Medical Coverage Policy | Enhanced External Counterpulsation (EECP)

EFFECTIVE DATE: 12|01|2014
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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

BlueCHiP for Medicare

EECP is medically necessary for members who have been diagnosed with disabling angina (Class III or Class IV, Canadian Cardiovascular Society Classification or equivalent classification) who, in the opinion of a cardiologist or cardiothoracic surgeon, are not readily amenable to surgical intervention, such as percutaneous transluminal coronary angioplasty (PTCA) or cardiac bypass, and:

1. Their condition is inoperable, or at high risk of operative complications or post-operative failure;
2. Their coronary anatomy is not readily amenable to such procedures; or
3. They have co-morbid states which create excessive risk.

PRIOR AUTHORIZATION

BlueCHiP for Medicare

Prior authorization is required for BlueCHiP for Medicare only and obtained via the online tool for participating providers. See the Related Policies section.

POLICY STATEMENT

BlueCHiP for Medicare

EECP is considered medically necessary for BlueCHiP for Medicare members with preauthorization for the specific conditions listed in the criteria.

Note: Medicare policy is developed separately from BCBSRI policy. Medicare policy incorporates consideration of governmental regulations from CMS (Centers for Medicare and Medicaid Services), such as national coverage determinations or local coverage determinations. In addition to benefit differences, CMS may reach different conclusions regarding the scientific evidence than does BCBSRI. Medicare and BCBSRI policies may differ. However, BlueCHiP for Medicare members must be offered, at least, the same services that Medicare offers.

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 Evidence of Coverage, Subscriber Agreement, or Benefit Booklet for limitations of benefits/coverage when services are 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

While EECP has been primarily researched as a treatment of chronic stable angina, it has also been used in patients with heart failure. The Vasomedical EECP® Therapy System Model has the following labeled indication under 510(k) clearance from U.S. Food and Drug Administration (FDA): "The EECP Therapy System Model TS3 with Pulse Oximetry is a noninvasive external counterpulsation device intended for the use in the treatment of patients with heart failure, stable or unstable angina pectoris, acute myocardial infarction, or cardiogenic shock." Cardiomedics Inc. has FDA 510(k) clearance to market the CardiAssist™ Counterpulsation System (K022107) and the CardiAssist ECP System (K010261) for the same indications as the Vasomedical EECP systems.

The evidence on the efficacy of EECP for treatment of chronic angina is insufficient to form conclusions. There is only 1 blinded randomized controlled trial (RCT) that includes clinical outcomes, and this trial reported benefit on only 1 of 4 main angina outcomes. Additional small RCTs report changes in physiologic measures associated with EECP but do not provide relevant evidence on clinical efficacy. The evidence from observational studies, including registry studies with large numbers of patients, adds little to determinations of efficacy. This is because of the variable natural history of angina, the multiple confounding variables for cardiac outcomes, and the potential for a placebo effect.

For the treatment of heart failure, the evidence is of a similar nature. There is 1 RCT that includes clinical outcomes, and these trial reports modest benefits on some outcomes and no benefit on others. The observational studies on EECP in heart failure have the same limitations as do the studies on chronic angina. There is very limited evidence on the use of EECP for indications other than chronic angina or heart failure. For these reasons, the use of EECP is considered not medically necessary for all indications for Commercial products as there is insufficient peer-reviewed scientific literature to demonstrate that the procedure is effective.

CODING

BlueCHiP for Medicare and Commercial Products

The following HCPCS code is medically necessary for BlueCHiP for Medicare with preauthorization when criteria are met and not medically necessary for Commercial products:

G0166

RELATED POLICIES
Preauthorization via Web-Based Tool for Procedures

PUBLISHED
Provider Update, August 2015
Provider Update, January 2015
Provider Update, November 2013
Provider Update, February 2011
Provider Update, June 2010
Provider Update, November 2008
Policy Update, January 2007

REFERENCES
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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.

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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.

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