ENHANCED EXTERNAL COUNTERPULSATION (EECP)
MED202.050
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COVERAGE:

Enhanced External Counterpulsation (EECP) and similar devices are considered experimental or investigational.

DESCRIPTION:

EECP is a noninvasive treatment that 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. 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 left ventricle contracts, it faces reduced aortic pressure to work against since 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 an acute myocardial infarction. 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 EKGs to trigger inflation and deflation, and optional use of pulse oximetry to measure oxygen saturation before and after treatment.

RATIONALE:

This policy is based on a 1999 TEC Assessment, which offered the following observations and conclusions:

• The most important evidence about EECP consists of data from the Multicenter Study of Enhanced External Counterpulsation (MUST-EECP). This study was a randomized, controlled, double-blinded protocol comparing active treatment to placebo among 139 patients with chronic stable angina.

• In this trial there was a statistically significant increase in time to ST segment depression in the treated patients vs. the sham treated patients, suggesting a real physiologic post-treatment effect of EECP. However, the clinical significance of this mean 37-
second increase is unclear. The trial also reported a significant reduction in the number of anginal episodes, but statistical significance was only reached when the analysis was limited to those patients who had completed 34 or more sessions. Thus it is unclear whether these results are related in part to selection bias or a true treatment effect.

- The Assessment concluded that there is not sufficient evidence to draw conclusions about the long-term benefits of EECP, its effects on morbidity or mortality, and its place in the continuum of management options for patients with chronic stable angina, particularly if it is suggested as an alternative to surgical revascularization.

2002 Update

EECP was the subject of a 2002 TEC Assessment. The TEC Assessment concluded that the evidence was insufficient to determine whether EECP improved the net health outcome or is as beneficial as any established alternatives in patients with chronic, stable angina. Therefore, the policy statement is unchanged. Specifically, the TEC Assessment offered the following observations and conclusions:

- There is insufficient evidence to draw conclusions about the benefits of EECP.
- The available evidence is limited by lack of comparison groups in more reported studies. The results of the randomized controlled trial (MUST-EECP) must be interpreted with caution, in view of the high subject dropout rate and uncertainty regarding the clinical significance of the reported improvement in physiologic measures, especially when intent-to-treat analysis is applied.
- Most recently, 5 studies have reported the outcomes of large numbers of patients treated in a number of different institutions. There are several problems with this kind of evidence. There is no comparison group, and thus it is impossible to determine whether such improvement is due to EECP.

Medicare Policy

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

“Coverage is provided for the use of ECP 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 PTCA or cardiac bypass because:

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

PRICING:
None

REFERENCES:
• BCBSA TEC Evaluation, Enhance External Counterpulsation for Treatment of Chronic Stable Angina Pectoris, 6/2002
• Medicare Policy: www.hcfa.gov/pubforms/PUB06PDF/part_35.pdf

DISCLAIMER:
State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, takes precedence over Medical Policy and must be considered first in determining coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Any benefits are subject to the payment of premiums for the date on which services are rendered. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically. HMO Blue Texas physicians who are contracted/affiliated with a capitated IPA/medical group must contact the IPA/medical group for information regarding HMO claims/reimbursement information and other general polices and procedures.