexin type 9 (PCSK9) gene. Less commonly, biallelic pathogenic variants in the low-density lipoprotein receptor adaptor protein 1 (LDLRAP1) gene may cause a rare autosomal recessive form of severe hypercholesterolemia. These variants impair LDL-C catabolism, resulting in elevated circulating LDL-C levels from early life.

FH may present as heterozygous FH (HeFH), in which one pathogenic variant is present, or homozygous FH (HoFH), in which two pathogenic variants are present. HeFH is more common, with an estimated prevalence of approximately 1 in 300 individuals worldwide. HoFH is rare, with an estimated prevalence of approximately 1 in 300,000 to 1 in 400,000 individuals, and is associated with more severe LDL-C elevations and earlier onset of ASCVD. Patients with HoFH often develop clinical manifestations during childhood and may have untreated LDL-C levels greater than 400 mg/dL. Physical findings associated with FH may include tendon or cutaneous xanthomas, xanthelasma, and corneal arcus, particularly when these findings occur at a young age.

The diagnosis of FH is generally based on clinical criteria, including LDL-C level, personal or family history of premature ASCVD, physical findings consistent with cholesterol deposition, and family history of markedly elevated cholesterol. Genetic testing may help confirm the diagnosis, particularly when the diagnosis is uncertain or when cascade screening of relatives is being considered; however, the absence of an identifiable pathogenic variant does not exclude FH. Evaluation should also include assessment for secondary causes of elevated LDL-C, such as thyroid, renal, hepatic, or biliary disease. The primary goal of treatment in patients with FH is to reduce ASCVD risk by lowering LDL-C using diet, lifestyle modification, and lipid-lowering therapies.

Patients with HoFH often require intensive combination therapy and may require LDL apheresis when available.

Treatment of HoFH requires prompt and aggressive LDL-C lowering to reduce the risk of premature ASCVD. Because some lipid-lowering therapies, including statins and PCSK9 inhibitors, rely at least in part on residual LDL-receptor function, response may be reduced in patients with HoFH, particularly those with LDL-receptor negative variants. Management typically requires intensive combination therapy, which may include a maximally tolerated statin, ezetimibe, PCSK9 inhibitors when residual LDL-receptor function is present, evinacumab, lomitapide, bempedoic acid, bile acid sequestrants, and LDL apheresis when available. Pediatric patients with HoFH should be managed by clinicians experienced in lipid disorders, and treatment is individualized based on age, LDL-C level, cardiovascular risk, genotype when available, tolerability, and response to therapy.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In December 2012, the U.S. FDA approved Juxtapid capsules as an adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available, to reduce LDL-C, TC, APO B, and non-HDL in patients with HoFH. In February 2026, the prescribing information was updated to state that Juxtapid is indicated as an adjunct to a low-fat diet and exercise and other low-density lipoprotein cholesterol (LDL-C) therapies to reduce LDL-C in adults and pediatric patients aged 2 years and older with homozygous familial hypercholesterolemia (HoFH). Because of the risk of hepatotoxicity, Juxtapid is available only through a restricted program called the Juxtapid Risk Evaluation and Mitigation Strategy (REMS) Program.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

Adults with HoFH

One single-arm, open-label, 78-week trial has been conducted in 29 patients with HoFH, 23 of whom completed at least one year of treatment. The initial dosage of Juxtapid was 5 mg daily, with titration up to 60 mg daily during an 18-week period based on safety and tolerability. In this trial, the mean age was 30.7 years (range, 18 to 55 years), 16 (55%) patients were men, 25 (86%) patients were Caucasian, 2 (7%) were Asian, 1 (3%) was African American, and 1 (3%) was multi-racial.

Five (17%) of the 29 patients with HoFH that participated in the clinical trial discontinued treatment due to an adverse reaction. The adverse reactions that contributed to treatment discontinuations included diarrhea (2 patients; 7%) and abdominal pain, nausea, gastroenteritis, weight loss, headache, and difficulty controlling INR on warfarin (1 patient each; 3%).

The most common adverse reactions were gastrointestinal, reported by 27 (93%) of 29 patients. Adverse reactions reported by ≥ 8 (28%) patients in the HoFH clinical trial included diarrhea, nausea, vomiting, dyspepsia, and abdominal pain. Other common adverse reactions, reported by 5 to 7 (17-24%) patients, included weight loss, abdominal discomfort, abdominal distension, constipation, flatulence, increased alanine aminotransferase (ALT), chest pain, influenza, nasopharyngitis, and fatigue.

The primary efficacy endpoint was percent change in LDL-C from baseline to Week 26. At Week 26, the mean and median percent changes in LDL-C from baseline were -40% (paired t-test $p < 0.001$) and -50%, respectively, based on the intent-to-treat population with last observation carried forward (LOCF) for patients who discontinued prematurely. The effect of Juxtapid on cardiovascular morbidity and mortality has not been determined.

Pediatric Patients with HoFH
A single-arm, open-label, 104-week trial evaluated Juxtapid coadministered with a low-fat diet in pediatric patients 5 to 17 years of age with HoFH who were receiving stable lipid-lowering therapy, including LDL apheresis when applicable. The trial included a 6-week run-in period, a 24-week efficacy phase, and an 80-week safety phase. Forty-three patients entered treatment after the run-in period; the mean age was 11 years, and baseline lipid-lowering therapy included statins in 91% of patients, ezetimibe in 74%, evolocumab in 12%, and LDL apheresis in 44%. Juxtapid dosing was escalated from an age-dependent starting dose to the maximum tolerated dose, and patients were instructed to continue a low-fat diet and take recommended vitamin E and fatty acid supplementation.

The primary endpoint was percent change in LDL-C from baseline to Week 24. At Week 24, mean LDL-C decreased by 49% from baseline (95% confidence interval [CI]: -59% to -38%). Mean decreases in LDL-C were 52% in patients 5 to 10 years of age and 46% in patients 11 to 17 years of age. In subgroup analysis, mean LDL-C decreased by approximately 36% in patients receiving LDL apheresis at baseline and 62% in patients not receiving LDL apheresis at baseline. During longer-term treatment over 2 years, mean LDL-C levels in the LDL apheresis subgroup gradually increased over time when apheresis was reduced or discontinued.

References

1. Juxtapid [package insert]. Amryt Pharmaceuticals. Dublin, Ireland. Updated February 2026.
2. National Lipid Association. LDL-C Management Simplified in Adults: Guidance from the National Lipid Association. 2025. Accessed September 2026.
3. UpToDate. Familial Hypercholesterolemia in Adults: Treatment. Accessed September 2026.
4. UpToDate. Familial Hypercholesterolemia in Adults: Overview. Accessed September 2026.
5. UpToDate. Familial Hypercholesterolemia in Children. Accessed September 2026.

Policy History

Original Effective Date: 03/20/2013
Current Effective Date: 01/01/2027
03/07/2013 Medical Policy Committee review
03/20/2013 Medical Policy Implementation Committee approval. New policy.

05/01/2014	Medical Policy Committee review
05/21/2014	Medical Policy Implementation Committee approval. Included options other than genetic testing in the patient selection criteria.
05/07/2015	Medical Policy Committee review
05/20/2015	Medical Policy Implementation Committee approval. Included options other than genetic testing in the patient selection criteria.
02/04/2016	Medical Policy Committee review
02/17/2016	Medical Policy Implementation Committee approval. Added requirement for use of Repatha, which is a cheaper alternative that has been studied more than this product. Clarified that Juxtapid should not be used with Kynamro or PCSK9 inhibitors. Treated should reflect a high intensity statin plus Zetia to coincide with more recent practice.
02/02/2017	Medical Policy Committee review
02/15/2017	Medical Policy Implementation Committee approval. Added the generic chemical names for Zetia (ezetimibe), Crestor (rosuvastatin), and Lipitor (atorvastatin). No coverage changes.
02/01/2018	Medical Policy Committee review
02/21/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/07/2019	Medical Policy Committee review
02/20/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/06/2020	Medical Policy Committee review
02/12/2020	Medical Policy Implementation Committee approval. Updated policy to reflect the discontinuation of Kynamro.
02/04/2021	Medical Policy Committee review
02/10/2021	Medical Policy Implementation Committee approval. Clarified that Juxtapid should not be used in combination with a new class of medications: adenosine triphosphate-citrate lyase (ACL) inhibitors.
02/03/2022	Medical Policy Committee review
02/09/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/02/2023	Medical Policy Committee review
02/08/2023	Medical Policy Implementation Committee approval. No change to coverage.
02/01/2024	Medical Policy Committee review
02/14/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/06/2025	Medical Policy Committee review
02/12/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/05/2026	Medical Policy Committee review
02/11/2026	Medical Policy Implementation Committee approval. Updated untreated LDL-C requirement from a level of greater than 500 mg/dl to a level of greater than 400 mg/dL.

10/01/2026 Pre Pharmacy and Therapeutics Committee review
10/07/2026 Pharmacy and Therapeutics Committee approval. Updated policy to reflect the FDA label update expanding the indication to adults and pediatric patients 2 years of age and older with HoFH. Revised patient selection criteria to include the updated age requirement, adherence to prerequisite therapy, use with maximally tolerated statin therapy, ezetimibe, and PCSK9 inhibitor therapy when appropriate (with exceptions for patients with two LDL-receptor negative alleles or patients 2 to 9 years of age), clarified HoFH diagnostic criteria by specifying that untreated and treated LDL-C thresholds must be accompanied by clinical manifestations of HoFH or parental lipid levels consistent with HeFH. Further defined statin intolerance within the eligibility criteria and updated LDL-C threshold requirements based on cardiovascular risk. Removed prior restrictions on use in combination with certain lipid-lowering therapies and added re-authorization criteria for continued therapy. Updated background, FDA approval, rationale/source, not medically necessary, investigational, and references sections.
Next Scheduled Review Date: 10/2027

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan's pharmacy benefit.