



CIGNA MEDICAL COVERAGE POLICY

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Subject Inert Gas Rebreathing for Cardiac Output Measurement

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Hyperlink to Related Coverage Policies

Indirect Measurement of Left Ventricular End Diastolic Filling Pressure (LVEDP): VeriCor®
Thoracic Electrical Bioimpedance for the Measurement of Cardiac Output

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Coverage Policy

CIGNA does not cover inert gas rebreathing for any indication, including for the measurement of cardiac output, because it is considered experimental, investigational or unproven.

General Background

Cardiac output, defined as the volume of blood pumped by the left ventricle in one minute, is an important hemodynamic measure used to guide therapy for acutely ill hospitalized patients. Measurement of cardiac output using a thermodilution catheter is generally considered the gold standard is usually used as the reference method when evaluating other methods of measurement. This is an invasive procedure, however, requiring placement of a catheter in the pulmonary artery. When a cardiac output measurement is needed, a small amount of cold saline is injected through the catheter, and as the heart pumps warm blood in and cold saline out (thermodilution), the temperature as measured by a thermal probe rises back to baseline. The area under the thermodilution curve is proportional to cardiac output.

The use of PA catheters was widespread in the 1970s but has gradually declined due to debate about the impact on patient outcomes and the risks and benefits of this invasive monitoring technique. Doppler echocardiography is a noninvasive method of evaluating cardiac output, but results are not as precise, and the technique is user-dependent. Cardiac output may be measured by magnetic resonance imaging and nuclear imaging techniques, but cardiac output measurement is not the primary purpose of these tests. Inert gas rebreathing, also referred to as foreign gas rebreathing, has been proposed as a noninvasive method to

evaluate cardiac output. Inert gas rebreathing has been proposed primarily for monitoring of patients with heart failure, although it has also been proposed for use in patients with pulmonary hypertension, atrial fibrillation, and in conjunction with stress tests. Thoracic electrical bioimpedance has also been proposed as a noninvasive method to monitor cardiac output. (Refer to separate Coverage Policy: Thoracic Electrical Bioimpedance for the Measurement of Cardiac Output.)

With inert gas rebreathing, the patient breathes a gas mixture containing two inactive compounds, one being blood soluble and the other blood insoluble, in a closed rebreathing assembly. When the blood-soluble gas comes in contact with the blood in the lung capillaries it is dissolved and washed out by the blood perfusing the lungs. The pulmonary blood flow, or cardiac output, is considered proportional to the rate of washout of the blood-soluble compound, which is measured continuously by a gas analyzer. The blood-insoluble compound is used to determine the lung volume, which is part of the equation used to calculate cardiac output. Inert gases used in this procedure include acetylene, nitrous oxide, and carbon dioxide (Dong et al., 2005).

Inert gas rebreathing has been evaluated in several case series, but no well designed randomized controlled trials have been conducted to compare the safety and efficacy of this technique with established methods of cardiac output measurement. In addition, the role of periodic cardiac output measurement in the clinical management of patients with heart failure and other circulatory disorders has not been established. Most drugs used in the treatment of heart failure are prescribed based on their ability to improve symptoms or survival and not on their effect on hemodynamic variables. There is insufficient evidence in the published medical literature to demonstrate that periodic cardiac output measurement by any method results in improved patient outcomes. The clinical utility of inert gas rebreathing has not been established.

U.S. Food and Drug Administration (FDA)

The CO₂ SMO Plus! With NICO (Novamatrix Medical Systems, Inc., Wallingford, CT) received FDA approval through the 510(k) process as a Class II device on October 16, 1998. A modified device, the NICO with MARS, Model 7300 (Respironics Novamatrix, Inc., Wallingford CT) received 510(k) approval on October 7, 2003. According to the 510(k) summary, the NICO Model 7300 is a multiparameter monitor (e.g., monitoring spirometer, carbon dioxide monitor, pulse oximeter, and cardiac output monitor with partial rebreathing valve). It noninvasively calculates cardiac output using established physiological principles by the application and removal of a rebreathed volume in a patient's breathing circuit and the analysis of that response. Approved indications for use include cardiac output monitoring via the method of partial rebreathing in adult patients receiving mechanical ventilation during general anesthesia and in the intensive care unit.

The Innocor™ Non-invasive Cardiac Output Monitor (Innovision A/S, Chicago, IL) received FDA approval through the 510(k) process on March 2, 2006. According to the 510(k) indications for use, the Innocor device is indicated for the determination of a number of hemodynamic parameters. Cardiac output is the principal measured parameter. Utilizing inert gas rebreathing, Innocor measures the relative levels of two inhaled gases of differing blood solubility over approximately three to four respirations and calculates pulmonary blood flow. The summary states that, in the absence of significant intrapulmonary shunt, pulmonary blood flow is equal to cardiac output.

Literature Review

Saur et al. (2009) conducted a prospective case series to evaluate the accuracy and reproducibility of cardiac output measurements obtained by inert gas rebreathing using the Innocor device compared to cardiovascular magnetic resonance (CMR), considered by the authors to be the non-invasive gold standard (n=305). There was good correlation between the two methods, with an average deviation of 0.2 ± 1.0 liters per minute and good reproducibility, with a mean bias of 0.2 ± 0.5 liters per minute. Measurements using inhaled nitric oxide were less accurate in higher or lower cardiac output ranges, however. The authors stated that the inert gas rebreathing system yielded reliable measures under most circulatory conditions but exceeded the proposed error level. The authors concluded that the value of this testing method in the clinical setting (i.e., the diagnosis and treatment of cardiac disease) must be further investigated.

Lang et al. (2007) conducted a prospective case series to evaluate the practicality of using the Innocor system to measure CO and peak oxygen consumption (VO₂) during exercise in patients with heart failure. A total of 92 consecutive exercise tests were conducted in 88 patients. Patients performed a graded maximal bicycle exercise test using a mouthpiece connected to the Innocor breathing system. Expired gas analysis was performed continuously throughout the test. Measurement of metabolic and CO were successful in 86% of the

tests. Most measurement failures were caused by too short an interval between rebreathing test measurements. In two patients, metabolic measurements could not be interpreted. The authors stated that combined metabolic stress testing with inert gas rebreathing can be easily performed in patients with heart failure, and a moderately good linear correlation was observed between peak VO_2 and peak CO. The authors concluded that widespread clinical application of this technique, and its prognostic value in the evaluation of patients with heart failure, should be evaluated in a large study with longer follow-up of clinical events.

Botero et al. (2004) conducted a prospective observational study (n=68) to compare the agreement among cardiac output measurements obtained with the NICO noninvasive cardiac output monitor, bolus thermodilution, and continuous thermodilution with transit-time flowmetry of the ascending aorta using an ultrasonic flow probe before and after cardiopulmonary bypass (CPB). The authors reported that before initiation of CPB, the accuracy for all three techniques was similar. After separation from CPB, there was a tendency for NICO to underestimate cardiac output and for the other methods to overestimate it. The authors concluded that NICO offers an alternative to invasive cardiac output measurement.

A prospective observational study conducted by Levy et al. (2004) evaluated the accuracy of noninvasive cardiac output measurement using partial rebreathing using NICO compared to measurement obtained by thermodilution. A total of 37 pediatric patients between the ages of 16 months and 12 years were included in the study. The differences between thermodilution and NICO measurements was greatest in children with a body surface area of $< 0.6\text{m}^2$ ventilated with tidal volumes of < 300 ml. The authors concluded that noninvasive measurement using partial rebreathing may provide clinically acceptable assessment of cardiac output in hemodynamically stable children with a body surface area (BSA) of $> 0.6\text{m}^2$ ventilated with tidal volumes of > 300 ml.

Hoepfer et al. (1998) conducted a small prospective case series to determine whether the thermodilution technique is reliable in patients with pulmonary hypertension, especially in the presence of severe tricuspid regurgitation and low cardiac output. The study was also designed to determine the utility of the acetylene rebreathing technique as a tool for noninvasive measurement of cardiac output in patients with pulmonary hypertension. A total of 105 cardiac output measurements in 25 patients were obtained using the thermodilution method, Fick method and acetylene rebreathing. The authors reported acceptable overall agreement of thermodilution and acetylene rebreathing with the direct Fick method, stating that in most cases the accuracy of both techniques is acceptable in patients with pulmonary hypertension, regardless of the presence of low cardiac output or tricuspid regurgitation. They concluded that acetylene rebreathing cannot fully replace thermodilution because other variables obtained during catheter testing such as right atrial pressure, pulmonary artery pressure, pulmonary capillary wedge pressure and blood gases are required for a complete assessment. However, the technique could serve as a complementary diagnostic tool for noninvasive follow-up of patients with pulmonary hypertension and assessment of changes in cardiac output after initiation of a new treatment.

Professional Societies/Organizations

Inert gas rebreathing is not mentioned in the American College of Cardiology (ACC) / American Heart Association (AHA) 2005 Guideline Update for the Diagnosis and Management of Heart Failure in the Adult. The authors state that there has been no established role for periodic invasive or noninvasive hemodynamic measurements in the management of heart failure. (Hunt, et al., 2005).

Summary

Inert gas rebreathing been proposed as a noninvasive method of cardiac output measurement. No well designed randomized controlled trials have been conducted to compare the efficacy of inert gas rebreathing to established methods of cardiac output measurement. Published studies include small numbers of patients, evaluate various devices and techniques, and focus on specific patient populations. There is insufficient evidence to demonstrate that the use of this technology results in improved patient outcomes. The clinical utility of inert gas rebreathing for cardiac output measurement has not been established.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Experimental/Investigational/Unproven/Not Covered:

CPT* Codes	Description
93799 [†]	Unlisted cardiovascular service or procedure
0104T	Inert gas rebreathing for cardiac output measurement during rest (Code deleted 01/01/2011)
0105T	Inert gas rebreathing for cardiac output measurement during exercise (Code deleted 01/01/2011)

[†]Experimental/Investigational/Unproven/Not Covered when used to report inert gas rebreathing.

ICD-9-CM Diagnosis Codes	Description
410.00-410.92	Acute myocardial infarction
413.0-413.9	Angina pectoris
414.00-414.07	Coronary atherosclerosis
414.2	Chronic total occlusion of coronary artery
414.8	Other specified forms of chronic ischemic heart disease
414.9	Chronic ischemic heart disease, unspecified
416.0	Primary pulmonary hypertension
416.8	Other chronic pulmonary heart disease
416.9	Chronic pulmonary heart disease, unspecified
427.31	Atrial fibrillation
427.32	Atrial flutter
428.0-428.9	Heart failure
V81.0	Screening for ischemic heart disease
V81.1	Screening for hypertension
V81.2	Screening for other and unspecified cardiovascular conditions
	All other codes

*Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	05/15/2008	0455	Inert Gas Rebreathing for Cardiac Output Measurement

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