Decision Memo for External Counterpulsation (ECP) Therapy (CAG-00002N)

Decision Summary

Amend Coverage Issues Manual section 35-74:

1. **The title will read**: EXTERNAL COUNTERPULSATION (ECP) FOR SEVERE ANGINA—COVERED (effective for services performed on or after July 1, 1999).
2. **The first sentence of the instruction will read**: External counterpulsation (ECP), commonly referred to as enhanced external counterpulsation, is a non-invasive outpatient treatment for coronary artery disease refractory to medical and/or surgical therapy.
3. All references to the acronym EECP will be deleted and replaced by ECP.
4. Paragraph 2 (Coverage is further limited…) will be deleted.

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Decision Memo

To: File: CAG-00002N
External Counterpulsation Therapy

From:

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RE: External Counterpulsation

Date: November 22, 1999

Background

External counterpulsation (ECP) is a noninvasive treatment developed for the treatment of end stage angina pectoris that is refractory to conventional therapy (i.e. surgery, angioplasty), acute myocardial infarction, and cardiogenic shock. External counterpulsation involves the sequential compression (inflation/deflation) of cuffs wrapped around the patient's calves, thighs, and buttocks. By timing the inflation/deflation sequence to the patient's cardiac cycle, the intention of ECP is to increase diastolic aortic pressure, thereby increasing coronary perfusion pressure possibly by enhancing the development of coronary collateral circulation and reducing the workload of the heart. Treatment usually consists of one-hour sessions, five days a week, for seven weeks.

Although the Food and Drug Administration has approved ECP devices for the uses mentioned above through the 510(K) process, most of the medical literature surrounding this treatment has focused on its use for the treatment of severe angina refractory to other medical and surgical treatment.

HCFA Coverage

Although manufacturers of this device had periodically presented information to HCFA, limited clinical and scientifically valid information precluded HCFA staff from issuing any positive coverage determination.

In December 1997, Vasomedical, Inc. (the manufacturer of the Vasomedical Enhanced External Counterpulsation System, model EECP-MC2) presented clinical data from the Multicenter Study of Enhanced External Counterpulsation (MUST-EECP). This multicenter, prospective, randomized, double-blinded, sham-controlled study evaluated the clinical benefits of ECP on patients with stable angina with Canadian Cardiovascular Society Functional (CCSF) Classification System scores I-III. Four primary outcomes were examined:

- angina counts;
- nitroglycerine usage;
- exercise duration (treadmill test); and
- time to >1–mm ST-segment depression during exercise.

139 patients were randomized in MUST-EECP. There were no statistically significant differences between groups in age, percent male, race, CCSF scores, previous percutaneous transluminal coronary angioplasty (PTCA), previous coronary artery bypass graft surgery (CABG) and cardiovascular medications. The group receiving active therapy had a longer history of angina, higher percentage of myocardial infarction, and more residual 3-vessel disease.

Results

There was no statistically significant difference between groups in change in exercise duration from baseline to posttreatment ($p > 0.3$) nor nitroglycerine use ($p > 0.1$).

In the intention to treat analysis, the active ECP group had fewer anginal episodes than the control group, but this trend did not reach statistical significance ($p < .09$). In patients who completed more than 34 active ECP sessions, the difference between groups in the change in angina counts were statistically significant ($p < .035$).

There was a statistically significant difference between groups in the change in time to exercise- induced ischemia from baseline to posttreatment ($p = .01$).

Current Policy

Prior to July 1, 1999, a national noncoverage policy for all uses of ECP was delineated in section 35-74 of the Medicare Coverage Issues Manual (CIM).

Subsequent to the presentation of the MUST-EECP data and further review by Coverage and Analysis staff, it was determined that this was a "reasonable and necessary" treatment for certain Medicare beneficiaries suffering from stable angina pectoris refractory to medical and/or surgical therapy.

Section 35-74 of the Medicare Coverage Issues Manual (CIM) was amended to remove the national noncoverage policy previously in place and allow coverage for this procedure under certain circumstances. This change became effective July 1, 1999.

Coverage of this therapy is provided for patients who have been diagnosed with disabling angina (Class III or Class IV, CCSF score or equivalent classification) who, in the opinion of a cardiologist or cardiothoracic surgeon are not readily amenable to surgical intervention.

Furthermore, coverage was limited to those enhanced external counterpulsation systems that have sufficiently demonstrated their medical effectiveness in treating patients with severe angina in well-designed clinical trials.

Enhanced External Counterpulsation (EECP) and External Counterpulsation (ECP)

Prior to the recent CIM revision, the national noncoverage policy referred to this procedure as "external counterpulsation (ECP)." Effective July 1, 1999 the wording of the instruction was changed to "Enhanced External Counterpulsation (EECP)." HCFA rationale for this change was based on the information presented by Vasomedical, Inc. which referred to their device as the "Enhanced External Counterpulsation (EECP®) System" and the name of the therapy as "Enhanced External Counterpulsation." Additionally, the majority of the medical literature regarding this procedure refers to EECP, and the MUST-EECP study was conducted using devices supplied by Vasomedical, Inc.

Currently, another device with 510(K) approval, manufactured by Cardiomedics, Inc. under the name "Cardiassist™" is marketed for use similar to the Vasomedical, Inc. model EECP-MC2. Cardiomedics, Inc. received this 510(K) approval in 1987 under the trade name " Cardiomedics External Counterpulsation System." Cardiomedics markets the Cardiassist™ device as an external counterpulsation (ECP) system that involves the sequential inflation of cuffs wrapped around the patients' calves, thighs, and buttocks.

The first 510(K) for a counterpulsation device was granted in 1980 to the Cardiassist Corp. This initial device used 2 water filled bladders which inflated at the same time. Currently, both devices on the market represent a substantial improvement in technology from the original device.

Recent Developments

In June of 1999, representatives from Cardiomedics, Inc. met with the director and staff members of the Coverage and Analysis Group to present the findings of an operational/functional analysis and comparison of the Cardiassist™ and EECP-MC2 devices performed by an independent product testing firm. This report concluded, "while there are ergonomic operator differences that the medical therapist using each device may prefer, from an operational and functional standpoint there are no discernable differences [between devices]."

At the same meeting, Cardiomedics staff also presented the findings of an unpublished retrospective collection of data from 21 serially treated patients who received 30-35 hours of counterpulsation using the Cardiassist™ device. This study found reductions in CCSF scores, anginal episodes, nitroglycerine usage, and hospitalizations in treated patients.

Information was also presented about the terminolgy (EECP) used in the CIM. Cardiomedics objected to the use of this term, suggesting that HCFA alter the language of the instruction so that coverage of this treatment would not exclude manufacturers other than Vasomedical.

It was explicitly stated at that time that this meeting represented a formal request by Cardiomedics for reconsideration of the national coverage policy for EECP. In a follow up letter to the company, Coverage and Analysis Director Grant Bagley indicated that the results of the functional analysis and the retrospective study, along with any additional data provided, would be compared with previous scientific studies and trials in order to determine whether "subject devices are sufficiently similar in functional characteristics and clinical outcomes to broaden our coverage policy." Dr. Bagley also noted that there were several other parties interested in reconsideration of this policy, and alerted Cardiomedics' staff to the possibility that Coverage and Analysis staff expected these parties to submit data for consideration. Cardiomedics responded promptly to HCFA's concerns with additional patient data and a more complete explanation of the submitted information.

While this source and type of data would not satisfy our criteria for a coverage decision, in this case the question is one of equivalence between devices. We believe that the data submitted is sufficient to demonstrate equivalent performance and therefore can be used in conjunction with our prior analysis to modify the existing policy.

On October 6, 1999, HCFA accepted as formal a request for reconsideration of the entire EECP policy submitted by Dr. Paul G. Deutsch, MD, on behalf of the Medicare Contractor Medical Director New Technology Workgroup. This request contained an analysis which suggested that HCFA misinterpreted the MUST-EECP study results.

While this request has outlined several valid concerns related to the data, we critically reviewed the initial results of the MUST-EECP study in our original determination. As a result, we were aware at the time of the initial coverage decision of every issue and limitation of the MUST-EECP study that Dr. Deutsch et al. raised. We still believe after review of this reconsideration as well as other supporting studies that a small group of patients with refractory angina pectoris can benefit from this therapy.

We acknowledge that questions regarding long term benefit of this therapy remain. However, we feel that those beneficiaries meeting the criteria outlined in the coverage instruction can derive clinical benefit from this treatment modality.

It is with this understanding that a small subset of patients with coronary artery disease refractory to conventional therapy should have access to the potential benefits from a full course of ECP treatment. Therefore, coverage for ECP will be provided to those Medicare beneficiaries who meet those criteria outlined in the CIM.

Final Action

Because of the common use of the term EECP by the medical community, the trademarked status of the acronym EECP® by Vasomedical, Inc., and the confusion caused by the language of the initial coverage instruction, we feel that a modification of the CIM is necessary to clarify this issue.

Decision

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