MEDICAL POLICY

POLICY TITLE	ENHANCED EXTERNAL COUNTERPULSATION (EECP)
POLICY NUMBER	MP 2.014

Effective Date:	10/1/2023

I. POLICY

External Counterpulsation (ECP) may be considered **medically necessary** using a United States Food and Drug Administration (FDA) approved device when **BOTH** of the following are met:

- The individual has been diagnosed with disabling chronic stable angina (Class III or Class IV, New York Heart Association Functional Classification of Cardiac Disability); **AND**
- A cardiologist or cardiothoracic surgeon, documented that the individual is not a candidate for surgical intervention, such as percutaneous coronary intervention (PCI) 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 which create excessive risk.

A full course of therapy usually consists of up to 35 one (1) hour treatments, which may be offered once or twice daily, usually five (5) days per week. This procedure must be done under direct supervision of a physician.

ECP for any other indication including, but not limited to, the following is considered **not medically necessary**:

- Unstable angina
- Acute myocardial infarction
- Cardiogenic shock
- Erectile dysfunction
- Ischemic stroke

Documentation in the medical record must contain a history and physical pertinent to the indications of this policy and be available upon request.

Repeat courses of ECP will be considered **medically necessary** for individuals with chronic stable angina if **ALL** the following criteria are met:

- Individual meets medical necessity criteria for ECP; **and**
- Prior ECP has resulted in a sustained improvement in symptoms, with:
  - A significant (greater than 25%) reduction in frequency of angina symptoms; **or**
  - Improvement by one or more angina classes; **and**
  - Three (3) or more months has elapsed from the prior ECP treatment.

Repeat courses of ECP for any other indication is considered **not medically necessary.**

Hydraulic versions of ECP devices are non-covered due to the limited use of the device.

New York Heart Association Functional Classification of Cardiac Disability:

Class I	Patients with cardiac disease but without limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.
Class II	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 III	Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary physical activity causes fatigue, palpitation, dyspnea, or anginal pain.
Class IV	Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency or of the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased

Source: American Heart Association, Classes of Heart Failure. 2017.

Cross-reference:

MP 1.057 Transmyocardial Revascularization

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:
https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

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III. DESCRIPTION/BACKGROUND

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Enhanced external counterpulsation (EECP) is a noninvasive treatment used to augment diastolic pressure, decrease left ventricular afterload, and increase venous return. It has been studied primarily as a treatment for individuals with refractory angina and heart failure.

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.

Regulatory Status

A variety of enhanced external counterpulsation (EECP) devices have been cleared for marketing by the Food and Drug Administration (FDA) through the 510(k) process. Examples of EECP devices with FDA clearance are outlined in Table 1.

Table 1: FDA-Cleared EECP Devices

Device	Manufacturer	Clearance Date	Indications
External Counterpulsation System	Vamed Medical Instrument	Sep 2019	• Chronic stable angina refractory to optimal anti-anginal medical therapy and without options for revascularization • In healthy patients to improve vasodilation, increase Vo2, and increase blood flow

Pure Flow External Counter-Pulsation Device	Xtreem Pulse	May 2018	• Chronic stable angina refractory to optimal anti-anginal medical therapy and without options for revascularization • In healthy patients to improve vasodilation, increase Vo2, and increase blood flow
Renew® NCP-5 External Counterpulsation System	Renew Group	Dec 2015	• Chronic stable angina refractory to optimal anti-anginal medical therapy and without options for revascularization • In healthy patients to improve vasodilation, increase Vo2, 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)	March 2005	• 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)	August 2004	• Stable or unstable angina pectoris • Acute myocardial infarction • Cardiogenic shock • Congestive heart failure
EECP® Therapy System	Vasomedical (Westbury, NY)	March 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.

IV. RATIONALE

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Summary of Evidence

For individuals who have heart failure who receive EECP, the evidence includes RCTs, observational studies, and systematic reviews. Relevant outcomes are overall survival, symptoms, morbid events, and functional outcomes. One RCT that reported on clinical outcomes found a modest benefit with EECP on some outcomes and no benefit on others. A second RCT reported improvements on the 6-minute walk test with EECP but had methodologic limitations; RCT findings ultimately proved inconclusive. The observational studies on EECP in heart failure have limited ability to inform the evidence on EECP due to the multiple confounding variables for cardiac outcomes and the potential for a placebo effect. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have other conditions related to ischemia or vascular dysfunction who receive EECP, the evidence includes RCTs, registry studies, and systematic reviews. Relevant outcomes are overall survival, symptoms, morbid events, and functional outcomes. Two RCTs have assessed use of EECP for treatment of central retinal artery occlusion; both trials had methodologic limitations. Registry studies of erectile function have reported improvements for some outcomes with ECCP, but design shortcomings limit conclusions drawn. EECP has also been used to treat acute ischemic stroke, but the evidence base in is not robust. EECP has been used in a small RCT to treat type 2 diabetes. Reported follow-up was short term. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

V. DEFINITIONS

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AFTERLOAD is the load or resistance, against which the left ventricle must eject its volume of blood during contraction. The resistance is produced by the volume of blood already in the vascular system and the vessel walls.

DIASTOLE is the normal period in the heart cycle during which the muscle fibers lengthen, the heart dilates, and the cavities fill with blood.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member’s health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member’s health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

Procedure codes								
92971	G0166							

ICD-10-CM Diagnosis Codes	Description
I20.1	Angina pectoris with documented spasm
I20.81	Angina pectoris with coronary microvascular dysfunction
I20.89	Other forms of angina pectoris
I25.111	Atherosclerotic heart disease of native coronary artery with angina pectoris with documented spasm
I25.112	Atherosclerotic heart disease of native coronary artery with refractory angina pectoris
I25.118	Atherosclerotic heart disease of native coronary artery with other forms of angina pectoris
I25.119	Atherosclerotic heart disease of native coronary artery with unspecified angina pectoris
I25.701	Atherosclerosis of coronary artery bypass graft(s), unspecified, with angina pectoris with documented spasm
I25.702	Atherosclerosis of coronary artery bypass graft(s), unspecified, with refractory angina pectoris

I25.708	Atherosclerosis of coronary artery bypass graft(s), unspecified, with other forms of angina pectoris
I25.709	Atherosclerosis of coronary artery bypass graft(s), unspecified, with unspecified angina pectoris
I25.711	Atherosclerosis of autologous vein coronary artery bypass graft(s) with angina pectoris with documented spasm
I25.712	Atherosclerosis of autologous vein coronary artery bypass graft(s) with refractory angina pectoris
I25.718	Atherosclerosis of autologous vein coronary artery bypass graft(s) with other forms of angina pectoris
I25.719	Atherosclerosis of autologous vein coronary artery bypass graft(s) with unspecified angina pectoris
I25.721	Atherosclerosis of autologous artery coronary artery bypass graft(s) with angina pectoris with documented spasm
I25.722	Atherosclerosis of autologous artery coronary artery bypass graft(s) with refractory angina pectoris
I25.728	Atherosclerosis of autologous artery coronary artery bypass graft(s) with other forms of angina pectoris
I25.729	Atherosclerosis of autologous artery coronary artery bypass graft(s) with unspecified angina pectoris
I25.731	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with angina pectoris with documented spasm
I25.732	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with refractory angina pectoris
I25.738	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with other forms of angina pectoris
I25.739	Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with unspecified angina pectoris
I25.751	Atherosclerosis of native coronary artery of transplanted heart with angina pectoris with documented spasm
I25.752	Atherosclerosis of native coronary artery of transplanted heart with refractory angina pectoris
I25.758	Atherosclerosis of native coronary artery of transplanted heart with other forms of angina pectoris
I25.759	Atherosclerosis of native coronary artery of transplanted heart with unspecified angina pectoris
I25.761	Atherosclerosis of bypass graft of coronary artery of transplanted heart with angina pectoris with documented spasm
I25.762	Atherosclerosis of bypass graft of coronary artery of transplanted heart with refractory angina pectoris

I25.768	Atherosclerosis of bypass graft of coronary artery of transplanted heart with other forms of angina pectoris
I25.769	Atherosclerosis of bypass graft of coronary artery of transplanted heart with unspecified angina pectoris
I25.791	Atherosclerosis of other coronary artery bypass graft(s) with angina pectoris with documented spasm
I25.792	Atherosclerosis of other coronary artery bypass graft(s) with refractory angina pectoris
I25.798	Atherosclerosis of other coronary artery bypass graft(s) with other forms of angina pectoris
I25.799	Atherosclerosis of other coronary artery bypass graft(s) with unspecified angina pectoris

IX. REFERENCES

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X. POLICY HISTORY

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MP 2.014	**CAC 1/28/03**
	CAC 10/28/03
	CAC 8/31/04
	CAC 8/30/05
	CAC 4/25/06
	CAC 3/27/07
	CAC 5/27/08
	CAC 5/26/09
	CAC 5/25/10 Consensus
	CAC 4/26/11 Consensus
	CAC 2/28/12 Adopt BCBSA. Procedure now considered investigational; previously considered medically necessary, Policy title revised from Enhanced External Counterpulsation (EECP) to Enhanced External

	Counterpulsation (EECP) for Chronic Angina or Heart Failure. FEP variation revised.
	CAC 3/26/13 Consensus review. References updated but no changes to the policy statement. Codes reviewed.
	CAC 1/28/14 Consensus. No change to policy statements. References updated. Rationale section and Policy guidelines added. Changed title - was Enhanced External Counterpulsation (EECP) for Chronic Stable Angina or Heart Failure.
	CAC 1/27/15 Consensus. No change to policy statements. References and rationale updated.
	CAC 1/26/16 Consensus. No change to policy statements. References and rationale updated. Coding updated**.**
	Admin update 1/1/17: Product variation section reformatted.
	CAC 3/28/17 Consensus review. No change to policy statements. References and rationale updated. Coding Reviewed.
	1/1/18 Admin Update: Medicare variations removed from Commercial Policies.
	1/15/18 Consensus review. No change to policy statements. References and rationale reviewed.
	1/15/19 Consensus review. No change to policy statements. Background and references updated. Rationale condensed.
	01/21/2020 Consensus review. No change to policy statements. References updated.
	1/5/2021 Major review. Policy statement changed from investigational to medically necessary when criteria met. References and Coding updated.
	7/28/2022 Administrative update. ICD-10 codes added I25.112, I25.702, I25.712, I25.722, I25.732, I25.752, I25.762. Effective 10/1/22
	9/8/2022 Consensus Review. No change to policy statement. References and rationale updated. Coding reviewed.
	09/07/2023 Consensus Review. No change to policy statement. Background, Rationale and References updated.
	09/11/2023 Administrative update. ICD10 code definitions revised due to new code. Added ICD10 codes I20.81 and I20.89. Removed ICD 10 I20.8. Effective 10/1/2023

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