



# Louisiana

## Enhanced External Counterpulsation (EECP)

Policy # 00036

Original Effective Date: 11/12/2001

Current Effective Date: 06/10/2024

*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 single<sup>1</sup> course of enhanced external counterpulsation (EECP) to be **eligible for coverage\*\*** when the criteria below are met:

- Disabling, chronic, stable angina (defined as Class III or Class IV Canadian Cardiovascular Society Classification angina or equivalent, see Policy guidelines); **and**
- Refractory to optimal medical therapy and not readily amenable to surgical intervention such as percutaneous transluminal coronary angioplasty (PTCA) or cardiac bypass due to **any** of the following:
  - Condition is inoperable; **or**
  - High risk of operative complications or postoperative failure; **or**
  - Coronary anatomy is not readily amenable to such procedures; **and**
- None of the comorbid conditions or contraindications that would result in excessive risk are present, including but not limited to the following:
  - Aortic insufficiency (regurgitation might prevent diastolic augmentation); **or**,
  - Uncontrolled arrhythmias such as atrial fibrillation, atrial flutter, ventricular tachycardia, sustained tachycardia with heart rate > 120 beats per minute, and frequent premature ventricular beats (might interfere with the device's triggering mechanism); **or**
  - Uncontrolled bleeding diatheses (INR > 2); **or**
  - Severe or decompensated heart failure; **or**
  - Deep vein thrombosis, varicosities, or stasis ulcers; **or**
  - Severe peripheral arterial disease or phlebitis (increased risk of thromboembolus); **or**

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- Severe hypertension with BP > 180/110 mmHg (treatment could produce diastolic blood pressure above acceptable limits); **or**
- Stroke.

### **Note:**

<sup>1</sup>A single course of treatment consists of a total of 35 hours of enhanced external counterpulsation (EECP); treatment is administered for one to two hours daily, 5 days a week, for approximately 3½ to 7 weeks.

Based on review of available data, the Company may consider a repeat course of enhanced external counterpulsation (EECP) therapy in individuals who met the criteria in section above, have chronic stable angina and who have objectively demonstrated a response to EECP to be **eligible for coverage\*\***. This would include those individuals who demonstrate one or more of the following:

- Early improvement in radionuclide stress perfusion imaging compared to a pre-EECP baseline; **or**
- Reduction in antianginal medication use; **or**
- Improvement in exercise tolerance.

## **When Services Are Considered Investigational**

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

The use of enhanced external counterpulsation (EECP) when the above patient selection criteria are not met and for all other indications is considered to be **investigational.\***

## **Policy Guidelines**

Canadian Cardiovascular Society Score: This organization defines anginal classes as follows:

- Class I - Ordinary physical activity (e.g., walking and climbing stairs) does not cause angina. Angina with strenuous or rapid prolonged exertion at work or recreation.
- Class II - Slight limitation of ordinary activity. Angina with walking or climbing stairs rapidly, walking uphill, walking more than 2 blocks on the level and climbing more than 1 flight of stairs at a normal pace.
- Class III - Marked limitation of ordinary physical activity. Angina with walking 1 to 2 blocks on the level and climbing 1 flight in normal conditions.

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- Class IV - Inability to carry on physical activity without discomfort. Anginal syndrome may be present at rest.

### **Background/Overview**

Enhanced external counterpulsation (EECP) 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. The proposed mechanism of action is the augmentation of diastolic pressure by displacement of a volume of blood backward into the coronary arteries during diastole when the heart is in a state of relaxation and 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. Also, when the left ventricular contracts, it faces reduced aortic counterpressure, because 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 acute myocardial infarction. In contrast, EECP is thought to provide a permanent effect on the heart by enhancing the 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 a week. The multiple components of the procedure include the use of the device itself, finger plethysmography to follow the blood flow, continuous electrocardiograms 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 individuals 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.*

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## **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. Food and Drug Administration product code: DRN.

**Table 1. FDA-Cleared EECP Devices**

Device	Manufacturer	Cleared	Indications
External Counterpulsation System	Vamed Medical Instrument	Sep 2019	<ul style="list-style-type: none"> <li>Chronic stable angina refractory to optimal anti-anginal medical therapy and without options for revascularization</li> <li>In healthy patients to improve vasodilation, increase Vo2, and increase blood flow</li> </ul>
Pure Flow External Counter-Pulsation Device	Xtreem Pulse	May 2018	<ul style="list-style-type: none"> <li>Chronic stable angina refractory to optimal anti-anginal medical therapy and without options for revascularization</li> <li>In healthy patients to improve vasodilation, increase Vo2, and increase blood flow</li> </ul>
Renew <sup>®‡</sup> NCP-5 External Counterpulsation System	Renew Group	Dec 2015	<ul style="list-style-type: none"> <li>Chronic stable angina refractory to optimal anti-anginal medical therapy and without options for revascularization</li> <li>In healthy patients to improve vasodilation, increase Vo2, and increase blood flow</li> </ul>
ECP Health System Model	ECP Health	Aug 2005	<ul style="list-style-type: none"> <li>Stable or unstable angina pectoris</li> <li>Acute myocardial infarction</li> <li>Cardiogenic shock</li> </ul>

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Device	Manufacturer	Cleared	Indications
External Counterpulsation System	Vamed Medical Instrument	Sep 2019	<ul style="list-style-type: none"> <li>Chronic stable angina refractory to optimal anti-anginal medical therapy and without options for revascularization</li> <li>In healthy patients to improve vasodilation, increase Vo2, and increase blood flow</li> </ul>
Pure Flow External Counter-Pulsation Device	Xtreem Pulse	May 2018	<ul style="list-style-type: none"> <li>Chronic stable angina refractory to optimal anti-anginal medical therapy and without options for revascularization</li> <li>In healthy patients to improve vasodilation, increase Vo2, and increase blood flow</li> </ul>
			<ul style="list-style-type: none"> <li>Congestive heart failure</li> </ul>
CardiAssist™‡ Counter Pulsation System	Cardiomedics	Mar 2005	<ul style="list-style-type: none"> <li>Ischemic heart disease by increasing perfusion during diastole in people with chronic angina pectoris, congestive heart failure, myocardial infarction, and cardiogenic shock</li> </ul>
ACS Model NCP-2 External Counterpulsation Device	Applied Cardiac Systems	Aug 2004	<ul style="list-style-type: none"> <li>Stable or unstable angina pectoris</li> <li>Acute myocardial infarction</li> <li>Cardiogenic shock</li> <li>Congestive heart failure</li> </ul>
EECP®‡ Therapy System	Vasomedical	Mar 2004	<ul style="list-style-type: none"> <li>Stable or unstable angina pectoris</li> <li>Acute myocardial infarction</li> <li>Cardiogenic shock</li> <li>Congestive heart failure</li> </ul>

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EECP: enhanced external counterpulsation; FDA: Food and Drug Administration; Vo2: oxygen consumption.

## **Rationale/Source**

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The use of EECP for the treatment of disabling, chronic, stable disabling angina in individuals 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 individuals 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 individuals who underwent a single 35-hour course of EECP. In this study treatment-group, individuals reported significant improvements compared to sham treated individuals 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 individuals. In this uncontrolled study, the individuals 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.

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Studies of EECP in angina individuals 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 individuals with either systolic or diastolic dysfunction who received EECP for their angina.

## **Supplemental Information**

### **Clinical Input From Physician Specialty Societies and Academic Medical Centers**

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 3 academic medical centers while this policy was under review in 2008 and 2010. Reviewers agreed with the conclusion that enhanced external counterpulsation was investigational. Some reviewers commented on the potential use of enhanced external counterpulsation in those with angina not amenable to surgical interventions.

### **Practice Guidelines and Position Statements**

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

### **Joint Guidelines from the American College of Cardiology Foundation, American Heart Association et al**

In 2012, the American College of Cardiology Foundation, American Heart Association, and 5 other medical societies published joint guidelines that recommended: "[patients with stable ischemic heart disease who indicate for enhanced external counterpulsation (EECP)] may be considered for relief of refractory angina." This recommendation was class IIb, based on level B evidence (ie, the efficacy of the intervention is not well established, and further studies would be helpful).

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In 2014, the American College of Cardiology Foundation and American Heart Association updated these joint guidelines. Based on this review, the groups did not change their recommendation on EECP from the 2012 guidelines.

In 2013, the American College of Cardiology Foundation and American Heart Association issued guidelines on the management of heart failure but did not address EECP. The 2017 focused update also did not address EECP.

### **U.S. Preventive Services Task Force Recommendations**

Not applicable.

### **Medicare National Coverage**

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

"Coverage is provided for the use of ECP [external counterpulsation] 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 decision also noted that while the U.S. Food and Drug Administration 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...."

### **Ongoing and Unpublished Clinical Trials**

A search of ClinicalTrials.gov in March 2023 did not identify any ongoing or unpublished trials that would likely influence this review.

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# Louisiana

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# Louisiana

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Policy # 00036

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## Policy History

Original Effective Date: 11/12/2001

Current Effective Date: 06/10/2024

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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.  |

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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.  
05/02/2019 Medical Policy Committee review  
05/15/2019 Medical Policy Implementation Committee approval. No change to coverage.

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# Louisiana

## Enhanced External Counterpulsation (EECP)

Policy # 00036

Original Effective Date: 11/12/2001

Current Effective Date: 06/10/2024

05/07/2020 Medical Policy Committee review

05/13/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

05/06/2021 Medical Policy Committee review

05/12/2021 Medical Policy Implementation Committee approval. Coverage eligibility unchanged. Updated FDA.

05/05/2022 Medical Policy Committee review

05/11/2022 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

05/04/2023 Medical Policy Committee review

05/10/2023 Medical Policy Implementation Committee approval. Patient selection completely revised. Added investigational denial statement for when criteria are not met.

05/02/2024 Medical Policy Committee review

05/08/2024 Medical Policy Implementation Committee approval. No change to coverage.

Next Scheduled Review Date: 05/2025

### 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 2023 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*

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

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-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. 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
- 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 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,

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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:** If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**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.

**NOTICE:** Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

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