LOUISIANA BLUE

Wearable Cardioverter Defibrillators

Policy # 00157
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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.

Note: Automatic Implantable Cardioverter Defibrillator (AICD) is addressed separately in medical policy 00008.

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 use of a Food and Drug Administration (FDA)-approved wearable cardioverter defibrillator (WCD) for the prevention of sudden cardiac death as interim treatment (90 days) to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility may be considered for an FDA-approved WCD for the prevention of sudden cardiac death as interim treatment (90 days) when **ANY** of the following criteria are met:

- Individual meets the criteria for an implantable cardioverter defibrillator (ICD, see indications in Medical Policy 00008 Automatic Implantable Cardioverter Defibrillator) but implantation of an ICD must be postponed because **ONE** of the following temporary contraindications to receiving an ICD placement exists:
  - Individual is treated for current systemic infection; **OR**
  - Individual has a medical condition that requires delay in initial ICD implantation (e.g., lack of vascular access or temporary critical need for anticoagulation); **OR**
- Individual with an ICD in whom removal of the ICD is required (e.g., due to a concurrent infection or malfunction) when the medical necessity for original implantation is still present, and the individual must undergo a waiting period before ICD can be replaced; **OR**
- Individual with an ejection fraction (LVEF) $\leq$ 35% who already had hemodynamic instability due to tachyarrhythmia and meets **ONE** of the following criteria:
  - Has ischemic cardiomyopathy within 40 days from a myocardial infarction and LVEF will be reassessed > 40 days after myocardial infarction; **OR**

  - Revascularization was performed (e.g., coronary artery bypass graft, percutaneous coronary intervention) within the past 90 days and LVEF will be reassessed > 90 days after revascularization; **OR**
  - Has newly diagnosed non-ischemic cardiomyopathy on guideline-directed medical therapy (guideline-directed management and therapy [GDMT], e.g., angiotensin-converting enzyme [ACE] inhibitors, angiotensin-receptor blockers [ARBs], beta blockers [BB]) initiated within the past 90 days and LVEF will be reassessed after > 3 months of GDMT; **OR**
- Criteria are met for initial ICD implantation in an individual on a waiting list for heart transplantation who will be managed as an outpatient.

Based on review of available data, the Company may consider **continued** use of wearable (external) cardioverter defibrillators (WCDs) for the prevention of sudden cardiac death as interim treatment for additional one month rental (beyond the initial 90 days) to be **eligible for coverage.****

Patient Selection Criteria
Coverage eligibility may be considered for continued use of WCD for the prevention of sudden cardiac death as interim treatment for additional one month rental (beyond the initial 90 days) when the following criteria are met:

- Physician attests to $\geq$ 90% daily use demonstrated by the individual's data reports downloaded from the manufacturer portal; AND
- An updated treatment plan from the treating provider documents the ongoing medical necessity of the WCD.

Note: If the individual responds to the maximal medical treatment and their condition improves after 90 days, the ICD may no longer be necessary and the WCD should be discontinued. However, if there is no improvement in the individual's condition, permanent ICD placement may be 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 wearable cardioverter-defibrillators for all other indications to be **investigational. ***

Policy Guidelines

It is uncommon for individuals to have a temporary contraindication to implantable cardioverter defibrillator (ICD) placement. The most common reason will be a systemic infection that requires treatment before the ICD can be implanted. The wearable cardioverter defibrillator (WCD) should

only be used short-term while the temporary contraindication (e.g., systemic infection) is being clinically managed. Once treatment is completed, the permanent ICD should be implanted.

Background/Overview

Sudden Cardiac Arrest

Sudden cardiac arrest (SCA) is the most common cause of death in patients with coronary artery disease.

Treatment

The implantable cardioverter defibrillator (ICD) has proven effective in reducing mortality for survivors of SCA and for patients with documented malignant ventricular arrhythmias. More recently, use of ICDs has been broadened by studies reporting a reduction in mortality for patients at risk for ventricular arrhythmias, such as patients with prior myocardial infarction (MI) and reduced ejection fraction (EF).

Implantable cardioverter defibrillators consist of implantable leads, which are placed percutaneously in the heart, that are connected to a pulse generator placed beneath the skin of the chest or abdomen. Placement of the ICD is a minor surgical procedure. Potential adverse events of ICD placement are bleeding, infection, pneumothorax, and delivery of unnecessary counter shocks. See medical policy 00008 Automatic Implantable Cardioverter Defibrillator (AICD) for further information on ICDs.

The wearable cardioverter defibrillator (WCD) is an external device intended to perform the same tasks as an ICD, without invasive procedures. It consists of a vest worn continuously underneath the patient's clothing. Part of this vest is the "electrode belt" that contains the cardiac-monitoring electrodes and the therapy electrodes that deliver a counter shock. The vest is connected to a monitor with a battery pack and alarm module worn on the patient's belt. The monitor contains the electronics that interpret the cardiac rhythm and determines when a counter shock is necessary. The alarm module alerts the patient to certain conditions by lights or voice messages, during which time a conscious patient can abort or delay the shock.

U.S. Food and Drug Administration (FDA)-labeled indications for the WCD are adults at risk for SCA who either are not candidates for or refuse an implantable ICD. Some experts have suggested that the indications for a WCD should be broadened to include other populations at high risk for SCA. The potential indications include:

- Bridge to transplantation (ie, the Use of a Wearable Defibrillator in Terminating Tachyarrhythmias in Patients at High Risk for Sudden Death [WEARIT] study population);
- Bridge to implantable device or clinical improvement (ie, the Patients at High Risk for Sudden Death after a Myocardial Infarction or Bypass Surgery not receiving an ICD for up to four months [BIROAD] study population):
    - Post bypass with EF less than 30%,

  - Post bypass with ventricular arrhythmias or syncope within 48 hours of surgery,
  - Post MI with EF less than 30%,
  - Post MI with ventricular arrhythmias within 48 hours;
- Drug-related arrhythmias (during drug washout or after, during evaluation of long-term risk);
- Patients awaiting revascularization;
- Patients too ill to undergo device implantation; and
- Patients who refuse device therapy.

According to the American College of Cardiology and American Heart Association (1998) guidelines on ICD use, the device is contraindicated in patients with terminal illness, in patients with drug-refractory class IV heart failure, in patients who are not candidates for transplantation, and in patients with a history of psychiatric disorders that interferes with the necessary care and follow-up postimplantation. It is not known how many patients refuse an ICD placement after it has been recommended. A subset of patients who may otherwise meet the established criteria for an ICD but may have a temporary contraindication for an implantable device such as infection may benefit from WCD. Similarly, a patient with an existing ICD and concurrent infection may require explantation of the ICD; a WCD may benefit this group during the time before reinsertion of ICD may be attempted.

The combined WEARIT and BIROAD study evaluated a prospective cohort of 289 patients at high risk for SCD but who did not meet criteria for an ICD or who could not receive an ICD for several months. The WEARIT-II Registry study reported on the results of patients with ischemic (n=805) or nonischemic cardiomyopathy (n=927) or congenital/inherited heart disease (n=268) who had been prescribed a WCD for risk assessment. At the end of the evaluation period, 42% of patients received an ICD and 40% of patients were no longer considered to need an ICD, most frequently because EF had improved.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In 2001, the Lifecor WCD®‡[1] 2000 system was approved by the FDA through the premarket approval process for "adult patients who are at risk for cardiac arrest and are either not candidates for or refuse an implantable defibrillator." The vest was renamed the LifeVest®‡.

In 2015, the FDA approved the LifeVest for "certain children who are at risk for sudden cardiac arrest, but are not candidates for an implantable defibrillator due to certain medical conditions or lack of parental consent."

In 2021, the FDA approved the ASSURE®‡ WCD for adult patients at risk for SCA who are not candidates for (or refuse) an ICD.

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FDA product code: MVK.

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.

Description

A wearable cardioverter defibrillator (WCD) is a temporary, external device that is an alternative to an implantable cardioverter defibrillator (ICD). It is primarily intended for temporary conditions for which an implantable device is contraindicated, or for the period during which the need for a permanent implantable device is uncertain.

Summary of Evidence

Overview of Wearable Cardioverter Defibrillator Versus Implantable Cardioverter Defibrillator

One randomized controlled trial (RCT) has compared wearable cardioverter defibrillators (WCDs) with usual guideline-based care and found no significant benefit to WCD over usual care. No studies have directly compared the performance of a WCD with a permanent implantable cardioverter defibrillator (ICD). One small study in an electrophysiology lab demonstrated that the WCD can correctly identify and terminate most induced ventricular arrhythmias. Similarly, a study of the ASSURE WCD in patients with cardiomyopathy found that the WCD detected all events recorded by an ICD with few false-positive shock alarms in a 30-day period. A cohort study of WCD use estimated that the percentage of successful resuscitations was approximately 70%. Multiple studies have demonstrated suboptimal adherence. Device failures were largely attributed to incorrect device use and/or nonadherence. A more recent registry study has reported a high compliance rate, although these results may be biased by self-selection. Collectively, this evidence indicates that the WCD can successfully detect and terminate arrhythmias in at least some patients but that overall performance in clinical practice might be inferior to a permanent ICD.

Temporary Contraindications

For individuals who have a temporary contraindication to an ICD who receive a WCD, the evidence includes prospective cohort studies and a technology assessment that assessed ICD devices, given the absence of evidence on WCD devices. Relevant outcomes are overall survival (OS), morbid events, functional outcomes, and treatment-related morbidity. A small number of patients meet established criteria for an ICD but have a transient contraindication for an implantable device, most commonly an infectious process. The available data have established that the WCD device can detect lethal arrhythmias and successfully deliver a countershock in most cases. In patients scheduled for

ICD placement, the WCD will improve outcomes as an interim treatment. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Immediate Post-Myocardial Infarction
For individuals who are in the immediate post-myocardial infarction (MI) period who receive a WCD, the evidence includes an RCT comparing WCD with guideline-based therapy, 2 cohort studies, and a systematic review. Relevant outcomes are OS, morbid events, functional outcomes, and treatment-related morbidity. The RCT reported no benefit of WCD over guideline-based therapy. The cohort study of 8453 patients showed that 252 shocks successfully terminated ventricular fibrillation (VF) or ventricular tachycardia (VT) (82% success rate), but without a control group, interpretation is difficult. Similarly, a retrospective cohort of Medicare data found that WCD use was associated with lower 1-year mortality than no WCD use, but potential biases were noted. Evidence from the systematic review was deemed of low to very low quality, and the reviewers had weak confidence in the reported estimates. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Post-Coronary Artery Bypass Graft Surgery at High Risk for Lethal Arrhythmias
For individuals who are post-coronary artery bypass graft (CABG) surgery and are at high risk for lethal arrhythmias, the evidence includes an RCT for ICD and a registry study. Relevant outcomes are OS, morbid events, functional outcomes, and treatment-related morbidity. For high-risk post-CABG patients, an RCT reported no difference in OS associated with early ICD placement. The registry study found survival benefits with WCD but had limited interpretation of data. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Awaiting Heart Transplantation at High Risk for Lethal Arrhythmias
For individuals who are awaiting heart transplantation and are at high risk for lethal arrhythmias, the evidence includes analyses of subsets of patients from the manufacturer registry, a subset from a prospective cohort study, and a case series. Relevant outcomes are OS, morbid events, functional outcomes, and treatment-related morbidity. These studies do not provide sufficient evidence to determine whether a WCD is of benefit compared with usual care. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Newly Diagnosed Nonischemic Cardiomyopathy
For individuals who have newly diagnosed nonischemic cardiomyopathy, the evidence includes an RCT for ICD and several retrospective analyses of WCD registry data. Relevant outcomes are OS, morbid events, functional outcomes, and treatment-related morbidity. The RCT found that prophylactic ICD placement for nonischemic cardiomyopathy did not improve mortality compared with usual care. Evidence from the retrospective analysis was not sufficient to determine whether WCD improves outcomes compared with usual care. Given the lack of evidence that ICD improves outcomes, WCD is not expected to improve outcomes under the conditions studied in these trials.

The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Peripartum Cardiomyopathy
For individuals who have peripartum cardiomyopathy, the evidence includes a retrospective registry data analysis and a small cohort study. Relevant outcomes are OS, morbid events, functional outcomes, and treatment-related morbidity. The registry study revealed that no shocks were delivered during use over an average of 124 days. The cohort study identified 4 episodes of appropriate electric shock over 133 days. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Clinical Input From Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2014 Input
In response to requests, further input was received from 2 physician specialty societies and 7 academic medical centers while this policy was under review in 2014. Input related to the role of wearable cardioverter defibrillators (WCDs) in preventing sudden cardiac death (SCD) among high-risk patients awaiting a heart transplant. Overall, input on the use of WCDs in this patient population was mixed. Some reviewers indicated that it may have a role among certain patients awaiting heart transplant, but there was no consensus on specific patient indications for use.

2013 Input
In response to requests, input was received from 3 physician specialty societies and 8 academic medical centers while this policy was under review in 2013. Overall, the input was mixed. Most, but not all, providing comments suggested that the WCD may have a role in select high-risk patients following acute myocardial infarction (MI) or in newly diagnosed cardiomyopathy. However, reviewers acknowledged the lack of evidence for benefit and consistency in the evidence in defining high-risk subgroups that may benefit.

Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in ‘Supplemental Information’ if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given

to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Heart Association et al
In 2018, the American Heart Association (AHA), the American College of Cardiology, and the Heart Rhythm Society published a guideline on the management of patients with ventricular arrhythmias and prevention of SCD. The guidelines note that "the patients listed in this recommendation are represented in clinical series and registries that demonstrate the safety and effectiveness of the wearable cardioverter-defibrillator. Patients with recent MI, newly diagnosed nonischemic cardiomyopathy, recent revascularization, myocarditis, and secondary cardiomyopathy are at increased risk of VT/SCA [ventricular tachycardia/sudden cardiac arrest]. However, the wearable cardioverter-defibrillator is of unproven benefit in these settings, in part because the clinical situation may improve with therapy and time." The specific recommendations are summarized in Table 1.

Level of evidence class IIa is moderate recommendation, class IIb is a weak recommendation, and class III is a moderate recommendation for no benefit or a strong recommendation for harm.

Table 1. Guidelines for Wearable Cardioverter Defibrillator Therapy

Recommendation	COR	LOE[c]
"In patients with an ICD and a history of SCA or sustained ventricular arrhythmia in whom removal of the ICD is required (as with infection), the WCD is reasonable for the prevention of SCD."[a]	IIa	B-NR
"In patients at an increased risk of SCD but who are not ineligible for an ICD, such as awaiting cardiac transplant, having an LVEF of 35% or less and are within 40 days from an MI, or have newly diagnosed nonischemic cardiomyopathy, revascularization within the past 90 days, myocarditis or secondary cardiomyopathy or a systemic infection, the WCD may be reasonable."[b]	IIb	B-NR

B-NR: Level B - nonrandomized; COR: class of recommendation; ICD: implantable cardioverter defibrillator; LOE: level of evidence; LVEF: left ventricular ejection fraction; MI: myocardial infarction; SCA: sudden cardiac arrest; SCD: sudden cardiac death; VT: ventricular tachycardia; WCD: wearable cardioverter defibrillator.

a Removal of an ICD for a period of time, most commonly due to infection, exposes the patient to risk of untreated VT/SCD unless monitoring and access to emergency external defibrillation is maintained. In 1 series of 354 patients who received the WCD, the indication was infection in 10%.32, For patients with a history of SCA or sustained ventricular arrhythmia, the WCD may allow

the patient to be discharged from the hospital with protection from VT/SCD until the clinical situation allows reimplantation of an ICD.

b The patients listed in this recommendation are represented in clinical series and registries that demonstrate the safety and effectiveness of the WCD. Patients with recent MI, newly diagnosed nonischemic cardiomyopathy, recent revascularization, myocarditis, and secondary cardiomyopathy are at increased risk of VT or SCD. However, the WCD is of unproven benefit in these settings, in part because the clinical situation may improve with therapy and time. In patients awaiting transplant, even with anticipated survival <1 year without transplant, and depending on clinical factors such as use of intravenous inotropes and ambient ventricular arrhythmia, a WCD may be an alternative to an ICD.

c B-NR: data derived from ≥1 nonrandomized trials or meta-analysis of such studies.

In 2016, the AHA published a scientific advisory on the WCD, The AHA stated that "because there is a paucity of prospective data supporting the use of the WCD, particularly in the absence of any published, randomized, clinical trials, the recommendations provided in this advisory are not intended to be prescriptive or to suggest an evidence-based approach to the management of patients with FDA [U.S. Food and Drug Administration]-approved indications for use." The specific recommendations are summarized in Table 2.

Table 2

Recommendation	**COR**	**LOE[a]**
"Use of WCDs is reasonable when there is a clear indication for an implanted/permanent device accompanied by a transient contraindication or interruption in ICD care such as infection."	IIa	C
"Use of WCDs is reasonable as a bridge to more definitive therapy such as cardiac transplantation."	IIa	C
"Use of WCDs may be reasonable when there is concern about a heightened risk of SCD that may resolve over time or with treatment of left ventricular dysfunction/ for example, in ischemic heart disease with recent revascularization, newly diagnosed nonischemic dilated cardiomyopathy in patients starting guideline-directed medical therapy, or secondary cardiomyopathy (tachycardia mediated, thyroid mediated, etc) in which the underlying cause is potentially treatable."	IIb	C

"WCDs may be appropriate as bridging therapy in situations associated with increased risk of death in which ICDs have been shown to reduce SCD but not overall survival such as within 40 days of MI."	IIb	C
"WCDs should not be used when nonarrhythmic risk is expected to significantly exceed arrhythmic risk, particularly in patients who are not expected to survive >6 months."	III	C

COR: class of recommendation; ICD: implantable cardioverter defibrillator; LOE: level of evidence; MI: myocardial infarction; SCD: sudden cardiac death; WCD: wearable cardioverter defibrillator.

a Level C evidence is based on limited data or expert opinion.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this review are listed in Table 3.

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05135403[a]	ASSURE WCD Clinical Evaluation - Post Approval Study (ACE-PAS)	5179	Feb 2025
Unpublished			

NCT05201495[a]	A Clinical Evaluation of the Jewel P-WCD in Subjects at High Risk for Sudden Cardiac Arrest	290	Nov 2023
NCT02816047	Indications for and Experience With the Wearable Cardioverter Defibrillator (WCD)–Austrian WCD Registry	450	Mar 2022 (unknown status)
	EURObservational research programme: Peripartum Cardiomyopathy (PPCM) Registry[b]		ongoing

NCT: national clinical trial.
a Denotes industry sponsored or co-sponsored study.
b Available at: https://www.escardio.org/Research/registries/global-registries-and-surveys-programme/PeriPartum-CardioMyopathy-PPCM-Registry.

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02/15/2005	Medical Policy Committee review
03/07/2005	Managed Care Advisory Council approval
03/14/2007	Medical Director review
03/21/2007	Medical Policy Committee approval. Coverage eligibility unchanged.
04/02/2008	Medical Director review
04/16/2008	Medical Policy Committee approval. Policy statement updated with patient selection criteria for interim treatment.
05/07/2008	Medical Director review
05/21/2008	Medical Policy Committee approval. Coverage eligibility changed from investigational to eligible for coverage with criteria.
05/07/2009	Medical Director review
05/20/2009	Medical Policy Committee approval. No change to coverage.
06/03/2010	Medical Policy Committee approval
06/16/2010	Medical Policy Implementation Committee approval. Title changed from “Wearable Cardioverter- Defibrillators as a Bridge to Implantable Cardioverter-Defibrillator Placement” to “Wearable Cardioverter- Defibrillators”. Coverage eligibility unchanged.
05/05/2011	Medical Policy Committee review
05/18/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/03/2012	Medical Policy Committee review
05/16/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/24/2013	Medical Policy Committee review. Policy Retired.
06/05/2025	Medical Policy Committee review
06/11/2025	Medical Policy Implementation Committee approval. Returned to active status.

Next Scheduled Review Date: 06/2026

Policy # 00157
Original Effective Date: 03/07/2005
Current Effective Date: 09/01/2025
Archived Date: 04/24/2013
Returned to Active Status: 09/01/2025

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2024 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Louisiana Blue Medical Policy Coverage Guidelines is with Louisiana Blue and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Louisiana Blue Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Louisiana Blue Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	93292, 93745
HCPCS	E0617, K0606, K0607, K0608, K0609
ICD-10 Diagnosis	All Related Diagnoses

*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.