



BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Enhanced External Counterpulsation (EECP)

Policy # 00036

Original Effective Date: 11/12/2001

Current Effective Date: 05/21/2014

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member's contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider enhanced external counterpulsation (EECP) to be **eligible for coverage**.

Patient Selection Criteria

Coverage eligibility for the use of enhanced external counterpulsation will be considered for individuals who have severe chronic stable angina (Class III or IV per the New York Heart Association [NYHA] classification* or equivalent) and the following criteria are met:

- Patient is not considered to be suitable candidate for angioplasty or revascularization; or
- Patient continues to experience angina despite surgical intervention.

New York Heart Association (NYHA) classification is as follows:

Class I Mild

Patients with cardiac disease but without resulting limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea or anginal pain.

Class II Mild

Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in fatigue, palpitation or dyspnea.

Class III Moderate

Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea or anginal pain

Class IV Severe

Unable to carry out any physical activity without discomfort. Symptoms of cardiac insufficiency at rest. If any physical activity is undertaken, discomfort is increased.

When Services Are Considered Investigational

Note: Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

The use of enhanced external counterpulsation (EECP) when patient selection criteria are not met is considered to be **investigational**.*

©2014 Blue Cross and Blue Shield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Enhanced External Counterpulsation (EECP)

Policy # 00036

Original Effective Date: 11/12/2001

Current Effective Date: 05/21/2014

Background/Overview

Enhanced external counterpulsation 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 five 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.

Note: This policy only addresses the outpatient use 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

While EECP has been primarily researched as a treatment of chronic stable angina, it has also been used in patients with heart failure. The Vasomedical EECP^{®±} Therapy System Model has the following labeled indication under 510(k) clearance from the U.S. 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 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.



BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Enhanced External Counterpulsation (EECP)

Policy # 00036

Original Effective Date: 11/12/2001

Current Effective Date: 05/21/2014

Centers for Medicare and Medicaid Services (CMS)

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.”

Rationale/Source

The use of EECP for the treatment of disabling, chronic, stable disabling angina in patients who are not suitable candidates for surgical intervention or who have failed surgical intervention has been established in the medical evidence. Several large-scale prospective studies evaluating the efficacy of EECP in patients with chronic stable angina demonstrate significant improvements in anginal symptoms, myocardial perfusion and output. One randomized, sham-controlled trial demonstrated significant improvement at 12 months in patients who underwent a single 35-hour course of EECP. In this study treatment-group, patients reported significant improvements compared to sham treated patients in all nine quality of life scales included on the Medical Outcomes Study SF-36 health survey, including the activities of daily living, ability to work, bodily pain and others.

EECP has also been studied for the treatment of congestive heart failure. In 2002, Soran and colleagues reported on a feasibility study of EECP as a treatment for congestive heart failure in 26 patients. In this uncontrolled study, the patients were treated with 35 daily, one-hour sessions and followed for six months after completion of the course of therapy. The study suggests that the treatment was safe and well tolerated. Based in part on the results of this study, a larger, randomized study has been launched, the PEECH trial (Prospective Evaluation of EECP in Congestive Heart Failure). Results of this trial have not yet been published.

The evidence regarding the use of EECP for other indications, including other anginal or cardiac conditions, such as including non-disabling stable angina or unstable angina is currently insufficient to allow conclusions to be made.

Studies of EECP in angina patients with severe left ventricular dysfunction suggest that improvement in anginal symptoms, as well as quality of life, are consistent, independent of degree of ventricular dysfunction, and sustainable for up to two years) Similar results were noted after one year in an observational study published in 2005 of 746 angina patients with either systolic or diastolic dysfunction who received EECP for their angina.

©2014 Blue Cross and Blue Shield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Enhanced External Counterpulsation (EECP)

Policy # 00036

Original Effective Date: 11/12/2001

Current Effective Date: 05/21/2014

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Enhanced External Counterpulsation (EECP) for Chronic Stable Angina or Congestive Heart Failure.2.02.06, 1:2014.
2. Blue Cross and Blue Shield Technology Evaluation Center (TEC). External Counterpulsation for Treatment of Chronic Stable Angina Pectoris and Chronic Heart Failure. TEC Assessments 2005; 20(Tab 12).
3. Luo C, Liu D, Du Z et al. Short-term effects of enhanced external counterpulsation on transthoracic coronary flow velocity and reserve in patients with coronary slow flow. *Int. J. Cardiol.* 2012; 154(1):84-5.
4. Arora RR, Chou TM, Jain D et al. The multicenter study of enhanced external counterpulsation (MUST-EECP): effect of EECP on exercise-induced myocardial ischemia and anginal episodes. *J Am Coll Cardiol* 1999; 33(7):1833-40.
5. Arora RR, Chou TM, Jain D et al. Effects of enhanced external counterpulsation on Health-Related Quality of Life continue 12 months after treatment: a substudy of the Multicenter Study of Enhanced External Counterpulsation. *J Investig Med* 2002; 50(1):25-32.
6. Holubkov R, Kennard ED, Foris JM et al. Comparison of patients undergoing enhanced external counterpulsation and percutaneous coronary intervention for stable angina pectoris. *Am J Cardiol* 2002; 89(10):1182-6.
7. Shechter M, Matetzky S, Feinberg MS et al. External counterpulsation therapy improves endothelial function in patients with refractory angina pectoris. *J Am Coll Cardiol* 2003; 42(12):2090-5.
8. Bondesson SM, Edvinsson ML, Pettersson T et al. Reduced peripheral vascular reactivity in refractory angina pectoris: Effect of enhanced external counterpulsation. *Journal of geriatric cardiology : JGC* 2011; 8(4):215-23.
9. Gloekler S, Meier P, de Marchi SF et al. Coronary collateral growth by external counterpulsation: a randomized controlled trial. *Heart* 2010; 96(3):202-7.
10. Buschmann EE, Utz W, Pagonas N et al. Improvement of fractional flow reserve and collateral flow by treatment with external counterpulsation (Art.Net.-2 Trial). *Eur J Clin Invest* 2009; 39(10):866-75.
11. 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.
12. Casey DP, Beck DT, Nichols WW et al. Effects of enhanced external counterpulsation on arterial stiffness and myocardial oxygen demand in patients with chronic angina pectoris. *Am. J. Cardiol.* 2011; 107(10):1466-72.
13. Martin JS, Beck DT, Aranda JM, Jr. et al. Enhanced External Counterpulsation (EECP) Improves Peripheral Artery Function and Glucose Tolerance in Subjects with Abnormal Glucose Tolerance. *J. Appl. Physiol.* 2011.
14. Amin F, Al Hajeri A, Civelek B et al. Enhanced external counterpulsation for chronic angina pectoris. *Cochrane Database Syst Rev* 2010; (2):CD007219.
15. Shah SA, Shapiro RJ, Mehta R et al. Impact of enhanced external counterpulsation on Canadian Cardiovascular Society angina class in patients with chronic stable angina: a meta-analysis. *Pharmacotherapy* 2010; 30(7):639-45.
16. McKenna C, McDaid C, Suekarran S et al. Enhanced external counterpulsation for the treatment of stable angina and heart failure: a systematic review and economic analysis. *Health Technol Assess* 2009; 13(24):iii-iv, ix-xi, 1-90.
17. Barsheshet A, Hod H, Shechter M et al. The effects of external counter pulsation therapy on circulating endothelial progenitor cells in patients with angina pectoris. *Cardiology* 2008; 110(3):160-6.
18. 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.
19. 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.
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.
21. Kumar A, Aronow WS, Vadnerkar A et al. Effect of enhanced external counterpulsation on clinical symptoms, quality of life, 6-minute walking distance, and echocardiographic measurements of left ventricular systolic and diastolic function after 35 days of treatment and at 1-year follow up in 47 patients with chronic refractory angina pectoris. *Am J Ther* 2009; 16(2):116-8.
22. Pettersson T, Bondesson S, Cojocar D et al. One year follow-up of patients with refractory angina pectoris treated with enhanced external counterpulsation. *BMC Cardiovasc Disord* 2006; 6:28.
23. Loh PH, Louis AA, Windram J et al. The immediate and long-term outcome of enhanced external counterpulsation in treatment of chronic stable refractory angina. *J Intern Med* 2006; 259(3):276-84.
24. Feldman AM, Silver MA, Francis GS et al. Enhanced external counterpulsation improves exercise tolerance in patients with chronic heart failure. *J Am Coll Cardiol* 2006; 48(6):1198-205.
25. Feldman AM, Silver MA, Francis GS et al. Treating heart failure with enhanced external counterpulsation (EECP): design of the Prospective Evaluation of EECP in Heart Failure (PEECH) trial. *J Card Fail* 2005; 11(3):240-5.

©2014 Blue Cross and Blue Shield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Blue Cross Blue Shield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Enhanced External Counterpulsation (EECP)

Policy # 00036

Original Effective Date: 11/12/2001

Current Effective Date: 05/21/2014

26. Abbottsmith CW, Chung ES, Varricchio T et al. Enhanced external counterpulsation improves exercise duration and peak oxygen consumption in older patients with heart failure: a subgroup analysis of the PEECH trial. *Congest Heart Fail* 2006; 12(6):307-11.
27. Soran O, Kennard ED, Kelsey SF et al. Enhanced external counterpulsation as treatment for chronic angina in patients with left ventricular dysfunction: a report from the International EECP Patient Registry (IEPR). *Congest Heart Fail* 2002; 8(6):297-302.
28. Lawson WE, Kennard ED, Holubkov R et al. Benefit and safety of enhanced external counterpulsation in treating coronary artery disease patients with a history of congestive heart failure. *Cardiology* 2001; 96(2):78-84.
29. Lawson WE, Silver MA, Hui JC et al. Angina patients with diastolic versus systolic heart failure demonstrate comparable immediate and one-year benefit from enhanced external counterpulsation. *J Card Fail* 2005; 11(1):61-6.
30. Vijayaraghavan K, Santora L, Kahn J et al. New graduated pressure regimen for external counterpulsation reduces mortality and improves outcomes in congestive heart failure: a report from the Cardiomedics External Counterpulsation Patient Registry. *Congest Heart Fail* 2005; 11(3):147-52.
31. Soran O, Fleishman B, Demarco T et al. Enhanced external counterpulsation in patients with heart failure: a multicenter feasibility study. *Congest Heart Fail* 2002; 8(4):204-8, 27.
32. Fraser SG, Adams W. Interventions for acute non-arteritic central retinal artery occlusion. *Cochrane Database Syst Rev* 2009; (1):CD001989.
33. Werner D, Michalk F, Harazny J et al. Accelerated reperfusion of poorly perfused retinal areas in central retinal artery occlusion and branch retinal artery occlusion after a short treatment with enhanced external counterpulsation. *Retina* 2004; 24(4):541-7.
34. 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.
35. Han JH, Leung TW, Lam WW et al. Preliminary findings of external counterpulsation for ischemic stroke patient with large artery occlusive disease. *Stroke* 2008; 39(4):1340-3.
36. Lin S, Liu M, Wu B et al. External counterpulsation for acute ischaemic stroke. *Cochrane Database Syst Rev* 2012; 1:CD009264.
37. Gibbons RJ, Abrams J, Chatterjee K et al. ACC/AHA 2002 guideline update for the management of patients with chronic stable angina--summary article: a report of the American College of Cardiology/American Heart Association Task Force on practice guidelines (Committee on the Management of Patients With Chronic Stable Angina). *J Am Coll Cardiol* 2003; 41(1):159-68.
38. Fraker TD, Jr., Fihn SD, Gibbons RJ et al. 2007 chronic angina focused update of the ACC/AHA 2002 guidelines for the management of patients with chronic stable angina: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines Writing Group to develop the focused update of the 2002 guidelines for the management of patients with chronic stable angina. *J Am Coll Cardiol* 2007; 50(23):2264-74.
39. Center for Medicare and Medicaid Services (CMS). National Coverage Determination for external counterpulsation (ECP) therapy for severe angina (20.20). Updated March 2006. Available online at: <http://www.cms.gov/transmittals/downloads/R50NCD.pdf>. Last accessed January 13, 2011.

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT)[®]†, copyright 2013 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

©2014 Blue Cross and Blue Shield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Enhanced External Counterpulsation (EECP)

Policy # 00036
Original Effective Date: 11/12/2001
Current Effective Date: 05/21/2014

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	92971
HCPCS	G0166
ICD-9 Diagnosis	All relevant diagnoses
ICD-9 Procedure	No codes

Policy History

Original Effective Date: 11/12/2001
Current Effective Date: 05/21/2014

10/18/2001 Medical Policy Committee review
11/12/2001 Managed Care Advisory Council approval
06/24/2002 Format revision. No substance change to policy.
10/21/2003 Medical Policy Committee review Format revision. No substance change to policy.
01/26/2004 Managed Care Advisory Council approval
01/04/2005 Medical Director review
01/18/2005 Medical Policy committee review
01/31/2005 Managed Care Advisory council approval. Investigational policy added
05/03/2006 Medical Director review
06/21/2006 Medical Policy Committee approval. Format revision, including, addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
05/02/2007 Medical Director review
05/23/2007 Medical Policy Committee approval. No change to coverage eligibility.
05/07/2008 Medical Director review
05/21/2008 Medical Policy Committee approval. No change to coverage eligibility.
05/07/2009 Medical Director review
05/20/2009 Medical Policy Committee approval. No change to coverage eligibility.
06/03/2010 Medical Policy Committee review
06/16/2010 Medical Policy Implementation Committee approval. No change to coverage eligibility.
05/05/2011 Medical Policy Committee review
05/18/2011 Medical Policy Implementation Committee approval. No change to coverage eligibility.
05/03/2012 Medical Policy Committee review
05/16/2012 Medical Policy Implementation Committee approval. No change to coverage eligibility.
05/02/2013 Medical Policy Committee review
05/22/2013 Medical Policy Implementation Committee approval. No change to coverage eligibility.
05/01/2014 Medical Policy Committee review
05/21/2014 Medical Policy Implementation Committee approval. No change to coverage eligibility.
Next Scheduled Review Date: 05/2015

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

©2014 Blue Cross and Blue Shield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Enhanced External Counterpulsation (EECP)

Policy # 00036

Original Effective Date: 11/12/2001

Current Effective Date: 05/21/2014

- B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. reference to federal regulations.

****Medically Necessary (or "Medical Necessity")** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. in accordance with nationally accepted standards of medical practice;
- B. clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.