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## 1.0 Description of the Procedure, Product, or Service

In the intensive care unit, hemodynamic monitoring using a pulmonary artery catheter (also referred to as right heart catheterization) is commonly used to provide diagnostic information and guide treatment decisions. Cardiac output is usually measured as part of such monitoring in recipients with heart failure, shock syndromes, and after coronary artery bypass graft surgery. Techniques include thermodilution, dye dilution, or the Fick method, although thermodilution is most often used. Thoracic electrical bioimpedance and inert gas re-breathing are two techniques that have been investigated for many years as a noninvasive alternative for measuring cardiac output. Bioimpedance is defined as the electrical resistance of tissue to the flow of current. For example, when small electrical signals are transmitted through the thorax, the pulsatile changes in volume and velocity of blood in the aorta, are inversely proportional to the stroke volume (cardiac output equals the stroke volume times heart rate). Inert gas re-breathing is based on the observation that the absorption and disappearance of a blood soluble gas is proportional to cardiac blood flow. The recipient is asked to breathe and re-breathe from a rubber bag filled with oxygen mixed with foreign gases; typically nitrous oxide and sulphur hexafluoride. The nitrous oxide is soluble in blood and is therefore absorbed during the blood's passage through the lungs at a rate that is proportional to the blood flow. The sulphur hexafluoride is insoluble in blood and therefore stays in the gas phase and is used to determine the lung volume from which the soluble gas is removed. These gases and carbon dioxide are measured continuously and simultaneously at the mouthpiece.

Development of a noninvasive measurement would permit more convenient and safer monitoring in the intensive care unit, and could be used for monitoring in other settings, such as the emergency room, on the general medical floor, or outpatient clinic. In the outpatient clinic thoracic bioimpedance has been investigated as a technique to optimize drug therapy in recipients with congestive heart failure. Echocardiography, transesophageal echocardiography (TEE), and Doppler ultrasound are other noninvasive methods for monitoring cardiac output.

The BioZTM is one of a number of electrical bioimpedance devices approved through the 510(k) process for marketing by the FDA that measures thoracic bioimpedance.

Innocor (Innovision, Denmark), an inert gas re-breathing device, received FDA approval through the 510(k) approval process in March 2006 as substantially equivalent to two predicate technologies, thermodilution and the direct Fick method. The Innocor device is approved for the determination of a number of hemodynamic parameters, principally cardiac output.

**Note:** This policy only addresses use of this technique in ambulatory care and outpatient settings.

## 2.0 Eligible Recipients

### 2.1 General Provisions

To be eligible, NCHC recipients must be enrolled on the date of service.

## 3.0 When the Procedure, Product, or Service Is Covered

### 3.1 General Criteria

NCHC covers procedures, products, and services related to this policy when they are medically necessary and

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available; **AND**
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

### 3.2 Specific Criteria

Not applicable. Refer to **Subsection 4.2**.

## 4.0 When the Procedure, Product, or Service Is Not Covered

### 4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental or investigational.

### 4.2 Specific Criteria

Thoracic bioimpedance and inert gas re-breathing in the outpatient setting are not covered. They are considered investigational. NC Health Choice does not provide coverage for investigational services.

### 4.3 Policy Guidelines

In 2001, the American College of Cardiology/American Heart Association issued guidelines for chronic heart failure. These guidelines indicate that bioimpedance "cannot be recommended at the present time because the accuracy of bioelectrical parameters has

not been defined in patients with chronic heart failure and it has not been shown to be more valuable than routine tests, including the physical examination. Moreover, it is not clear whether serial noninvasive hemodynamic measurements can be used to gauge the efficacy of treatment or to identify patients most likely to deteriorate symptomatically during long-term followup."

In 2002, the Agency for Healthcare Research and Quality (AHRQ) published a technology assessment of thoracic electrical bioimpedance (TEB), which concluded that limitations in available studies did not allow the agency to draw meaningful conclusions to determine whether the accuracy of TEB compared to other hemodynamic parameters.

In contrast to thoracic bioimpedance, there is relatively little published literature on inert gas re-breathing, although a literature search suggests that this technique has been used as a research tool for many years. A literature search did not identify any clinical articles exploring how inert gas re-breathing may be used to improve patient management in the outpatient setting.

## **5.0 Requirements for and Limitations on Coverage**

### **5.1 Prior Approval**

Prior approval is not applicable as non-invasive measurements of cardiac hemodynamics of the outpatient setting are not covered. Refer to **Subsection 4.2**.

## **6.0 Providers Eligible to Bill for the Procedure, Product, or Service**

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **AND**
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

## **7.0 Additional Requirements**

### **7.1 Compliance**

Providers must comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

## 8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 2010

Revision Information:

Date	Section Revised	Change
July 1, 2010		Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 "NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY."
September 30, 2011	Throughout	Policy Date of Termination

## Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

### A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

### B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

### C. Procedure Code(s)

Not applicable. Refer to **Subsection 4.2**.

### D. Modifiers

Providers are required to follow applicable modifier guidelines.

### E. Billing Units

The appropriate procedure code(s) used determines the billing unit(s).

### F. Place of Service

Outpatient Hospital and Office

### G. Co-payments

Co-payment(s) may apply to covered prescription drugs and services.

### H. Reimbursement

Providers must bill their usual and customary charges.