Enhanced External Counterpulsation (EECP)

Policy # 00036
Original Effective Date: 11/12/2001
Current Effective Date: 08/01/2018

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 a course of up to 35 sessions of enhanced external counterpulsation (EECP) (using FDA-approved external counterpulsation systems) to be **eligible for coverage**.

Patient Selection Criteria
Coverage eligibility for the use of enhanced external counterpulsation (EECP) 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 in the opinion of a cardiologist or cardiovascular surgeon, e.g. the patient is inoperable or at high risk for complications, or the coronary anatomy is not suitable for revascularization; or
- Patient continues to experience angina despite optimal pharmacologic therapy and coronary revascularization.

Note:
A single course of EECT consists of 35 one- hour treatment sessions, usually 5 sessions per week over a period of approximately 7 weeks. There is no proven benefit to extending a course of EECP beyond 35 sessions.

Repeat courses of EECP treatment will require review of supporting documentation and might be considered if patient had a significant reduction in frequency of angina symptoms/episodes and three or more months have elapsed from the prior EECP treatment.

This procedure must be performed under direct supervision of a physician. The physician must be present in the office suite and immediately available to provide assistance and direction throughout the time the personnel is performing the service.

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.***

Background/Overview

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 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.

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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)

A variety of EECP devices have been cleared for marketing by the FDA through the 510(k) process. Examples of EECP devices with FDA clearance are outlined in Table 1. FDA product code: DRN.

Table 1. FDA-Cleared EECP Devices

Device	Manufacturer	Clearance Date	Indications
Renew® NCP-5 External Counterpulsation System	Renew Group (Rockville, MD)	Dec 2015	• Treatment of chronic stable angina refractory to optimal anti-anginal medical therapy and without options for revascularization • In healthy patients to improve vasodilation, increase VO_2, and increase blood flow
ECP Health System Model	ECP Health	Aug 2005	• Stable or unstable angina pectoris • Acute myocardial infarction • Cardiogenic shock • Congestive heart failure
CardiAssist™ Counter Pulsation System	Cardiomedics (Irvine, CA)	Mar 2005	• Treatment of ischemic heart disease by increasing perfusion during diastole in people with chronic angina pectoris, congestive heart failure, myocardial infarction, and cardiogenic shock
ACS Model NCP-2 External Counterpulsation Device	Applied Cardiac Systems (Laguna Hills, CA)	Aug 2004	• Stable or unstable angina pectoris • Acute myocardial infarction • Cardiogenic shock • Congestive heart failure
EECP® Therapy System	Vasomedical (Westbury, NY)	Mar 2004	• Stable or unstable angina pectoris • Acute myocardial infarction • Cardiogenic shock • Congestive heart failure

EECP: enhanced external counterpulsation; FDA: Food and Drug Administration; VO_2: oxygen consumption.

Centers for Medicare and Medicaid Services (CMS)
Medicare has published a national coverage decision regarding EECP that mandates coverage for the following indications:

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"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 EEPC. 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.

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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.
05/07/2015	Medical Policy Committee review
05/20/2015	Medical Policy Implementation Committee approval. No change to coverage eligibility.
05/05/2016	Medical Policy Committee review
05/18/2016	Medical Policy Implementation Committee approval. No change to coverage eligibility.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
05/04/2017	Medical Policy Committee review
05/17/2017	Medical Policy Implementation Committee approval. No change to coverage eligibility.
05/03/2018	Medical Policy Committee review
05/16/2018	Medical Policy Implementation Committee approval. Criteria revised to approve a total of 35 sessions with an FDA approved device.

Next Scheduled Review Date: 05/2019

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 2017 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.

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Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

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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-10 Diagnosis	All related diagnoses

*****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. 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
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.

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