

Kerendia[®] (finerenone)

Policy # 00765

Original Effective Date: 12/13/2021

Current Effective Date: 05/01/2026

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.*

Chronic Kidney Disease associated with Type 2 Diabetes

Based on review of available data, the Company may consider Kerendia^{®†} (finerenone) for the treatment of chronic kidney disease associated with type 2 diabetes to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for Kerendia (finerenone) for the treatment of chronic kidney disease associated with type 2 diabetes will be considered when the following criteria are met:

Initial

- Patient has a diagnosis of chronic kidney disease associated with type 2 diabetes mellitus; AND
- Patient is 18 years of age or older; AND
- Patient has a urinary albumin to creatinine ratio (UACR) greater than or equal to 30 mg/g; AND
*(Note: This specific patient selection criterion is an additional Company requirements for coverage eligibility) and will be denied as not medically necessary** if not met)*
- Patient is on a maximally tolerated labeled dose of an angiotensin converting enzyme inhibitor (ACE-I) OR a maximally tolerated labeled dose of an angiotensin receptor blocker (ARB) unless contraindicated or not tolerated.
*(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)*

Continuation

- Patient received an initial approval for the requested medication; AND
- Patient is tolerating the requested medication; 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)*
- Patient's serum potassium level is less than or equal to 5.5 mEq/L.

Heart Failure

Based on review of available data, the Company may consider Kerendia (finerenone) for the treatment of heart failure with left ventricular ejection fraction (LVEF) greater than or equal to 40% to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for Kerendia (finerenone) for the treatment of heart failure with left ventricular ejection fraction (LVEF) greater than or equal to 40% will be considered when the following criteria are met:

Initial

- Patient has a diagnosis of heart failure with a left ventricular ejection fraction (LVEF) greater than or equal to 40%; AND
- Patient is 18 years of age or older; AND
- Patient has an estimated glomerular filtration rate (eGFR) greater than or equal to 25 ml/min/1.73m²; AND
- Patient has a serum potassium level less than or equal to 5 mEq/L; AND
- Patient has tried OR is currently using a sodium-glucose cotransporter-2 (SGLT 2) inhibitor unless there is clinical evidence or patient history that suggests the use of an SGLT 2 inhibitor will be ineffective or cause an adverse reaction to the patient.

*(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)*

Continuation

- Patient has an initial authorization for the requested medication; AND
- Patient is tolerating the requested medication; 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)*

- Patient has a left ventricular ejection fraction (LVEF) greater than or equal to 40%; AND
- Patient has a serum potassium level less than or equal to 6 mEq/L.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Kerendia (finerenone) when the following criteria are not met to be **not medically necessary****:

- Chronic kidney disease with type 2 diabetes:
 - Patient has a UACR greater than or equal to 30 mg/g
 - Patient is on a maximally tolerated labeled dose of an ACE-I OR a maximally tolerated labeled dose of an ARB unless contraindicated or not tolerated
 - For continuation requests: Patient is tolerating the requested medication
- Heart failure:
 - Patient has tried OR is currently using an SGLT 2 inhibitor unless there is clinical evidence or patient history that suggests the use of an SGLT 2 inhibitor will be ineffective or cause an adverse reaction to the patient
 - For continuation requests: Patient is tolerating the requested medication

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 Kerendia (finerenone) when the patient selection criteria are not met (with the exception of those denoted as **not medically necessary****) to be **investigational**.*

Background/Overview

Kerendia is a non-steroidal mineralocorticoid receptor antagonist (MRA) indicated to reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure (HF) in adult patients with chronic kidney disease associated with type 2 diabetes and to reduce the risk of CV death, hospitalization for HF, and urgent HF visits in adults with HF with left ventricular ejection fraction (LVEF) greater than or equal to 40%. The recommended starting dosage is 10 mg or 20 mg orally once daily based on eGFR and serum potassium thresholds. Increase the dosage after 4 weeks to the target dose of 20 mg once daily in patients with CKD associated with type 2 diabetes based on eGFR and serum potassium thresholds. For patients with HF with LVEF greater than or equal to 40%, increase dosage after 4 weeks to the target dose of 20 mg or 40 mg once daily based on eGFR and serum potassium thresholds. See the package insert for complete dosing details.

Chronic Kidney Disease associated with Type 2 Diabetes

Chronic kidney disease (CKD) due to diabetes occurs in 20% to 40% of patients with diabetes. CKD can progress to end stage kidney disease, which could require dialysis or kidney transplantation and is associated with increased cardiovascular risk. CKD is defined as persistent eGFR less than 60 mL/min/1.73 m², albuminuria (albumin: creatinine ratio greater than or equal to 30 mg/g), or other markers of kidney damage, such as hematuria or structural abnormalities. These measurements can vary within individuals over time; therefore, persistence for at least 3 months is required for diagnosis.

For patients with type 2 diabetes and CKD with albuminuria who are receiving maximally tolerated doses of an ACE inhibitor or ARB, the American Diabetes Association (ADA) Standards of Care (2025) recommend treatment with a nonsteroidal MRA with demonstrated benefit to improve cardiovascular outcomes and to reduce the risk of CKD progression. For patients with type 2 diabetes and CKD, Kerendia is recommended to reduce the risk of hospitalization for HF. In the CKD section of the ADA guidelines, sodium-glucose cotransporter-2 (SGLT 2) inhibitors (if eGFR is greater than or equal to 20 mL/min/1.73 m²) with demonstrated benefit or glucagon like peptide 1 (GLP-1) inhibitors with demonstrated benefit is recommended in patients with type 2 diabetes and CKD to reduce CKD progression and CV events. The 2022 Kidney Disease Improving Global Outcomes (KDIGO) guidelines suggest the use of a nonsteroidal mineralocorticoid receptor antagonist, such as Kerendia, in patients with type 2 diabetes, an eGFR greater than or equal to 25 mL/min per 1.73 m², normal serum potassium concentration, and albuminuria (albumin: creatinine ratio greater than or equal to 30 mg/g) despite a maximum tolerated dose of a renin-angiotensin system (RAS) inhibitor (an ACE-I or ARB being first line). A consensus report from the ADA/Kidney Disease Improving

Global Outcomes (KDIGO) (2022) for diabetes management in CKD recommends Kerendia for patients with type 2 diabetes, eGFR greater than or equal to 25 mL/min/1.73 m², normal serum potassium concentration, and albuminuria (albumin: creatinine ratio greater than or equal to 30 g/g) despite a maximum tolerated dose of renin-angiotensin system (RAS) inhibitor therapy. The KDIGO Clinical Practice Guideline for the Evaluation and Management of CKD (2024) reaffirms the KDIGO statements from 2022. In addition, the 2024 KDIGO update cites that for patients with type 2 diabetes and CKD, Kerendia is most appropriate for those who are at high risk of CKD progression and CV events with persistent albuminuria despite other standard-of-care therapies. The guidelines also state that Kerendia can be added to a RAS inhibitor or an SGLT-2 inhibitor for the treatment of type 2 diabetes and CKD.

Heart Failure (LVEF greater than or equal to 40%)

Heart failure is a complex clinical syndrome that results from any structural or functional impairment of ventricular filling or ejection of blood according to the 2022 American Heart Association (AHA), American College of Cardiology (ACC), and Heart Failure Society of America Guidelines for the Management of HF. The primary clinical features of HF are dyspnea and fatigue, which may limit exercise tolerance, and fluid retention, which may lead to pulmonary and/or splanchnic congestion and/or peripheral edema. Some patients have exercise intolerance but little evidence of fluid retention, whereas others complain primarily of edema, dyspnea, or fatigue. Heart failure has been classified into 4 categories: HF with preserved ejection fraction (LVEF greater than or equal to 50%), HF with mildly reduced ejection fraction (LVEF 41% to 49%), HF with improved ejection fraction (previous LVEF less than or equal to 40% and a follow-up measurement of LVEF greater than 40%), and HF with reduced ejection fraction (LVEF less than or equal to 40%). According to ACC/AHA guidelines, HF is classified into four stages which reflect the development and progression of the disease and incorporate the evolving role of biomarkers and cardiac structural changes in identifying patients at risk for developing HF. Therapeutic interventions in each stage aim to modify risk factors (stage A), treat risk and structural heart disease to prevent HF (stage B), and reduce symptoms, morbidity, and mortality (stages C and D). The NYHA classification is used to characterize symptoms and functional capacity of patients with symptomatic (stage C, NYHA class II and III) heart failure or advanced heart failure (stage D). The NYHA functional classification is an independent predictor of mortality and is widely used in clinical practice to determine the eligibility of patients for treatment strategies.

Table 1. NYHA Functional Classification

NYHA Class	Patients with Cardiac Disease (Description of HF Related Symptoms)
Class I (Mild)	Patients with cardiac disease but without limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation (rapid or pounding heartbeat), dyspnea (shortness of breath), or anginal pain (chest pain).
Class II (Mild)	Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.

Class III (Moderate)	Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea, or anginal pain.
Class IV (Severe)	Patients with cardiac disease resulting in the inability to carry on any physical activity without discomfort. Symptoms of heart failure or the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.

The Criteria Committee of the New York Heart Association. Nomenclature and Criteria for Diagnosis of Diseases of the Heart and Great Vessels. 9th ed. Boston, Mass: Little, Brown & Co; 1994:253-256

Table 2. Classification of HF by LVEF

Type of HF According to LVEF	Criteria
HFrEF (HF with reduced EF)	LVEF $\leq 40\%$
HFimpEF (HF with improved EF)	Previous LVEF $\leq 40\%$ and a follow-up measurement of LVEF $> 40\%$
HFmrEF (HF with mildly reduced EF)	- LVEF 41% – 49% - Evidence of spontaneous or provokable increased LV filling pressures (e.g., elevated natriuretic peptide, noninvasive and invasive hemodynamic measurement)
HFpEF (HF with preserved EF)	- LVEF $\geq 50\%$ - Evidence of spontaneous or provokable increased LV filling pressures (e.g., elevated natriuretic peptide, noninvasive and invasive hemodynamic measurement)

Guideline-directed medical therapy (GDMT) for heart failure is outlined in the 2022 American Heart Association, American College of Cardiology, and Heart Failure Society of America guidelines for the management of heart failure. Of note, the clinical trial data for Kerendia in HF have not yet been incorporated into current HF guidelines. Also, GDMT for individuals with a diagnosis of HFrEF (LVEF 40% or lower) is not within the scope of this policy and is not addressed.

For symptomatic patients with established diagnosis of HFmrEF (LVEF 41-49%), the following drug classes have been noted with class 1-2b recommendations:

- Diuretics, as needed (1)
- SGLT 2 inhibitors (2a)
- ACE inhibitor, ARB, or angiotensin receptor neprilysin inhibitor (ARNi) (2b)
- MRA (2b)
- Evidence-based beta blockers for HFrEF (2b) (e.g., bisoprolol, carvedilol, metoprolol succinate extended release)

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For patients with HFpEF (LVEF greater than or equal to 50%), the following drug class have been noted with class 1-2b recommendations:

- Titrate blood pressure medication to attain guideline recommended target in patients with hypertension (1)
- SGLT 2 inhibitors (2a)
- MRAs (2b)
- ARB (2b)
- ARNi (2b)

The American College of Cardiology (ACC) Expert Consensus Decision Pathway for HFpEF (2023) recommends the following drug classes for patients with a diagnosis of HFpEF:

- First line: SGLT 2 inhibitor
 - GLT 2 inhibitors significantly reduce the risk of hospitalization for HF and cardiovascular death across all ejection fractions subgroups. Two SGLT 2 inhibitors (Farxiga™ [dapagliflozin tablets, authorized generic] and Jardiance® [empagliflozin tablets])[‡] have demonstrated a significant reduction in the composite of CV death and hospitalization for HF among patients with HF with LVEF greater than 40% and are recommended for all patients with HFpEF and HFmrEF.
- Second line considerations:
 - Titrate a loop diuretic for patients with fluid retention; NYHA class II-IV
 - Add an MRA for those with fluid retention, women (all LVEFs), and men with LVEF less than 55% to 60%
 - Add an ARNi for women (all LVEFs) and men with LVEF less than 55% to 60%
 - Add an ARB for ARNi-eligible patients when an ARNi is not feasible (ACE inhibitors are not a reasonable alternative)

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Kerendia is a non-steroidal mineralocorticoid receptor antagonist indicated to reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease associated with type 2 diabetes. In July of 2025, Kerendia was approved for use in reducing the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visits in adult patients with heart failure with left ventricular ejection fraction (LVEF) greater than or equal to 40%.

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.

Chronic Kidney Disease associated with Type 2 Diabetes

The FIDELIO-DKD and FIGARO-DKD studies were randomized, double-blind, placebo-controlled, multicenter studies in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D). CKD associated with type 2 diabetes was defined as either having an urinary albumin to creatinine ratio (UACR) of 30 to 300 mg/g, estimated glomerular filtration rate (eGFR) 25 to 60 mL/min/1.73 m² and diabetic retinopathy, or as having an UACR of ≥ 300 mg/g and an eGFR of 25 to 75 mL/min/1.73 m² in the FIDELIO-DKD trial and as having an UACR of 30 mg/g to < 300 mg/g and an eGFR of 25 to 90 mL/min/1.73m², or an UACR ≥ 300 mg/g and an eGFR ≥ 60 mL/min/1.73m² in the FIGARO-DKD trial. Both trials excluded patients with known significant non-diabetic kidney disease. All patients were to have a serum potassium ≤ 4.8 mEq/L at screening and be receiving standard of care background therapy, including a maximum tolerated labeled dose of an angiotensin-converting enzyme inhibitor (ACE-I) or angiotensin receptor blocker (ARB). Patients with a clinical diagnosis of chronic heart failure with reduced ejection fraction and persistent symptoms (New York Heart Association class II to IV) were excluded. The starting dose of Kerendia was based on screening eGFR (10 mg once daily in patients with an eGFR of 25 to < 60 mL/min/1.73 m² and 20 mg once daily in patients with an eGFR ≥ 60 mL/min/1.73 m²). The dose of Kerendia could be titrated during the study, with a target dose of 20 mg daily.

The primary objective of the FIDELIO-DKD study was to determine whether Kerendia reduced the incidence of a sustained decline in eGFR of $\geq 40\%$, kidney failure (defined as chronic dialysis, kidney transplantation, or a sustained decrease in eGFR to < 15 mL/min/1.73m²), or renal death. The secondary outcome was a composite of time to first occurrence of CV death, non-fatal MI, non-fatal stroke or hospitalization for heart failure.

The primary objective of the FIGARO-DKD study was to determine whether Kerendia reduced the time to first occurrence of CV death, non-fatal MI, non-fatal stroke or hospitalization for heart failure. The secondary outcome was a composite of time to kidney failure, a sustained decline in eGFR of 40% or more compared to baseline over at least 4 weeks, or renal death.

IN FIDELIO-DKD, a total of 5,674 patients were randomized to receive Kerendia (N = 2,833) or placebo (N = 2,841) and were followed for a median of 2.6 years. At baseline, the mean eGFR was 44 mL/min/1.73m², with 55% of patients having an eGFR < 45 mL/min/1.73m². Median UACR was 852 mg/g, and mean glycated hemoglobin A1c (HbA1c) was 7.7%. Approximately 46% of patients had a history of atherosclerotic cardiovascular disease.

At baseline, 99.8% of patients were treated with an ACE-I or ARB. Approximately 97% were on an antidiabetic agent (insulin [64.1%], biguanides [44%], glucagon-like peptide-1 [GLP-1] receptor agonists [7%], sodium-glucose cotransporter 2 [SGLT-2] inhibitors [5%]), 74% were on a statin, and 57% were on an antiplatelet agent.

Kerendia reduced the incidence of the primary composite endpoint of a sustained decline in eGFR of $\geq 40\%$, kidney failure, or renal death (HR 0.82, 95% CI 0.73-0.93, p = 0.001). The treatment effect reflected a reduction in a sustained decline in eGFR of $\geq 40\%$ and progression to kidney failure. There were few renal deaths during the trial.

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Kerendia also reduced the incidence of the secondary composite endpoint of cardiovascular (CV) death, non-fatal myocardial infarction (MI), non-fatal stroke or hospitalization for heart failure (HR 0.86, 95% CI 0.75-0.99, $p = 0.034$). The treatment effect reflected a reduction in CV death, non-fatal MI, and hospitalization for heart failure.

In FIGARO-DKD, a total of 7352 patients were randomized to receive Kerendia ($N = 3683$) or placebo ($N = 3666$) and were followed for 3.4 years. As compared to FIDELIO-DKD, baseline eGFR was higher in FIGARO-DKD (mean eGFR 68, with 62% of patients having an eGFR ≥ 60 mL/min/1.73 m²) and median UACR was lower (308 mg/g). Otherwise, baseline patient characteristics and background therapies were similar in the two trials.

In FIGARO-DKD, Kerendia reduced the incidence of the primary composite endpoint of CV death, non-fatal MI, nonfatal stroke or hospitalization for heart failure (HR 0.87, 95% CI 0.76-0.98, $p = 0.026$). The treatment effect was mainly driven by an effect on hospitalization for heart failure, though CV death also contributed to the treatment effect.

The purpose of this policy is to ensure that Kerendia is being used per its FDA approved indication as well as to ensure that the most effective and proven medications for the condition(s) are utilized prior to the use of Kerendia.

Heart Failure (LVEF $\geq 40\%$)

FINEARTS-HF was a randomized, double-blind, placebo-controlled, multicenter study in adult patients with heart failure (NYHA class II–IV) with documented LVEF $\geq 40\%$. Patients were required to have an eGFR ≥ 25 mL/min/1.73m² and serum potassium ≤ 5.0 mEq/L at screening and randomization and were receiving background heart failure medical treatment, including diuretics. The primary endpoint was the composite of cardiovascular (CV) death and total (first and recurrent) heart failure events comprised of hospitalization for heart failure and urgent heart failure visits. In this trial, 3003 patients were randomized to Kerendia and 2998 were randomized to placebo and were followed for a median of 2.7 years. Patients with eGFR ≥ 25 to < 60 mL/min/1.73m² initiated Kerendia 10 mg and patients with eGFR ≥ 60 mL/min/1.73m² initiated Kerendia 20 mg. Both groups were titrated up to a target dose of Kerendia 20 mg and 40 mg, respectively. At month 6, approximately 65% of the patients reached their target dose. The majority of patients were on loop diuretics (87%), an ACE inhibitor or ARB (79%), or an ARNi (9%), and 14% were on SGLT-2 inhibitors. Kerendia reduced the risk of the primary composite endpoint compared to placebo (Relative Risk [RR] 0.84, 95% CI 0.74-0.95, $p = 0.007$). The Kerendia and placebo event curves separated early and continued to diverge over the study period. Kerendia reduced the risk of the secondary endpoint of total heart failure events (hospitalization for HF or urgent HF visit) compared to placebo (RR 0.82, 95% CI 0.71-0.94, $p = 0.006$). The treatment effect for the primary endpoint was consistent across all pre-specified subgroups, including sex, LVEF, NYHA class, eGFR, time since latest heart failure event, SGLT-2 inhibitor therapy, and diabetes mellitus status.

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11/04/2021	Medical Policy Committee review
11/10/2021	Medical Policy Implementation Committee approval. New policy.
12/01/2022	Medical Policy Committee review
12/14/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/02/2023	Medical Policy Committee review
02/08/2023	Medical Policy Implementation Committee approval. Updated eligibility criteria and relevant sections based on new trial, FIGARO-DKD. Removed diabetic retinopathy and eGFR and UACR ranges from policy criteria that were specific to FIDELIO-DKD study.
11/02/2023	Medical Policy Committee review
11/08/2023	Medical Policy Implementation Committee approval. Removed criterion requiring a patient to NOT have New York Heart Association Class II-IV heart failure.

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11/07/2024	Medical Policy Committee review
11/13/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/05/2026	Medical Policy Committee review
01/07/2026	Medical Policy Implementation Committee approval. Added coverage criteria for the new indication of HF with LVEF $\geq$ 40%. Updated background information and rationale.
04/02/2026	Medical Policy Committee review
04/10/2026	Medical Policy Implementation Committee approval. For CKD associated with T2DM, removed requirements of eGFR and potassium ranges and trial and failure of an SGLT-2 inhibitor from policy criteria; updated criterion to clarify that ACE-I or ARB therapy is required unless contraindicated or not tolerated. For heart failure, removed requirements related to LVEF assessment within the past 12 months, NYHA Functional Class, and severe hepatic impairment from the policy criteria. Revised the criterion to eliminate the requirement for a specific SGLT 2 inhibitor and to allow exception when clinical evidence or patient history suggests an SGLT 2 inhibitor might be ineffective or cause an adverse reaction. Updated age criterion to 18 years of age or older.

Next Scheduled Review Date: 04/2027

*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

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- 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.