Electrical Bioimpedance for Cardiac Output Measurement (for Louisiana Only)

Policy Number: CS034LA.~~I~~J
Effective Date: ~~November 1, 2020~~**TBD**

➲ Instructions for Use

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Application

This Medical Policy only applies to the state of Louisiana.

Coverage Rationale

Electrical bioimpedance is unproven and not medically necessary for measuring cardiac output due to insufficient evidence of efficacy.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
93701	Bioimpedance-derived physiologic cardiovascular analysis

Description of Services

Measurement of cardiac output **(CO)** is used to evaluate global cardiac function. Changes in ~~cardiac output~~**CO** may be used to identify changes in hemodynamic status~~,~~ to confirm the need for or the efficacy of treatment and may be routinely monitored in critically ill individuals or perioperatively in high-risk individuals.

The most common, reasonably accurate measurement of ~~cardiac output~~**CO** is thermodilution catheterization (TDC). However, this is an invasive technique that requires placement of a catheter in the pulmonary artery and carries risks.

Transthoracic electric bioimpedance (TEB), also called impedance plethysmography or impedance cardiography (ICG), is a noninvasive method that has been evaluated in the measurement of ~~cardiac output.~~**CO.** This method involves applying a small electrical current through electrodes placed on the neck and sides of the chest. The pulsatile flow of blood causes fluctuations in the current, and the device calculates ~~cardiac output~~**CO** from the impedance waveform. TEB has been used as an alternative to invasive methods in the management of several heart-related conditions, including congestive heart failure (CHF), pacemaker calibration, and heart transplant.

Methods to estimate CO in a completely noninvasive manner include noninvasive pulse wave analysis (using a finger cuff method or automated radial artery applanation tonometry), thoracic electrical bioimpedance and bioreactance, pulse wave transit time, and partial carbon dioxide rebreathing. All these technologies have been evaluated in cardiothoracic surgery patients, but the validation studies describing the measurement performance in comparison with invasive reference methods have shown inconsistent and, in part, contradictory results. In addition, all technologies have major limitations with regard to the applicability during routine clinical care in the operating room or the intensive care unit. Therefore, the methods for noninvasive CO estimation described still require technological improvements with regard to measurement performance and clinical applicability before they can be recommended for routine perioperative hemodynamic management of cardiothoracic surgery patients outside of studies (Saugel et al. 2019).

Clinical Evidence

There is insufficient quality evidence in the clinical literature demonstrating the long-term efficacy and clinical utility of electrical bioimpedance compared to standard diagnostic measures for cardiac output (CO). Further well-designed studies are necessary.

Lu et al. (2021) conduced a single-center, pragmatic, randomized controlled trial (RCT) to assess the efficacy of an impedance cardiography (ICG) guided treatment strategy on improving blood pressure (BP) control. The study included 102 adults with a mean age of 54 +14 years who were seen in an outpatient hypertension clinic. The patients were randomized 1:1 to either a hemodynamic group (n=51) or to a standard care group (n=51). All participants had ICG performed at each visit, but the ICG findings were not revealed in the standard arm to physicians or patients. There were no statistically significant differences in the number and class of anti-hypertensive medications, patient demographic, clinical, BP or ICG variables at baseline between the hemodynamic group and the control group. Therapy was initiated in all patients after randomization and the physicians in both groups were encouraged to prescribe medications consistent with the standard of care for their population. The ICG data was provided to the physicians for patients in the hemodynamic group and a patient centered treatment program was created

based on each patient's hemodynamic profile. All patients were required to return to the clinic for a follow-up visit between 4 and 12 weeks after the baseline visit for their BP to be measured. The primary study end points were changes in systolic BP (SBP) and diastolic BP (DBP) from baseline while secondary end points include achievement of BP goal of <140/90mm Hg and changes in SBP and DBP by baseline BP, age, sex and BMI. The authors reported that both SBP and DBP reductions were significantly greater in the hemodynamic group from baseline to follow-up visit when compared to the standard care group (SBP reductions: 19.9±10.7 vs 12.0±11.8mm Hg, p<0.001; DBP reduction: 11.3±6.2 vs 4.9±9.9mm Hg, p<0.001) and that the final BP was lower in the hemodynamic group compared with the standard care group as was the proportion of patients who achieved BP goal of <140/90mm Hg. The authors concluded that their study showed that an ICG-guided treatment strategy was more effective in reducing BP than standard therapy. They noted that the study was limited by the small number of participants and relatively short follow-up, the single-center design, the lack of monitoring of medication compliance and the lack of assessing for any behavior or lifestyle modification in the patients. The authors recommended further large-scale studies to provide more definitive evidence.

A prospective, single-center, observational study by Costa et al. (2021) was conducted using bioelectrical impedance vector analysis (BIVA) to assess variations in hydration status after cardiac surgery related to the use of extracorporeal circulation. The study included 76 patients with a median age of 60 years and 81.6% male who underwent elective or urgent cardiac surgery. Most of the study participants (n=47) underwent coronary artery bypass grafting (CABG) electively (n=46) and with extracorporeal circulation used in 19 cases. The authors noted that the BIVA estimation of fluid change over time showed a mild increase in total body water immediately after surgery through the next 24 hours of postoperative care. They noted that, in CABG patients, the fluid accumulation after the procedure was attributable to the use of extracorporeal circulation. The authors noted that the study had several limitations including the variability in body size, the small number of participants and the lack of comparison of BIVA with other methods for assessing fluid status. The authors concluded that BIVA could be a useful method for monitoring fluid status in the setting of goal directed therapy to maintain euvolemia in cardiac surgical patients and that future studies should be done that test whether clinical interventions guided by the data gathered during BIVA monitoring would lead to improved outcomes.

Sanders et al. (2020) conducted a systematic review and meta analysis of studies comparing ~~cardiac output~~**CO** measurement by electrical cardiometry and a reference method. Pooled bias, limits of agreement (LoA) and mean percentage error (MPE) were calculated using a random-effects model. A pooled MPE of less than 30% was considered clinically acceptable. A total of 13 studies in adults (620 patients) and 11 studies in pediatrics (603 patients) were included. For adults, pooled bias was 0.03 L min-1 [95% CI −0.23; 0.29], LoA −2.78 to 2.84 L min-1 and MPE 48.0%. For pediatrics, pooled bias was −0.02 L min-1 [95% CI −0.09; 0.05], LoA −1.22 to 1.18 L min-1 and MPE 42.0%. Inter-study heterogeneity was high for both adults ($I^2 = 93\%$, $p < 0.0001$) and pediatrics ($I^2 = 86\%$, $p < 0.0001$). Despite the low bias for both adults and pediatrics, the authors concluded that the MPE was not clinically acceptable. Limitations of the study included population selection bias, assortment of outcome measures for LoA and MPE, and reference method differences. The authors concluded that cardiometry cannot replace thermodilution and transthoracic echocardiography for the measurement of absolute ~~cardiac output~~**CO** values and that future research should explore it's clinical use and indications.

~~Heart Disease or Heart Failure~~

~~In a systematic review and meta-analysis, Joosten et al. (2017) evaluated the accuracy and precision of non-invasive cardiac output monitoring devices in perioperative medicine including non-invasive pulse contour analysis, thoracic electrical bioimpedance/bioreactance, and CO2 rebreathing. A total of 37 studies (1543 patients) were included. Mean CO of both methods was 4.78 litres min-1. Bias was presented as the reference method minus the tested methods in 15 studies. Only six studies assessed the random error (repeatability) of the tested device. The overall random-effects pooled bias (limits of agreement) and the percentage error were -0,13 [-2.38, 2.12] litres min-1 and 47%, respectively. Inter-study sensitivity heterogeneity was high (I2=83%, P<0.001). The colleagues concluded that with a wide percentage error, completely non-invasive CO devices are not interchangeable with bolus thermodilution. Additional studies are warranted to demonstrate the role of non-invasive cardiac output monitoring devices in improving the quality of care.~~

~~In a prospective longitudinal cohort trial, Andreas et al. (2016) evaluated the use of bioimpedance cardiography in patients with pregnancy-associated cardiovascular pathologies to determine if it would provide additional outcome-relevant information and serve as a predictive instrument for pregnancy-associated diseases. Cardiac output and concomitant hemodynamic data were recorded bioimpedance cardiography in 242 pregnant women from the 11th-13th week of gestation every 5th week as well as at two occasions post-partum. Cardiovascular adaptation during pregnancy is characterized by distinct patterns which may be altered in women at risk for preeclampsia or reduced birthweight. In the authors' opinion, the assessment of cardiac parameters by bioimpedance cardiography is an option to measure cardiac output in pregnant women without additional risks. Additional studies are needed in this patient population to confirm the applicable use of bioimpedance cardiography. Limitations included low number of preeclampsia patients with a new onset of hypertension despite the high number of participating women and lack of analysis of several participants due to a secondary diagnosis of gestational diabetes, thyroid disease and twin pregnancy which impacted measurements.~~

~~In a RCT, Taylor et al. (2011) compared measures of cardiac output using either continuous electrical bioimpedance cardiography (Physioflow, Neumedx) or direct Fick measurement in children with congenital heart disease who were undergoing diagnostic cardiac catheterization (n=65). Results generally showed poor to very poor correlation between the two measurements. Study authors concluded that electrical bioimpedance cardiography was unreliable in children with congenital heart disease.~~

~~Kamath et al. (2009) conducted a blinded RCT evaluating a subgroup of patients with advanced heart failure (n=170) derived from the Evaluation Study of Congestive Heart Failure and Pulmonary Artery Catheterization Effectiveness (ESCAPE) trial. Of 170 patients, 82 underwent right heart catheterization. Impedance cardiography was compared with invasively measured hemodynamics using simple correlation analysis and overall impedance cardiography hemodynamic profiles. The study authors also determined whether impedance cardiography measurements were associated with subsequent death or hospitalization within six months of the end of the study. Study results demonstrated that there was modest correlation between impedance cardiography and invasively measured cardiac output. However, thoracic fluid content measured by impedance cardiography was not a reliable measure of pulmonary capillary wedge pressure. There was also poor agreement between impedance cardiography and invasively measured hemodynamic profiles. Results of sensitivity, specificity, positive predictive value, and negative predictive were mostly poor. No individual variable alone or in combination was associated with~~

~~outcome. Study authors concluded that impedance cardiography did not have prognostic utility in hospitalized patients with advanced heart failure.~~

~~Massari et al. (2019) conducted a retrospective study to verify the accuracy of bioelectrical impedance vector analysis (BIVA) in predicting the LOS in AHF patients. A total of 706 patients (367 males; mean age: 78 ± 10 y) who had been admitted to hospital with an AHF event were enrolled. All underwent anthropometric and clinical evaluation, baseline transthoracic echocardiography, and biochemical and BIVA evaluations. The comparison among the clinical characteristics of congestion, LOS, and hyperhydration status revealed that the higher the hydration status, the longer the LOS (from 7.36 d [interquartile range: 7.34–7.39 d] in normohydrated patients to 9.04 d [interquartile range: 8.85– 9.19 d] in severe hyperhydrated patients; P < 0.05). At univariate analysis, brain natriuretic peptide, blood urea nitrogen, New York Heart Association class, hemoglobin, hydration index, and peripheral edema all had a statistically significant influence on LOS. At multivariate analysis, only brain natriuretic peptide (P < 0.0001), blood urea nitrogen (P = 0.011), and hydration index (P < 0.0001) were significantly associated to LOS. The authors concluded that Congestion evaluated by BIVA is an independent predictor of length of total hospital stay in HF patients with acute decompensation. The quick and reliable detection of congestion permits the administration of target therapy for AHF, thus reducing LOS and treatment costs.~~

~~Cotter et al. (2004) published a prospective double-blind comparison of a noninvasive, continuous whole-body bioimpedance system (NICO system) and thermodilution cardiac output determinations in 122 cardiac patients in three different groups: during cardiac catheterization (n=40); before, during, and after coronary bypass surgery (n=51); and while being treated for acute congestive heart failure (CHF) exacerbation (n=31). CO was measured at one time point in patients undergoing coronary catheterization; before, during, and after bypass surgery in patients undergoing coronary bypass surgery; and before and during vasodilator treatment in patients treated for acute heart failure. The overall correlation between the whole body bioimpedance system cardiac index and the thermodilution cardiac index was r=0.886. The authors concluded that whole-body bioimpedance measurements with the NICO system are accurate in a wide range of cardiac clinical situations.~~

~~Leslie et al. (2004) compared thoracic bioimpedance with thermodilution in patients with stable chronic heart failure. A total of 282 paired measurements of cardiac output from 11 patients were evaluated. The study showed a correlation between thoracic bioimpedance and thermodilution but also demonstrated a poor level of agreement. Thoracic bioimpedance underestimated cardiac output compared with thermodilution, and this was greater with higher cardiac outputs. The investigators indicated that the study did not support the use of thoracic bioimpedance in its current form as an alternative to thermodilution in patients with stable chronic heart failure.~~

~~Following coronary artery bypass grafting, Kaukinen, et al. (2003) prospectively compared the values obtained by continuous cardiac output monitoring with whole-body impedance cardiography with values measured using the bolus and continuous thermodilution methods (n=20) after coronary artery bypass grafting. The authors found that agreement between whole-body impedance cardiography and bolus thermodilution was slightly inferior to that between the bolus and continuous thermodilution methods.~~

~~The European Society of Cardiology (ESC) guidelines for the diagnosis and treatment of acute and chronic heart failure do not specifically address electrical bioimpedance as a technique for diagnosing heart failure. The guideline states that imaging and other~~

~~studies should only be performed when they have a meaningful clinical consequence (Ponikowski et al., 2016).~~

~~Hypertension~~

A (2019[FDL1]) ECRI Institute product brief on the ClearSight noninvasive hemodynamic monitoring system reviewed one systematic review with meta-analysis, seven clinical studies, and abstracts of 6 clinical studies. The studies reported on 1,220 patients with search dates of January 1, 2014, through November 19, 2019. One randomized controlled trial (RCT) found no benefit from ClearSight monitoring in improving patient outcomes compared with invasive monitoring in patients undergoing abdominal surgery. Another RCT reported ClearSight reduced intraoperative hypotension rate in surgery patients when compared with oscillometric BP monitoring, and an RCT found ClearSight reduced intraoperative hypotension rate, nausea, and vomiting during cesarean delivery under spinal anesthesia. Other studies focused on CO measurement comparability, CO/cardiac index (CI) measurement comparability, and BP comparability. Some limitations noted by the authors were that the cohort studies had single-center focus, small patient enrollment, and between-study variations for acceptable thresholds. Additionally, most of the cohort studies may have bias in result interpretation because the clinicians were not blinded to the measurements of the reference test or ClearSight. Only one RCT reported patient-oriented outcomes (mortality, quality of life) or hospital-oriented outcomes. The report states large double-blind comparative cohort studies are needed to confirm ClearSight's diagnostic accuracy. Additionally, double-blind RCTs comparing ClearSight with standard of care in specific settings and patient populations were recommended. The report concluded that for measuring CO, the evidence suggests the ClearSight system is not equivalent and cannot replace standard invasive procedures.

Kurpaska et al. (2019) conducted a study to evaluate the clinical value of impedance cardiography (ICG) in the hemodynamic assessment of patients with arterial hypertension (AH) during exercise, particularly the differences between subgroups based on sex and the presence of dyspnea. Ninety-eight patients with AH (52 women; 54.5±8.2 years of age) were evaluated for levels of N-terminal pro-B-type brain natriuretic peptide (NT-proBNP), exercise capacity (cardiopulmonary exercise testing (CPET) and the 6-min walk test (6MWT)), and exercise ICG. Patients with AH were stratified into the following four subgroups: males without dyspnea (MnD, n=38); males with dyspnea (MD, n=8); females without dyspnea (FnD, n=27); and females with dyspnea (FD, n=25). In comparison with the MnD subgroup, the FnD subgroup demonstrated significantly higher NT-proBNP levels; lower exercise capacity (shorter 6MWT distance, lower peak oxygen uptake (VO2), lower O2 pulse); higher peak stroke volume index (SVI); and higher SVI at the anaerobic threshold (AT). In comparison with the other subgroups, the FD subgroup walked a shorter distance during the 6MWT distance; had a steeper **ventilation/carbon dioxide production (**VE/VCO2**)** slope; had lower values of peak stroke volume (SV) and peak ~~cardiac output (~~CO~~)~~; and had a smaller change in CO from rest to peak. However, no other differences were identified (NT-proBNP, left ventricular diastolic dysfunction, or CPET parameters). The authors concluded that exercise ~~impedance cardiography~~**ICG** revealed an impaired hemodynamic response to exercise in hypertensive females with dyspnea. In patients with unexplained exercise intolerance, ~~impedance cardiography~~**ICG** may complement traditional exercise tests. These findings should be confirmed with larger patient populations.

In a 2018 prospective, cross-sectional study Panagiotou et al compared ~~impedance cardiography (~~ICG~~)~~ against ~~thermodilution (~~TD~~)~~ and cardiac magnetic resonance (CMR) in the measurement of ~~cardiac output~~**CO** in patients under investigation for pulmonary arterial hypertension (PAH)**,** ~~.~~ ~~C~~**c**ardiography (COICG) technology (PhysioFlow®) with (i) contemporaneous TD measurements (COTD) at rest and steady-state exercise during right

heart catheterization and (ii) CMR measurements (COCMR) at rest obtained within 72 hr. The results showed Paired COICG and COTD measurements were obtained in 25 subjects at rest and 16 subjects at exercise. COCMR measurements were obtained in 16 subjects at rest. There was unsatisfactory correlation and agreement between COICG and COTD at rest (r=0·42, P=0·035; bias: 1·21 l min-1 , 95% CI: -2·33 to 4·75 l min-1) and exercise (r=.65, P=.007; bias: 1·41 l min-1; 95% CI: -3·99 to 6·81 l min-1) and in the change in COICG and COTD from rest to exercise (r=0·53, P=0·033; bias: 0·76 l min-1 , 95% CI: -3·74 to 5·26 l min-1). There was also a lack of correlation and unsatisfactory agreement between resting COICG and COCMR (r=0·38, P=0·1; bias: 1·40 l min-1, 95% CI: -2·48 to 5·28 l min-1). In contrast, there was close correlation and agreement between resting COTD and COCMR (r=0·87, P<0·001; bias: -0·16 l min-1, 95% CI: -1·97 to 1·65). The authors concluded that in a representative population of patients under investigation for PAH, ICG showed insufficient qualitative and quantitative value in the measurement of resting and exercise ~~cardiac output~~**CO** when compared with TD and CMR.

In a systematic review and meta-analysis, Joosten et al. (2017) evaluated the accuracy and precision of non-invasive CO monitoring devices in perioperative medicine including non-invasive pulse contour analysis, thoracic electrical bioimpedance/bioreactance, and CO2 rebreathing. A total of 37 studies (1543 patients) were included. Mean CO of both methods was 4.78 liters min−1. Bias was presented as the reference method minus the tested methods in 15 studies. Only six studies assessed the random error (repeatability) of the tested device. The overall random-effects pooled bias (limits of agreement) and the percentage error were −0,13 [−2.38 , 2.12] liters min−1 and 47%, respectively. Inter-study sensitivity heterogeneity was high (I2=83%, P<0.001). The authors concluded that with a wide percentage error, completely non-invasive CO devices are not interchangeable with bolus TD. Additional studies are warranted to demonstrate the role of non-invasive CO monitoring devices in improving the quality of care.

In a prospective longitudinal case series, Andreas et al. (2016) evaluated the use of bioimpedance cardiography in patients with pregnancy-associated cardiovascular pathologies to determine if it would provide additional outcome-relevant information and serve as a predictive instrument for pregnancy-associated diseases. Cardiac output and concomitant hemodynamic data were recorded bioimpedance cardiography in 242 pregnant women from the 11th–13th week of gestation every 5th week as well as at two occasions post-partum. Cardiovascular adaptation during pregnancy is characterized by distinct patterns which may be altered in women at risk for preeclampsia or reduced birthweight. In the authors' opinion, the assessment of cardiac parameters by bioimpedance cardiography is an option to measure CO in pregnant women without additional risks. Additional studies are needed in this patient population to confirm the applicable use of bioimpedance cardiography. Limitations included low number of patients with preeclampsia and new onset of hypertension despite the high number of participating women and lack of analysis of several participants due to a secondary diagnosis of gestational diabetes, thyroid disease and twin pregnancy which impacted measurements.

Krzesinski et al. (2013) conducted a RCT of 128 patients (average age 42.9± 11.1 years) with AH to study the effectiveness of antihypertensive therapy based on hemodynamic assessment by ICG. The patients were randomized into groups: (1) empiric, and (2) hemodynamic, in which treatment choice considered ICG results. After 12 weeks, evaluation of treatment effects was performed and included office blood pressure (BP) measurement and ambulatory BP monitoring. The authors found that all final BP values were lower in the hemodynamic group, significantly for office systolic BP (empiric vs. hemodynamic: 136.1 vs. 131.6 mmHg; p=0.036) and diastolic BP (87.0 vs. 83.7 mmHg; p=0.013), as well as night-time systolic BP (121.3 vs. 117.2 mmHg; p=0.023) and diastolic BP (71.9 vs. 68.4

mmHg; p=0.007). Therapy based on ICG significantly increased the reduction in office systolic BP (11.0 vs. 17.3 mmHg; p=0.008) and diastolic BP (7.7 vs. 12.2 mmHg; p=0.0008); as well as 24-h mean systolic BP (9.8 vs. 14.2 mmHg; p=0.026), daytime systolic BP (10.5 vs. 14.8 mmHg; p=0.040), and night-time systolic BP (7.7 vs. 12.2 mmHg; p=0.032). The authors concluded antihypertensive treatment based on ICG can significantly increase BP reduction in hypertensive patients. The authors note that the obtained results should be applied with caution in women and in patients with significant chronic diseases as both were minorities in this study. This study reports the lack of long-term patient health outcomes of ICG monitoring as a limitation. Additionally, incomplete masking of intervention assignment and a relatively high loss to follow-up further limit the findings of this study.

In a prospective test validation study, Taylor et al. (2011) compared measures of CO using either continuous electrical bioimpedance cardiography (Physioflow, Neumedx) or direct Fick measurement in children with congenital heart disease who were undergoing diagnostic cardiac catheterization (n=65). Results generally showed poor to very poor correlation between the two measurements. Study authors concluded that electrical bioimpedance cardiography was unreliable in children with congenital heart disease.

Ferrario et al. (2010) conducted a meta-analysis of five studies (n=759), including two RCTs (n=268) and three nonrandomized controlled trials (n=491) evaluating ICG to guide treatment decisions in hypertensive patients. The combined odds ratio (OR) for the two RCTs was 2.41 (95% CI, 1.44-4.05; P=0.0008) favoring treatment monitoring with ICG. An OR of 2.41 indicates that ICG was two times more likely to achieve a goal BP reading than if the technology was not used. More than 65% of patients across all five studies achieved a BP reading of <140/90 mmHg. Study authors concluded that there is clinical utility in using ICG as an adjunct to treatment decisions for hypertensive patients. The authors note the major limitation of this study is that the meta-analysis was based on only two RCTs and a small subject size of less than 300 individuals.

Kamath et al. (2009) conducted a test validation study evaluating a subgroup of patients with advanced heart failure (n=170) derived from the Evaluation Study of Congestive Heart Failure and Pulmonary Artery Catheterization Effectiveness (ESCAPE) trial. Of 170 patients, 82 underwent right heart catheterization. Impedance cardiography was compared with invasively measured hemodynamics using simple correlation analysis and overall ICG hemodynamic profiles. The study authors also determined whether ICG measurements were associated with subsequent death or hospitalization within six months of the end of the study. Study results demonstrated that there was modest correlation between ICG and invasively measured CO. However, thoracic fluid content measured by ICG was not a reliable measure of pulmonary capillary wedge pressure. There was also poor agreement between ICG and invasively measured hemodynamic profiles. Results of sensitivity, specificity, positive predictive value, and negative predictive were mostly poor. No individual variable alone or in combination was associated with outcome. Study authors concluded that ICG did not have prognostic utility in hospitalized patients with advanced heart failure.

In a nonrandomized controlled trial, Peacock et al. (2006) evaluated the impact of ICG in 89 patients with dyspnea. Physicians documented diagnosis and treatment plans before and after viewing ICG data. Impedance cardiography data changed the working diagnosis in 12 (13%) patients and medications administered in 35 (39%) patients. For diagnoses categorized as cardiac or noncardiac, the diagnosis obtained with ICG was identical to the diagnosis obtained using the usual means in 67% of patients. The investigators concluded that ICG data probably resulted in changes in diagnosis and therapeutic

planning during the evaluation of dyspneic patients. However, the accuracy of a diagnosis led by ICG diagnosis needs to be substantiated by a standardized diagnostic approach. The study is further limited by lack of randomization.

Cotter et al. (2004) published a prospective double-blind comparison of a noninvasive, continuous whole-body bioimpedance system (NICO system) and TD cardiac output determinations in 122 cardiac patients in three different groups: during cardiac catheterization (n = 40); before, during, and after coronary bypass surgery (n = 51); and while being treated for acute congestive heart failure (CHF) exacerbation (n = 31). Cardiac output was measured at one time point in patients undergoing coronary catheterization; before, during, and after bypass surgery in patients undergoing coronary bypass surgery; and before and during vasodilator treatment in patients treated for acute heart failure. The overall correlation between the whole-body bioimpedance system cardiac index and the TD cardiac index was r=0.886. The authors concluded that whole-body bioimpedance measurements with the NICO system are accurate in rapid, noninvasive measurement and the follow-up of CO in a wide range of cardiac clinical situations.

Leslie et al. (2004) compared thoracic bioimpedance with TD in patients with stable chronic heart failure. A total of 282 paired measurements of CO from 11 patients were evaluated. The study showed a correlation between thoracic bioimpedance and TD but also demonstrated a poor level of agreement. Thoracic bioimpedance underestimated CO compared with TD, and this was greater with higher COs. The investigators indicated that the study did not support the use of thoracic bioimpedance in its current form as an alternative to TD in patients with stable chronic heart failure.

Following coronary artery bypass grafting, Kaukinen, et al. (2003) prospectively compared the values obtained by continuous CO monitoring with whole-body ICG with values measured using the bolus and continuous TD methods (n=20) after coronary artery bypass grafting. The authors found that agreement between whole-body ICG and bolus TD was slightly inferior to that between the bolus and continuous TD methods.

The Agency for Healthcare Research and Quality (AHRQ) published a technology assessment on thoracic electrical bioimpedance. The technology assessment was commissioned by the Centers for Medicare and Medicaid Services (CMS) for use in coverage policy revisions. The assessment concluded that there was insufficient evidence for meaningful conclusions on the accuracy or clinical usefulness of electrical bioimpedance. The data provided in the available studies suggested that electrical bioimpedance measurements generally correlated similarly with measurements obtained by other testing modalities. Limitations were noted in most reported studies with a scarcity of articles reporting patient outcomes. CMS issued a decision memorandum announcing their intent to refine their national coverage policy regarding TEB for cardiac-related indications. Based on the review of evidence as a whole, CMS decided to continue coverage for all previously covered indications with only minor wording modifications except for general coverage in persons with suspected or known cardiovascular disease due to the paucity of studies evaluating the impact of TEB in these persons. CMS found no clinical evidence to make any changes in the previous non-coverage indications (Jordan, 2002).

Clinical Practice Guidelines

American College of Cardiology (ACC)/American Heart Association (AHA)/Heart Failure Society of American (HFSA)

The updated ACC/AHA/HFSA guideline on the management of heart failure in adults does not address electrical bioimpedance (Writing Committee Members, 2022).

European Society of Cardiology (ESC)

The updated ESC guidelines for the diagnosis and treatment of acute and chronic heart failure state that whether wearable technologies for monitoring heart rate and rhythm (such as bio-impedance) offer additional benefits to conventional home telemonitoring is uncertain (McDonagh, 2021).

~~Ferrario et al. (2010) conducted a meta-analysis of five studies (n=759), including two RCTs (n=268) and three nonrandomized controlled trials (n=491) evaluating impedance cardiography to guide treatment decisions in hypertensive patients. The combined odds ratio (OR) for the two RCTs was 2.41 (95% CI, 1.44-4.05; P=0.0008) favoring treatment monitoring with impedance cardiography. An OR of 2.41 indicates that impedance cardiography was two times more likely to achieve a goal blood pressure reading than if the technology was not used. More than 65% of patients across all 5 studies achieved a blood pressure reading of <140/90 mmHg. Study authors concluded that there is clinical utility in using impedance cardiography as an adjunct to treatment decisions for hypertensive patients.~~

~~Dyspnea~~

~~Génot et al. (2015) conducted a prospective analysis (n=77) of bioimpedance vector analysis (BIVA) for the diagnosis of acute heart failure (AHF) in patients presenting with acute dyspnea to the emergency department (ED). Four parameters were assessed: resistance (R), reactance (Ra), total body water (TBW), and extracellular body water (EBW). Brain natriuretic peptide (BNP) measures and cardiac ultrasound studies were performed in all patients at admission. Patients were classified into AHF and non-AHF groups retrospectively by cardiologists. Of the 4 BIVA parameters, Ra was significantly lower in the AHF compared to non-AHF group (32.7±14.3 vs 45.4±19.7; P<.001). Brain natriuretic peptide levels were significantly higher in the AHF group (1050.3±989 vs 148.7±181.1ng/L; P<.001). Reactance levels were significantly correlated to BNP levels (r=-0.5; P<.001). Patients with different mitral valve Doppler profiles (E/e'≤8, E/e' ≥9 and <15, and E/e'≥15) had significant differences in Ra values (47.9±19.9, 34.7±19.4, and 31.2±11.7, respectively; P=.003). Overall, the sensitivity of BIVA for AHF diagnosis with a Ra cutoff at 39Ω was 67% with a specificity of 76% and an area under the curve at 0.76. However, Ra did not significantly improve the area under the curve of BNP for the diagnosis of AHF (P=not significant).The authors concluded that in this patient population, BIVA was significantly related to the AHF status but did not improve the diagnostic performance for AHF in addition to BNP alone.~~

~~In a nonrandomized controlled trial, Peacock et al. (2006) evaluated the impact of impedance cardiography in 89 patients with dyspnea. Physicians documented diagnosis and treatment plans before and after viewing impedance cardiography data. Impedance cardiography data changed the working diagnosis in 12 (13%) patients and medications administered in 35 (39%) patients. For diagnoses categorized as cardiac or noncardiac, the diagnosis obtained with impedance cardiography was identical to the diagnosis obtained using the usual means in 67% of patients. The investigators concluded that impedance cardiography data probably resulted in changes in diagnosis and therapeutic planning during the evaluation of dyspneic patients. However, the accuracy of a diagnosis led by impedance cardiography diagnosis needs to be substantiated by a standardized diagnostic approach.~~

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~~Professional Societies~~

~~*American College of Cardiology (ACC)/American Heart Association (AHA)/Heart Failure Society of America (HFSA)*~~

~~The updated ACC/AHA and HFSA guideline on the management of heart failure in adults does not address electrical bioimpedance (Yancy et al., 2017).~~

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

A number of devices for bioimpedance measurement of ~~cardiac output~~**CO** have been approved for marketing by the FDA as Class II devices. See the following website for more information (use product code DSB)**. Available at**: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed ~~July 8~~**June 7**, 202**2**~~0~~)

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Policy History/Revision Information

Date	Summary of Changes
TBD	Supporting Information • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version CS034LA.I

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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