Cardiac Hemodynamic Monitoring for the Management of Heart Failure in the Outpatient Setting

Policy # 00287
Original Effective Date: 01/31/2005
Current Effective Date: 08/14/2023

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: Biventricular Pacemakers (Cardiac Resynchronization Therapy) for the Treatment of Heart Failure is addressed separately in medical policy 00009.

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 cardiac hemodynamic monitoring for the management of heart failure using implantable direct pressure monitoring of the pulmonary artery (PA), thoracic bioimpedance, inert gas rebreathing, and arterial pressure during the Valsalva maneuver in the ambulatory care and outpatient setting to be investigational.*

Policy Guidelines
This policy refers only to the use of stand-alone cardiac output measurement devices designed for use in ambulatory care and outpatient settings. The use of cardiac hemodynamic monitors or intrathoracic fluid monitors that are integrated into other implantable cardiac devices, including implantable cardioverter defibrillators, cardiac resynchronization therapy devices, and cardiac pacing devices, is addressed in medical policy 00009.

Background/Overview
Chronic Heart Failure
Patients with chronic heart failure are at risk of developing acute decompensated heart failure, often requiring hospital admission. Patients with a history of acute decompensation have the additional risk of future episodes of decompensation and death. Reasons for the transition from a stable, chronic state to an acute, decompensated state include disease progression, as well as acute events such as

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coronary ischemia and dysrhythmias. While precipitating factors are frequently not identified, the most common preventable cause is noncompliance with medication and dietary regimens.

Management
Strategies for reducing decompensation, and thus the need for hospitalization, are aimed at early identification of patients at risk for imminent decompensation. Programs for early identification of heart failure are characterized by frequent contact with patients to review signs and symptoms with a health care provider, education, and medication adjustments as appropriate. These encounters may occur face-to-face in the office or at home, or via cellular or computed technology.

Precise measurement of cardiac hemodynamics is often employed in the intensive care setting to carefully manage fluid status in acutely decompensated heart failure. Transthoracic echocardiography, transesophageal echocardiography, and Doppler ultrasound are noninvasive methods for monitoring cardiac output on an intermittent basis for the more stable patient but are not addressed herein. A variety of biomarkers and radiologic techniques may be used for dyspnea when the diagnosis of acute decompensated heart failure is uncertain.

The criterion standard for hemodynamic monitoring is pulmonary artery catheters and central venous pressure catheters. However, they are invasive, inaccurate, and inconsistent in predicting fluid responsiveness. Several studies have demonstrated that catheters fail to improve outcomes in critically ill patients and may be associated with harm. To overcome these limitations, multiple techniques and devices have been developed that use complex imaging technology and computer algorithms to estimate fluid responsiveness, volume status, cardiac output and tissue perfusion. Many are intended for use in outpatient settings but can be used in the emergency department, intensive care unit, and operating room. Four methods are reviewed here: implantable pressure monitoring devices, thoracic bioimpedance, inert gas rebreathing, and arterial waveform during the Valsalva maneuver. Use of the last 3 is not widespread because of several limitations including use of proprietary technology making it difficult to confirm their validity and lack of large randomized controlled trials to evaluate treatment decisions guided by these hemodynamic monitors.
FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Noninvasive Left Ventricular End-Diastolic Pressure Measurement Devices

In 2004, the VeriCor®‡ (CVP Diagnostics), a noninvasive left ventricular end-diastolic pressure measurement device, was cleared for marketing by U.S. Food and Drug Administration (FDA) through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices for the following indication:

"The VeriCor is indicated for use in estimating non-invasively, left ventricular end-diastolic pressure (LVEDP). This estimate, when used along with clinical signs and symptoms and other patient test results, including weights on a daily basis, can aid the clinician in the selection of further diagnostic tests in the process of reaching a diagnosis and formulating a therapeutic plan when abnormalities of intravascular volume are suspected. The device has been clinically validated in males only. Use of the device in females has not been investigated."

FDA product code: DXN.

Thoracic Bioimpedance Devices

Multiple thoracic impedance measurement devices that do not require invasive placement have been cleared for marketing by the FDA through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices used for peripheral blood flow monitoring. Table 1 presents an inexhaustive list of representative devices (FDA product code: DSB).

Table 1. Noninvasive Thoracic Impedance Plethysmography Devices

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Clearance Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>BioZ®‡ Thoracic Impedance Plethysmograph</td>
<td>SonoSite</td>
<td>2009</td>
</tr>
<tr>
<td>Zoe®‡ Fluid Status Monitor</td>
<td>Noninvasive Medical Technologies</td>
<td>2004</td>
</tr>
<tr>
<td>Cheetah Starling SV</td>
<td>Cheetah Medical</td>
<td>2008</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Clearance Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>PhysioFlow®‡ Signal Morphology-based Impedance Cardiography (SM-ICG™‡)</td>
<td>Vasocom, now NeuMeDx</td>
<td>2008</td>
</tr>
<tr>
<td>ReDS™ Wearable System</td>
<td>Sensible Medical Innovations</td>
<td>2015</td>
</tr>
</tbody>
</table>

Also, several manufacturers market thoracic impedance measurement devices integrated into implantable cardiac pacemakers, cardioverter defibrillator devices, and cardiac resynchronization therapy devices. Thoracic bioimpedance devices integrated into implantable cardiac devices are addressed in medical policy 00009.

**Inert Gas Rebreathing Devices**

In 2006, the Innocor®‡ (Innovision), an inert gas rebreathing device, was cleared for marketing by the FDA through the 510(k) process. The FDA determined that this device was substantially equivalent to existing inert gas rebreathing devices for use in computing blood flow. FDA product code: BZG.

**Implantable Pulmonary Artery Pressure Sensor Devices**

In 2014, the CardioMEMS™‡ Heart Failure Monitoring System (CardioMEMS, now Abbott) was approved for marketing by the FDA through the premarket approval process. This device consists of an implantable pulmonary artery (PA) sensor, which is implanted in the distal PA, a transvenous delivery system, and an electronic sensor that processes signals from the implantable PA sensor and transmits PA pressure measurements to a secure database. The device originally underwent FDA review in 2011, at which point FDA found no reasonable assurance that the monitoring system would be effective, particularly in certain subpopulations, although the FDA agreed this monitoring system was safe for use in the indicated patient population. In 2022, the CardioMEMS™‡ HF Monitoring System received expanded approval for the treatment of New York Heart Association (NYHA) Class II-III patients who had been hospitalized at least 1 time in the prior year and/or had elevated natriuretic peptides.
Several other devices that monitor cardiac output by measuring pressure changes in the PA or right ventricular outflow tract have been investigated in the research setting but have not received the FDA approval. They include the Chronicle® implantable continuous hemodynamic monitoring device (Medtronic), which includes a sensor implanted in the right ventricular outflow tract, and the ImPressure® device (Remon Medical Technologies), which includes a sensor implanted in the PA.

Note: This medical policy only addresses the use of these technologies in ambulatory care and outpatient settings.

**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 federal regulations, other plan medical policies, and accredited national guidelines.

A variety of outpatient cardiac hemodynamic monitoring devices are intended to improve quality of life and reduce morbidity for patients with heart failure by decreasing episodes of acute decompensation. Monitors can identify physiologic changes that precede clinical symptoms and thus allow preventive intervention. These devices operate through various mechanisms, including implantable pressure sensors, thoracic bioimpedance measurement, inert gas rebreathing, and estimation of left ventricular end-diastolic pressure by arterial pressure during the Valsalva maneuver.

**Summary of Evidence**
For individuals who have heart failure in outpatient settings who receive hemodynamic monitoring with an implantable pulmonary artery pressure sensor device, the evidence includes randomized controlled trials (RCTs) and nonrandomized studies. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. One implantable pressure monitor, the CardioMEMS device, has U.S. Food and Drug Administration (FDA) approval. The pivotal CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA III Heart Failure Patients (CHAMPION) RCT reported a statistically significant 28% decrease in heart failure-related hospitalizations (HFH) in patients
implanted with the CardioMEMS device compared with usual care. However, trial results were potentially biased in favor of the treatment group due to the use of additional nurse communication to enhance protocol compliance with the device. The manufacturer conducted multiple analyses to address potential bias from the nurse interventions. Results were reviewed favorably by the FDA. While these analyses demonstrated the consistency of benefit of the CardioMEMS device, all such analyses have methodologic limitations. Early safety data have been suggestive of a higher rate of procedural complications, particularly related to pulmonary artery injury. While the U.S. CardioMEMS post-approval study and CardioMEMS European Monitoring Study for Heart Failure (MEMS-HF) study reported a significant decrease in HFH with few device- or system-related complications at 1 year, the impact of nursing interventions remains unclear. The subsequent Hemodynamic GUIDEd Management of Heart Failure (GUIDE-HF) RCT failed to meet its primary efficacy endpoint, the composite of HFH, urgent heart failure visits, and death at 1 year. With the approval of the FDA, the statistical analysis plan was updated to pre-specify sensitivity analyses to assess the impact of COVID-19 on the trial. For the 72% of patients who completed follow-up prior to the public health emergency declaration in March 2020, a statistically significant 19% reduction in the primary endpoint was reported, driven by a 28% reduction in HFH. However, lifestyle changes during the COVID-19 pandemic such as changes in physical activity, exposure to infections, willingness to seek medical care, and adherence to medications are unmeasured and add imprecision to treatment effect estimates, as do alterations in provider behaviors. Enrollment of NYHA Class II patients was significantly enriched in the first 500 patients, potentially impacting the pre-COVID-19 analysis. Overall, the beneficial effect of CardioMEMS, if any, appears to be on the hospitalization outcome of the composite. Both urgent heart failure visits and death outcomes had hazard ratios (HR) favoring the control group with wide confidence intervals including the null value in pre-COVID-19, during-COVID-19, and overall analyses of the GUIDE-HF trial. No significant differences were observed in secondary quality of life and functional status outcomes. While the HFH reduction of 28% found in the pre-COVID-19 analysis is consistent with findings from the CHAMPION trial, it is unclear whether physician knowledge of treatment assignment biases the decision to hospitalize and administer intravenous diuretics. Given that the intervention is invasive and intended to be used for a highly prevalent condition and, in light of the absence of a demonstrated benefit on mortality and functional outcomes, the lack of periprocedural safety data, and unclear impact of COVID-19 on remote monitoring in the GUIDE-HF trial, the net benefit of the CardioMEMS device remains uncertain. Concerns may be clarified by the ongoing GUIDE-HF RCT that proposes to enroll 2600 subjects for its open access phase and the recruiting German non-
industry-sponsored PASSPORT-HF trial. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have heart failure in outpatient settings who receive hemodynamic monitoring by thoracic bioimpedance, the evidence includes uncontrolled prospective studies and case series. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. There is a lack of RCT evidence evaluating whether the use of these technologies improves health outcomes over standard active management of heart failure patients. The case series have reported physiologic measurement-related outcomes and/or associations between monitoring information and heart failure exacerbations, but do not provide definitive evidence on device efficacy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have heart failure in outpatient settings who receive hemodynamic monitoring with inert gas rebreathing, no studies have been identified on clinical validity or clinical utility. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have heart failure in outpatient settings who receive hemodynamic monitoring of arterial pressure during the Valsalva maneuver, a single study was identified. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. The study assessed the use of left ventricular end-diastolic pressure (LVEDP) monitoring and reported an 85% sensitivity and an 80% specificity to detect LVEDP greater than 15 mm Hg. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

**Supplemental Information**

**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
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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 College of Cardiology et al
In 2017, the American College of Cardiology (ACC), the American Heart Association (AHA), and the Heart Failure Society of America (HFSA) issued joint guidelines on the management of heart failure that offered no recommendations for the use of ambulatory monitoring devices.

In the 2022 update to the heart failure management guidelines, 2 recommendations were provided regarding remote hemodynamic monitoring in heart failure. These recommendations are summarized below in Table 2.

Table 2. 2022 ACC/AHA/HFSA Recommendation for Wearables and Remote Monitoring (including Telemonitoring and Device Monitoring)

<table>
<thead>
<tr>
<th>Class of Recommendation</th>
<th>Level of Evidence</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>2b (Weak Evidence)</td>
<td>B-R (Moderate quality randomized evidence)</td>
<td>1. &quot;In selected adult patients with NYHA class III HF and history of HF hospitalization in the past year or elevated natriuretic peptide levels, on maximally tolerated doses of GDMT with optimal device therapy, the usefulness of wireless monitoring of PA pressure by an implanted hemodynamic monitor to reduce the risk of subsequent HF hospitalizations is uncertain.&quot;</td>
</tr>
</tbody>
</table>

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Value Statement: Uncertain Value (B-NR) (Moderate quality nonrandomized evidence)

2. "In patients with NYHA class III HF with a HF hospitalization within the previous year, wireless monitoring of the PA pressure by an implanted hemodynamic monitor provides uncertain value."


Adapted from Heidenreich et al (2022).

National Institute for Health and Care Excellence
In 2021, the National Institute for Health and Care Excellence (NICE) issued a new interventional procedures guidance regarding the use of percutaneous implantation of pulmonary artery pressure sensors for monitoring the treatment of chronic heart failure. The Institute's recommendation stated that "Evidence on the safety and efficacy of percutaneous implantation of pulmonary artery pressure sensors for monitoring treatment of chronic heart failure is adequate to support using this procedure provided that standard arrangements are in place for clinical governance, consent, and audit."

In 2018, the Institute updated their guidelines on chronic heart failure management and did not include outpatient hemodynamic monitoring as a recommendation.

Heart Failure Society of America
In 2018, the Heart Failure Society of America Scientific Statements Committee (2018) published a white paper consensus statement on remote monitoring of patients with heart failure.

The committee concluded that: "Based on available evidence, routine use of external RPM devices is not recommended. Implanted devices that monitor pulmonary arterial pressure and/or other parameters may be beneficial in selected patients or when used in structured programs, but the value of these devices in routine care requires further study."

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

Medicare National Coverage
In 2014, the Centers for Medicare & Medicaid Services updated its 2006 decision memorandum on thoracic electrical bioimpedance. Medicare's national coverage determination found thoracic bioimpedance to be reasonable and necessary for the following indications:

- Differentiation of cardiogenic from pulmonary causes of acute dyspnea;
- Optimization of atrioventricular interval for patients with atrioventricular sequential cardiac pacemakers;
- Monitoring of continuous inotropic therapy for patients with terminal heart failure;
- Evaluation for rejection in patients with a heart transplant as a predetermined alternative to myocardial biopsy; and

While Medicare permits coverage of thoracic bioimpedance in these conditions, it has acknowledged that there is a "…general absence of studies evaluating the impact of using thoracic bioimpedance for managing patients with cardiac disease…." Medicare does not cover the use of thoracic bioimpedance in the management of hypertension due to inadequate evidence.

Medicare has also specified that thoracic bioimpedance is not covered for "the management of all forms of hypertension (with the exception of drug-resistant hypertension…)." Further, Medicare specified that:

"[Contractors] have discretion to determine whether the use of TEB [thoracic bioimpedance] for the management of drug-resistant hypertension is reasonable and necessary. Drug resistant hypertension is defined as failure to achieve goal blood pressure in patients who are adhering to full doses of an appropriate 3-drug regimen that includes a diuretic."

There is no Medicare national coverage determination on implantable direct pressure monitoring, inert gas rebreathing, and arterial pressure with Valsalva.

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

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT04223271^a</td>
<td>Heart Failure Event Advance Detection Trial (HEADstart)</td>
<td>165</td>
<td>Apr 2021 (unknown)</td>
</tr>
<tr>
<td>NCT03476590</td>
<td>A New Model of Medical Care With Use of Modern Methods of Non-invasive Clinical Assessment and Telemedicine in Patients With Heart Failure (AMULET)</td>
<td>605</td>
<td>Jun 2021 (ongoing)</td>
</tr>
<tr>
<td>NCT02954341^a</td>
<td>CardioMEMS HF System OUS Post Market Study</td>
<td>300800</td>
<td>Dec 2023 (ongoing)</td>
</tr>
<tr>
<td>NCT03387813^a</td>
<td>Hemodynamic-GUIDEd Management of Heart Failure (GUIDE-HF)</td>
<td>3600</td>
<td>Feb 2024 (recruiting)</td>
</tr>
<tr>
<td>NCT04398654</td>
<td>Pulmonary Artery Sensor System Pressure Monitoring to Improve Heart Failure (HF) Outcomes (PASSPORT-HF)</td>
<td>554</td>
<td>May 2024 (recruiting)</td>
</tr>
<tr>
<td>NCT04441203</td>
<td>Patient SELF-management With Hemodynamic Monitoring: Virtual Heart Failure Clinic and Outcomes (SELFle-HF)</td>
<td>150</td>
<td>Jun 2024 (not yet recruiting)</td>
</tr>
<tr>
<td>NCT03020043</td>
<td>CardioMEMS Registry of the Frankfurt Heart Failure Center</td>
<td>500</td>
<td>Dec 2025 (recruiting)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.
^a Denotes industry-sponsored or cosponsored trial.
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Policy History
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12/07/2004 Medical Director review

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12/14/2004  Medical Policy Committee review
01/31/2005  Managed Care Advisory Council approval
07/07/2006  Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged
02/07/2007  Medical Director review
02/04/2009  Medical Director review
02/19/2009  Medical Policy Committee approval. No change to coverage eligibility.
02/04/2010  Medical Policy Committee approval
02/17/2010  Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/03/2011  Medical Policy Committee review
03/16/2011  Medical Policy Implementation Committee approval. This policy replaces medical policies 00116 and 00151 to create a single policy addressing cardiac hemodynamic monitoring for the management of heart failure in the outpatient setting.
03/01/2012  Medical Policy Committee review
03/21/2012  Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/16/2012  Policy Retired
06/02/2016  Medical Policy Committee review
06/20/2016  Medical Policy Implementation Committee approval. Policy returned to active status.
01/01/2017  Coding update: Removing ICD-9 Diagnosis Codes
06/01/2017  Medical Policy Committee review
06/21/2017  Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/05/2018  Medical Policy Committee review
07/11/2018  Medical Policy Implementation Committee approval. Changed “arterial pressure/Valsalva” to “arterial pressure during the Valsalva maneuver”. Coverage eligibility unchanged.
01/01/2019  Coding update
07/03/2019  Medical Policy Committee review
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07/18/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/10/2019 Coding update
06/10/2020 Coding update
07/02/2020 Medical Policy Committee review
07/08/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/01/2021 Medical Policy Committee review
07/14/2021 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/01/2021 Coding update
06/24/2022 Coding update
08/04/2022 Medical Policy Committee review
08/10/2022 Medical Policy Implementation Committee approval. Rearranged the order of considerations in the investigational statement. Coverage eligibility unchanged.
07/06/2023 Medical Policy Committee review
07/12/2023 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 07/2024

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

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>33289, 93264, 93701, 93799</td>
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<tr>
<td>HCPCS</td>
<td>C2624</td>
</tr>
<tr>
<td>ICD-10 Diagnosis</td>
<td>All related Diagnoses</td>
</tr>
</tbody>
</table>

*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.
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**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.