



HealthNet

National Medical Policy

Subject: Esophageal Doppler Cardiac Output Monitoring

Policy Number: NMP447

Effective Date*: February 2009

**This National Medical Policy is subject to the terms in the
IMPORTANT NOTICE
at the end of this document**

Current Policy Statement

Commercial Members

Health Net, Inc. considers Esophageal Doppler Monitoring (EDM), as an adjunct to central venous pressure monitoring (CVP) and conventional clinical assessment, medically necessary for the intra-operative evaluation of patients undergoing surgical procedures with an expected substantial blood loss or fluid shifts requiring fluid replacement.

Health Net, Inc. considers Esophageal Doppler Monitoring investigational and therefore not medically necessary for the optimization of intravenous fluid replacement in all other instances (e.g., ICU, PACU, ER) due to lack of evidence in the peer review literature demonstrating improved patient outcomes as compared to currently used methods for monitoring.

Medicare Members

Health Net Inc. considers Esophageal Doppler Monitoring (EDM) a nationally covered indication for monitoring of cardiac output for ventilated patients in the ICU and operative patients with a need for intra-operative fluid optimization.

Abbreviations

EDM	Esophageal Doppler Monitor
CVP	Central Venous pressure
CO	Cardiac Output
PAC	Pulmonary Artery Catheter
TEE	Transesophageal Echocardiography
FTc	Corrected flow time
PCWP	Pulmonary capillary wedge pressure
PEEP	Positive end-expiratory pressure
AHRQ	Agency for Healthcare Research and Quality
CMS	Centers for Medicare & Medicaid Services

Codes Related To This Policy

ICD-9 Codes

Too numerous to mention

CPT Codes

76999 Unlisted ultrasound procedure (e.g, diagnostic, interventional)

HCPCS Codes

N/A

Scientific Rationale

Cardiac output (CO) refers to the volume of blood ejected from the heart over a period of time. It can be calculated by multiplying the stroke volume by the heart rate. Cardiac output is routinely monitored in critically ill patients and perioperatively in patients at high risk for morbidity and mortality as changes in cardiac output may be used to identify a change in the hemodynamic status of a patient. Methods currently used to monitor cardiac output include pulmonary artery catheter (PAC) with thermodilution, Fick technique, transesophageal echocardiography (TEE), thoracic electrical bioimpedance, ultrasonic cardiac output monitoring and indicator-dilution technique.

Esophageal Doppler monitoring (EDM), a type of transesophageal echocardiogram monitoring device, determines cardiac output by measuring the blood flow velocity in the descending aorta by means of a Doppler transducer at the tip of a flexible probe in a tracheally intubated patient. Following introduction of the probe, it is advanced gently until the tip is located approximately at the mid-thoracic level; it is then rotated so that the transducer faces the aorta and a characteristic aortic velocity signal is obtained. The ultrasound transducer is mounted at a fixed angle that is known by the cardiac output computer and used to correct the resulting Doppler shift frequency to provide an accurate velocity measurement. Essentially, the device measures stroke volume by multiplying the cross-sectional area of the aorta by the time-integrated velocity of blood flow. The cross-sectional area of the descending aorta is measured using M-mode ultrasonography or is calculated using a proprietary algorithm using the patient's age and body mass index. Once the stroke volume is determined, it is multiplied by the heart rate to yield the cardiac output. In addition to heart rate, EDM can provide estimates on preload and cardiac contractility. Examples of currently FDA approved devices include the CardioQ (Deltex Medical Ltd) and the HemoSonic 200 hemodynamic monitor (Arrow International).

Proposed advantages of EDM include its ease of use, minimally invasive, and is not associated with major complications. This monitoring can be initiated rapidly, and can be applied when pulmonary artery catheterization cannot be accomplished or is contraindicated. EDM provides information on cardiac preload, contractility, stroke volume and cardiac output. Potential limitations of esophageal Doppler include operator dependency, difficulties in probe placement, difficulty interpreting the signal during periods of arrhythmia and the lack of central venous access.

Walsh et al (2008) performed a meta-analysis of studies that compared doppler-guided intra-operative fluid management to standard practice in patients undergoing major abdominal surgery. Four trials, comprising 393 patients, were identified. The authors reported that EDM guided fluid management algorithm resulted in fewer postoperative complications and shorter hospital stays. There were no significant differences in the quantities of intra-operative fluids administered although there was some evidence of heterogeneity with respect to this outcome.

A review evaluating the utility of EDM as a minimally invasive monitor of CO (Laupland et al. 2002) identified twenty-five publications comparing EDM and PAC measurement of CO in a broad range of patients. There was a good overall correlation between CO determined by EDM and thermodilution (n = 18 studies) and minimal bias (n = 13). The precision of EDM was only fair overall as assessed by limits of agreement. The EDM technique was found to be responsive in detecting changes in thermodilution CO and was reliable demonstrating both low intra- and inter-observer variation. EDM was reportedly easy to insert after minimal training and was safe, with no significant complications identified. The reviewers concluded that EDM is a practical, reliable, and valid device for measuring CO in perioperative and critically ill patients, however, they noted that further studies with larger numbers of patients are needed to determine if the limited precision observed is inherent to the technique, the diagnoses of patients studied, or the small sample sizes.

A systematic review conducted by the Agency for Healthcare Research and Quality (AHRQ) at the request of the Centers for Medicare & Medicaid Services (CMS) identified five studies with a total of 453 patients that compared the efficacy of EDM plus central venous pressure (CVP) monitoring plus conventional clinical assessment to CVP plus conventional clinical assessment to optimize intravenous fluid replacement during surgery. The AHRQ reported the median quality of the five studies was high, and the age-applicability to the Medicare population was fair. No studies compared the efficacy of EDM to thermodilution with a PAC for optimization of intravenous fluid replacement. Two studies compared EDM plus conventional clinical assessment to conventional clinical assessment and one of these studies (Venn et al.) also compared esophageal Doppler monitoring to CVP. The median quality of these two studies and their age-applicability to the Medicare population was high. The AHRQ concluded that the addition of EDM for guided fluid replacement to a protocol using CVP and conventional clinical assessment during surgery leads to a clinically significant reduction in the rate of major and total complications in surgical patients compared to CVP plus conventional clinical assessment alone. They also reported that the addition of EDM to the same protocol also reduces the length of hospital stay for surgical patients (clinical significance uncertain).

The AHRQ reported the strength of evidence is weak to support that the addition of EDM for guided fluid replacement to conventional clinical assessment alone during surgery leads to a clinically significant reduction in the length of hospital stay compared to conventional clinical assessment alone. The low number of studies precluded a quantitative estimate of the reduction in length of hospital stay.

The AHRQ noted no serious adverse events were associated with EDM. They identified nineteen studies with a total of 654 patients that specifically stated that EDM probes did not cause any complications. The number of patients represented in these studies were relatively small. They concluded the available evidence suggests that EDM probes are relatively low-risk devices, as reporting of even minor morbidity has been infrequent thus far.

The AHRQ found insufficient evidence to allow conclusions regarding the effectiveness of EDM in hospitalized patients in nonoperative settings. One study (McKendry et al.) compared the efficacy of EDM plus CVP plus conventional clinical assessment to CVP plus conventional clinical assessment for optimization of intravenous fluid replacement in patients admitted to cardiac intensive care following

cardiac surgery. This study was judged to be of high quality based on ECRI ratings. Generalizability to the Medicare population was fair. However, this was a single small study without a demonstrably large treatment effect on the outcomes of interest. Therefore, the AHRQ found insufficient evidence to allow conclusions regarding the effectiveness of EDM in hospitalized patients in non-operative settings.

Review History

February 2009 Medical Advisory Council, initial approval

Patient Education Websites

English

1. MedlinePlus. Endotracheal intubation. Available at:
<http://www.nlm.nih.gov/medlineplus/ency/article/003449.htm>

Spanish

1. MedlinePlus. Intubación endotraqueal. Available at:
<http://www.nlm.nih.gov/medlineplus/spanish/ency/article/003449.htm>

This policy is based on the following evidence-based guidelines:

1. AHRQ Technology Assessment. Esophageal Doppler Ultrasound-Based Cardiac Output Monitoring for Real-Time Therapeutic Management of Hospitalized Patients. Jan 2007 Available at:
<http://www.cms.hhs.gov/determinationprocess/downloads/id45TA.pdf>

References

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<https://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?from2=viewdecisionmemo.asp&id=196&>
2. CMS. NCD for Ultrasound Diagnostic Procedures (220.5) Effective 5/2007. Available at:
http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=220.5&ncd_version=3&basket=ncd%3A220%2E5%3A3%3AUltrasound+Diagnostic+Procedures
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11. Wakeling HG, McFall MR, Jenkins CS, et al. Intraoperative oesophageal Doppler guided fluid management shortens postoperative hospital stay after major bowel surgery. *Br J Anaesth.* 2005 Nov; 95(5): 634-42
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13. Kim K, Kwok I, Chang H, Han T. Comparison of cardiac outputs of major burn patients undergoing extensive early escharectomy: esophageal Doppler monitor versus thermodilution pulmonary artery catheter. *J Trauma.* 2004 Nov; 57(5): 1013-7.
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Important Notice

General Purpose.

Health Net's National Medical Policies (the "Policies") are developed to assist Health Net in administering plan benefits and determining whether a particular procedure, drug, service or supply is medically necessary. The Policies are based upon a review of the available clinical information including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the drug or device, evidence-based guidelines of governmental bodies, and evidence-based guidelines and positions of select national health professional organizations. Coverage determinations are made on a case-by-case basis and are subject to all of the terms, conditions, limitations, and exclusions of the member's contract, including medical necessity requirements. Health Net may use the Policies to determine whether under the facts and circumstances of a particular case, the proposed procedure, drug, service or supply is medically necessary. The conclusion that a procedure, drug, service or supply is medically necessary does not constitute coverage. The member's contract defines which procedure, drug, service or supply is covered, excluded, limited, or subject to dollar caps.

Policy Effective Date and Defined Terms.

The date of posting is not the effective date of the Policy. The Policy is effective as of the date determined by Health Net. All policies are subject to applicable legal and regulatory mandates and requirements for prior notification. If there is a discrepancy between the policy effective date and legal mandates and regulatory requirements, the requirements of law and regulation shall govern. * In some states, prior notice or posting on the website is required before a policy is deemed effective. For information regarding the effective dates of Policies, contact your provider representative. The Policies do not include definitions. All terms are defined by Health Net. For information regarding the definitions of terms used in the Policies, contact your provider representative.

Policy Amendment without Notice.

Health Net reserves the right to amend the Policies without notice to providers or Members. In some states, prior notice or website posting is required before an amendment is deemed effective.

No Medical Advice.

The Policies do not constitute medical advice. Health Net does not provide or recommend treatment to members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

No Authorization or Guarantee of Coverage.

The Policies do not constitute authorization or guarantee of coverage of particular procedure, drug, service or supply. Members and providers should refer to the Member contract to determine if exclusions, limitations, and dollar caps apply to a particular procedure, drug, service or supply.

Policy Limitation: Member's Contract Controls Coverage Determinations.

The determination of coverage for a particular procedure, drug, service or supply is not based upon the Policies, but rather is subject to the facts of the individual clinical case, terms and conditions of the member's contract, and requirements of applicable laws and regulations. The contract language contains specific terms and conditions, including pre-existing conditions, limitations, exclusions, benefit maximums, eligibility, and other relevant terms and conditions of coverage. In the event the Member's contract (also known as the benefit contract, coverage document, or evidence of coverage) conflicts with the Policies, the Member's contract shall govern. Coverage decisions are the result of the terms and conditions of the Member's benefit contract. The Policies do not replace or amend the Member's contract. If there is a discrepancy between the Policies and the Member's contract, the Member's contract shall govern.

Policy Limitation: Legal and Regulatory Mandates and Requirements

The determinations of coverage for a particular procedure, drug, service or supply is subject to applicable legal and regulatory mandates and requirements. If there is a discrepancy between the Policies and legal mandates and regulatory requirements, the requirements of law and regulation shall govern.

Policy Limitations: Medicare and Medicaid

Policies specifically developed to assist Health Net in administering Medicare or Medicaid plan benefits and determining coverage for a particular procedure, drug, service or supply for Medicare or Medicaid members shall not be construed to apply to any other Health Net plans and members. The Policies shall not be interpreted to limit the benefits afforded Medicare and Medicaid members by law and regulation.