

Corporate Medical Policy

Enhanced External Counterpulsation (EECP)

File Name:	enhanced_external_counterpulsation_eecp
Origination:	9/2002
Last CAP Review:	4/2011
Next CAP Review:	4/2012
Last Review:	4/2011

Description of Procedure or Service

Enhanced external counterpulsation (EECP) is a noninvasive treatment that uses timed, sequential inflation of pressure cuffs on the calves, thighs, and buttocks to augment diastolic pressure, decrease left ventricular afterload, and increase venous return. Augmenting diastolic pressure displaces a volume of blood backward into the coronary arteries during diastole when the heart is in a state of relaxation and the resistance in the coronary arteries is at a minimum. The resulting increase in coronary artery perfusion pressure may enhance coronary collateral development or increase flow through existing collaterals. In addition, when the left ventricle contracts, it faces a reduced aortic pressure to work against, since the counterpulsation has somewhat emptied the aorta. EECP has been primarily investigated as a treatment for chronic stable angina.

Intra-aortic balloon counterpulsation is a more familiar, invasive form of counterpulsation that is used as a method of temporary circulatory assistance for the ischemic heart, often after an acute myocardial infarction. In contrast, EECP is thought to provide a permanent effect on the heart by enhancing the development of coronary collateral development. A full course of therapy usually consists of 35 one-hour treatments, which may be offered once or twice daily, usually 5 days per week. The multiple components of the procedure include the use of the device itself, finger plethysmography to follow the blood flow, continuous electrocardiograms (EKGs) to trigger inflation and deflation, and optional use of pulse oximetry to measure oxygen saturation before and after treatment.

While EECP has been primarily researched as a treatment of chronic stable angina, it has also been used in patients with congestive heart failure. The Vasomedical EECP® Therapy System Model has the following labeled indication under 510(k) clearance from the U.S. Food and Drug Administration (FDA):

"The EECP Therapy System Model TS3 with Pulse Oximetry is a non-invasive external counterpulsation device intended for the use in the treatment of patients with congestive heart failure, stable or unstable angina pectoris, acute myocardial infarction, or cardiogenic shock."

Cardiomedics, Inc. has FDA 510(k) clearance to market the CardiAssist Counterpulsation System (K022107) and the CardiAssist ECP System (K010261) for the same indications as the Vasomedical EECP® systems.

Note: This policy only addresses the outpatient cardiac uses of EECP, i.e., for the treatment of chronic stable angina or congestive heart failure. This policy does not address its use for unstable angina pectoris, acute myocardial infarction, or cardiogenic shock.

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will provide coverage for Enhanced External Counterpulsation when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

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Benefits Application

Please refer to Certificate for availability of benefits. This policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore certificate language should be reviewed before applying the terms of the policy.

When Enhanced External Counterpulsation (EECP) is covered

Coverage is provided for the use of EECP for patients who have been diagnosed with disabling angina (New York Heart Association Class III or IV, or equivalent classification) who, in the opinion of a cardiologist or cardiothoracic surgeon, are refractory to maximum medical therapy and are not readily amenable to surgical intervention, such as PTCA or cardiac bypass because:

- Their condition is inoperable, or at high risk of operative complications or post-operative failure; **or**
- Their coronary anatomy is not readily amenable to such procedures; **or**
- They have co-morbid states that create excessive risk.

When Enhanced External Counterpulsation (EECP) is not covered

The use of EECP is considered investigational for all other indications not noted above including, but not limited to the treatment of Class II angina, arrhythmia, aortic insufficiency, peripheral vascular disease or phlebitis, severe hypertension, acute retinal artery occlusion, acute myocardial infarction, cardiogenic shock or congestive heart failure.

Policy Guidelines

A 2005 BCBSA TEC Assessment regarding EECP for chronic stable angina stated there was insufficient evidence to draw conclusions about the benefits of EECP. This TEC Assessment included congestive heart failure in the analysis and concluded the evidence supporting the role of EECP as an effective treatment for heart failure is lacking in both quantity and quality.

Medicare has published a national coverage decision regarding EECP that mandates coverage for the following indications:

"Coverage is provided for the use of EECP for patients who have been diagnosed with disabling angina who, in the opinion of a cardiologist or cardiothoracic surgeon, are not readily amenable to surgical intervention, such as percutaneous transluminal coronary angioplasty or cardiac bypass because: 1) Their condition is inoperable, or at high risk of operative complications or post-operative failure; 2) Their coronary anatomy is not readily amendable to such procedures; or 3) They have co-morbid states which create excessive risk."

Medicare's coverage policy also notes that while the FDA has cleared EECP "for use in treating a variety of cardiac conditions, including stable or unstable angina pectoris, acute myocardial infarction and cardiogenic shock, the use of this device to treat cardiac conditions other than stable angina pectoris is not covered..."

Additional research into the use of EECP for other ischemic conditions such as stroke, peripheral artery disease, central retinal artery occlusion, and erectile dysfunction are inadequate to draw conclusions about impact on net health outcome.

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Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: G0166, 92971

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual, 2.02.06, 7/12/02

ECRI Target Fact Sheet External counterpulsation (ECP) for treatment of stable angina, Target Report #233, June 2002

ECRI Windows on Medical Technology, External Counterpulsation for the Treatment of Stable Angina Issue No. 34. June 2000.

Specialty Matched Consultant Review - 9/2002

BCBSA Medical Policy Reference Manual, 2.02.06, 04/29/03

Fitzgerald, C.P., Lawson, W.E., Kennard, E.D., (2003) Enhanced External Counterpulsation as initial revascularization treatment for angina refractory to medical therapy. *Cardiology*, 100, 129-135.

Specialty Matched Consultant Advisory Panel - 6/2004

ECRI Target Report #233 (2005, January) External counterpulsation for treatment of chronic stable angina pectoris and chronic heart failure. Retrieved November 17, 2005 from http://www.target.ecri.org/summary/detail.aspx?doc_id=233&q=eecp&h1=1.

BCBSA TEC Assessment [Electronic Version]. June 2005

Center for Medicare and Medicaid Services (CMS). External Counterpulsation (ECP) Therapy. National Coverage Determination, Manual Section Number 20.20. Retrieved 2/21/06 from <http://www.cms.hhs.gov>

Medical Advisory Secretariat, Ontario Ministry of Health and Long-Term Care (March 2006). Health Technology Policy Assessment for Enhanced External Counterpulsation (EECP). Retrieved 11/30/07 from http://www.health.gov.on.ca/english/providers/program/ohtac/tech/reviews/pdf/rev_eecp_030106.pdf

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.06. 12/12/06

Soran O, Kennard ED, Bart BA et al. Impact of external counterpulsation treatment on emergency department visits and hospitalizations in refractory angina patients with left ventricular dysfunction. *Congest Heart Fail* 2007; 13(1):36-40.

Loh PH, Cleland JG, Louis AA et al. Enhanced external counterpulsation in the treatment of chronic refractory angina: a long-term follow-up outcome from the International Enhanced External Counterpulsation Patient Registry. *Clin Cardiol* 2008; 31(4):159-64.

Lawson WE, Hui JC, Kennard ED et al. Effect of enhanced external counterpulsation on medically refractory angina patients with erectile dysfunction. *Int J Clin Pract* 2007; 61(5):757-62.

Han JH, Leung TW, Lam WW et al. Preliminary findings of external counterpulsation for ischemic

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stroke patient with large artery occlusive disease. Stroke. 2008; 39(4):1340-3.

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.06. 10/07/08

Specialty Matched Consultant Advisory Panel – 3/2010

Senior Medical Director review 8/2010

Fraser SG, Adams W. Interventions for acute non-arteritic central retinal artery occlusion. Cochrane Database Syst Rev 2009; (1):CD001989.

Braith RW, Conti CR, Nichols WW et al. Enhanced external counterpulsation improves peripheral artery flow-mediated dilation in patients with chronic angina: a randomized sham-controlled study. Circulation 2010; 122(16):1612-20

Thakkar BV, Hirsch AT, Satran D et al. The efficacy and safety of enhanced external counterpulsation in patients with peripheral arterial disease. Vasc Med 2010; 15(1):15-20.

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.06, 2/10/11

Specialty Matched Consultant Advisory Panel review 4/2011

Policy Implementation/Update Information

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| 9/02 | Policy removed from Ventricular Assist Devices and written as its own policy. No change in criteria or coverage. |
| 2/04 | Policy statement change from not covered for "external ventricular assist devices" to not covered for "enhanced external counterpulsation". Formatting changes made. |
| 7/29/04 | Added CPT code 92971 to Billing and Coding Information. Specialty Matched Consultant Advisory Panel review 06/08/2004 with no changes made in criteria. References added. |
| 3/30/06 | Medical Policy Oversight Committee review and discussion 2/27/06. Policy status changed from investigational to medically necessary when policy criteria is met. Medical necessity guidelines added to sections "When EECP is covered" and "When EECP is not covered." Rationale for coverage added to Policy Guidelines section. Policy number added to Key Words. References updated. Specialty Matched Consultant Advisory Panel review 2/27/06. |
| 4/7/08 | References updated. Specialty Matched Consultant Advisory Panel review 3/12/08. No change to policy statement. (adn) |
| 10/26/09 | Policy statement changed to read: "BCBSNC will not provide coverage for enhanced external counterpulsation. It is considered investigational and BCBSNC does not cover investigational services." Information in the When EECP Is Covered section deleted and replace with the statement, "not applicable." Information in the When EECP Is Not Covered section replaced with the statement, "Enhanced external counterpulsation is considered investigational for all indications, including but not limited to, treatment of chronic stable angina pectoris, congestive heart failure, erectile dysfunction, or ischemic stroke." Rationale in the Policy Guidelines section updated with BCBSA TEC Assessment and Medicare information. Use of EECP in patients who meet the Medicare coverage criteria noted above may be approved on an individual consideration basis. Notification given 10/26/09. Effective date 2/02/10. (adn) |
| 4/27/10 | Specialty Matched Consultant Advisory Panel review 3/24/2010. Medical Policy number removed. No changes to policy. (mco) |

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9/14/10 Policy statement revised to read: “BCBSNC will provide coverage for Enhanced External Counterpulsation when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.” Added the following criteria to When Covered section: “Coverage is provided for the use of EECP for patients who have been diagnosed with disabling angina (New York Heart Association Class III or IV, or equivalent classification) who, in the opinion of a cardiologist or cardiothoracic surgeon, are refractory to maximum medical therapy and are not readily amenable to surgical intervention, such as PTCA or cardiac bypass because: Their condition is inoperable, or at high risk of operative complications or post-operative failure; or Their coronary anatomy is not readily amenable to such procedures; or They have co-morbid states that create excessive risk.” Revised the When Not Covered section to read: “The use of EECP is considered investigational for all other indications not noted above including, but not limited to the treatment of Class II angina, arrhythmia, aortic insufficiency, peripheral vascular disease or phlebitis, severe hypertension, acute retinal artery occlusion, acute myocardial infarction, cardiogenic shock or congestive heart failure.” Removed the following statement from the Policy Guidelines section: “Use of EECP in patients who meet the Medicare coverage criteria noted above may be approved on an individual consideration basis.” (mco)

5/10/11 Policy guidelines updated. References updated. Specialty Matched Consultant Advisory Panel review 4/2011. (mco)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.