Medical Coverage Policy |Enhanced External Counterpulsation (EECP)

EFFECTIVE DATE: 12|01|2014
POLICY LAST UPDATED: 05|01|2018

OVERVIEW
This policy documents coverage guidelines for BlueCHiP for Medicare 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, as well as for other indications such as erectile dysfunction and ischemic stroke.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
BlueCHiP for Medicare
EECP is covered for BlueCHiP for Medicare 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 BlueCHiP for Medicare policies. Therefore, BlueCHiP for Medicare policies may differ from Commercial products. In some instances, benefits for BlueCHiP for Medicare 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 there is insufficient peer-reviewed scientific literature to demonstrate that the procedure is effective.
.

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 uses timed, sequential inflation of pressure cuffs on the calves, thighs, and buttocks to augment diastolic pressure, decrease left ventricular (LV) 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 LV contracts, it faces a reduced aortic pressure to work against, 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 and invasive form of counterpulsation that is used as a method of temporary circulatory assistance for the ischemic heart, often after an acute myocardial infarction

(MI). 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 5 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 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 the Renew® NCP-5 External Counterpulsation System, ECP Health System Model, CardiAssist™Counter Pulsation System, ACS Model NCP-2 External Counterpulsation Device, and the EECP® Therapy System.

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. Therefore, observational studies, including registry studies with large numbers of patients, add little to determinations of efficacy. The evidence is insufficient to determine the effects of the technology on health outcomes.

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 the effects of the technology on health outcomes. Therefore this service is considered not medically necessary for Commercial products.
.

CODING

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

RELATED POLICIES

None

PUBLISHED

Provider Update, July 2018
Provider Update, May 2017
Provider Update, August 2016
Provider Update, August 2015
Provider Update, January 2015
Provider Update, November 2013
Provider Update, February 2011
Provider Update, June 2010

REFERENCES

1. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination for external counterpulsation (ECP) therapy fo severe angina (20.20): https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=97&ncdver=2&bc=AgAAgAAAAAAAAA%3d%3d&

2. Fihn SD, Gardin JM, Abrams J et al. 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS Guideline for the diagnosis and management of patients with stable ischemic heart disease: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, and the American College of Physicians, American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. J Am Coll Cardiol 2012; 60(24):e44-e164.

3. 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.

4. 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.

5. Bondesson SM, Edvinsson ML, Pettersson T et al. Reduced peripheral vascular reactivity in refractory angina pectoris: Effect of enhanced external counterpulsation. J Geriatr Cardiol 2011; 8(4):215-23.

6. Abbottsmith CW, Chung ES, Varricchione 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. Nov-Dec 2006; 12(6):307-311.

7. 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. Jun 1999; 33(7):1833-1840.

8. 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. Jan 2002; 50(1):25-3211813825

9. Gloekler S, Meier P, de Marchi SF, et al. Coronary collateral growth by external counterpulsation: a randomised controlled trial. Heart. Feb 2010; 96(3):202-207.

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. Oct 2009; 39(10):866-875.

11. Fihn SD, Blankenship JC, Alexander KP, et al. 2014 ACC/AHA/AATS/PCNA/SCAI/STS focused update of the guideline for the diagnosis and management of patients with stable ischemic heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines, and the American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. J Am Coll Cardiol. Nov 4 2014;64(18):1929-1949. PMID 25077860

CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice. Blue Cross & Blue Shield of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.