Medical Coverage Policy | Enhanced External Counterpulsation (EECP)

EFFECTIVE DATE: 12|01|2014
POLICY LAST UPDATED: 05|17|2023

OVERVIEW
This policy documents coverage guidelines for Medicare Advantage Plans and Commercial Products for enhanced external counterpulsation (EECP) used in outpatient treatment. 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 patients with refractory angina and heart failure.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Medicare Advantage Plans
EECP is covered for Medicare Advantage Plan members.

Note: Blue Cross & Blue Shield of Rhode Island (BCBSRI) must follow Centers for Medicare and Medicaid Services (CMS) guidelines, such as national coverage determinations or local coverage determinations for all Medicare Advantage Plan policies. Therefore, Medicare Advantage Plan policies may differ from Commercial products. In some instances, benefits for Medicare Advantage Plans may be greater than what is allowed by the CMS.

Commercial Products
EECP used in outpatient treatment is not medically necessary for all indications, including but not limited to, treatment of chronic stable angina pectoris, heart failure, erectile dysfunction, or ischemic stroke as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

COVERAGE
Benefits may vary between groups/contracts. Please refer to the appropriate section of the Benefit Booklet, Evidence of Coverage or Subscriber Agreement for services not medically necessary.

BACKGROUND
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 35one-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.

Commercial Products

For individuals who have chronic stable angina who receive EECP, the evidence includes randomized controlled trials (RCTs), observational studies, and systematic reviews. Relevant outcomes are overall survival, symptoms, morbid events, and functional outcomes. There is a single-blind RCT that includes clinical outcomes, and it reported benefit on only 1 of 4 main angina outcomes. Additional small RCTs have reported changes in physiologic measures associated with EECP but did not provide relevant evidence on clinical efficacy. Because of the variable natural history of angina, the multiple confounding variables for cardiac outcomes, and the potential for a placebo effect, more RCT evidence is needed. Observational studies, including registry studies with large numbers of patients, add little to determinations of efficacy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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 but not 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 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.

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 and the manufacturers are: External Counterpulsation System (Vamed Medical Instrument), Pure Flow External Counter-Pulsation Device (Xtreem Pulse), Renew® NCP-5 External Counterpulsation System (Renew Group), ECP Health System Model (ECP Health), CardiAssist™Counter Pulsation System (Cardiomedics), ACS Model NCP-2 External Counterpulsation Device (Applied Cardiac Systems), and the EECP® Therapy System (Vasomedical).

For individuals who have chronic stable angina who receive enhanced external counterpulsation (EECP), the evidence includes randomized controlled trials (RCTs), observational studies, and systematic reviews. Relevant outcomes are overall survival, symptoms, morbid events, and functional outcomes. There is a single blinded RCT that includes clinical outcomes, and it reported benefit on only 1 of 4 main angina outcomes. Additional small RCTs have reported changes in physiologic measures associated with EECP but did not provide relevant evidence on clinical efficacy. Because of the variable natural history of angina, the multiple confounding variables for cardiac outcomes, and the potential for a placebo effect, RCT evidence is needed. Observational studies, including registry studies with large numbers of patients, add little

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Medicare Advantage Plans
Medicare has published a national coverage decision on EECP that allows 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 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.

CODING

Medicare Advantage Plans and Commercial Products
The following HCPCS code is covered for Medicare Advantage Plans and not medically necessary for Commercial Products:
G0166 External counterpulsation, per treatment session

RELATED POLICIES

None

PUBLISHED

Provider Update, July 2023
Provider Update, September 2022
Provider Update, July 2021
Provider Update, July 2020
Provider Update, July 2019

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