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

Decision Summary

Amend CIM 35-74 to indicate that this policy **only** pertains to ECP devices intended for the treatment of certain cardiac conditions.

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Decision Memo

TO: Administrative File CAG-00002R

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SUBJECT: National Coverage Determination

DATE: July 10, 2001

This memo serves four purposes: (1) describes external counterpulsation (ECP); (2) reviews the history of Medicare's coverage process for ECP and provides a description of the current issue; (3) presents the relevant information related to this request; and (4) delineates the reasons for amending the national coverage determination to limit the ECP policy only to ECP devices intended for the treatment of certain cardiac conditions.

Clinical Background

ECP is a noninvasive therapy 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. ECP 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 (FDA) has cleared ECP devices for the indications mentioned above through the 510(K) process, most of the medical literature surrounding this therapy has focused on its use for the treatment of severe angina refractory to other medical and surgical treatment.

Medicare Coverage Process and 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 new data from a large randomized trial[1] and further review by Coverage and Analysis staff, it was determined that this therapy was a "reasonable and necessary" treatment only for certain Medicare beneficiaries suffering from stable angina pectoris refractory to medical and/or surgical therapy.[2]

Section 35-74 was amended to remove the national noncoverage policy previously in place and allow coverage for this procedure under certain circumstances. Coverage for ECP is only provided for patients 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. This change became effective July 1, 1999.

Effective July 1, 1999, the wording of the instruction was changed to "Enhanced External Counterpulsation (EECP)." The Centers for Medicare and Medicaid Services (CMS), formerly the Health Care Financing Administration (HCFA), rationale for this change was based on the information presented by Vasomedical, Inc., which referred to its 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.

Soon after this decision, another manufacturer, Cardiomedics Inc., presented information about the EECP terminology used in the CIM. Cardiomedics Inc. objected to the use of this trademarked term, suggesting that CMS alter the language of the instruction so that coverage of this treatment would not exclude manufacturers other than Vasomedical. CMS accepted Cardiomedic's formal request to reconsider this decision on July 9, 1999.

On October 6, 1999, CMS accepted a request for reconsideration of the entire EECP policy submitted on behalf of the Medicare Contractor Medical Director New Technology Workgroup. The Workgroup request included a detailed analysis of how we allegedly materially misinterpreted the MUST-EECP study, on which the original coverage determination was primarily based. The Workgroup believed that the study did not present sufficient data to support Medicare's coverage of ECP for the treatment of disabling angina. Because both requests asked us to reconsider our national policy referring to ECP, we combined them to further evaluate this service.

After a review of these reconsideration requests, we concluded that a small group of patients with refractory angina pectoris could still potentially benefit from this therapy, and we maintained the positive coverage determination previously discussed. Furthermore, we amended the CIM to remove any reference to the trademarked term EECP, and removed language which had limited coverage of this therapy to specific ECP systems.[3]

In this revision, language was maintained in the CIM which stated that "other uses of this [ECP] device and similar devices remain non-covered." The intention of this phrase was to exclude coverage of ECP devices and similar devices for the treatment of cardiac conditions **other** than stable angina pectoris, (for example, acute myocardial infarction and cardiogenic stroke).

Current Request

On April 11, 2001, CMS accepted a request from the Circulator Boot Corporation to reconsider the ECP policy. In its request, the Circulator Boot Corporation pointed out that the original evidence considered for this [ECP] policy did not support CMS' statement that "other uses of this device and similar devices remain non-covered." This request was based on the contention that CMS had misinterpreted the ECP evidence to include non-coverage of other end diastolic pneumatic compression devices cleared by the FDA for non-cardiac conditions. Furthermore, the Circulator Boot Corporation pointed out that CIM 35-74 explicitly defines ECP as a non-invasive outpatient treatment for coronary artery disease refractory to medical and or surgical therapy, with no specific mention of coverage or noncoverage for other non -cardiac indications.

This request was initiated by the Circulator Boot Corporation after several months of dialogue with Medicare contractors, who, according to the company, had been denying claims for the Circulator Boot based on CIM 35-74 subsequent to the revised ECP policy. In communications received from Medicare contractors, the company was told that "the specific reason for non-coverage of Circulator Boot therapy is that, based on Medicare's review of the information and use of the Circulator Boot, it has been concluded that the device and its use is similar to that of ECP."[4] Because the device was considered similar to ECP devices used for cardiac conditions, it could be said to fall within the CIM's exclusion of coverage for "similar devices."

In a follow-up letter dated June 24, 2000,[5] and provided to CMS as part of the request, the Circulator Boot Corporation outlined the primary differences between the Circulator Boot and ECP devices. These included differences in indications, contraindications, number of pneumatic bags and/or treatment areas, and pressure, timing and sequence of bag inflations. At the core of its request, the Circulator Boot Corporation contends that the Circulator Boot was designed for the treatment of vascular diseases of the lower extremity and therefore differs significantly from ECP devices that are designed for the treatment of cardiac conditions.

According to the 510(k) summary information included in the FDA's clearance letter dated August 14, 1997, the Circulator Boot was found to be equivalent to the original Circulator Boot, the Jobst Extremity Pump, and the Cardiassist ECP device. For classification and review purposes, the FDA has historically placed the Circulator Boot in the "Device, Counter-Pulsating, External" category, along with ECP and other similar devices, although the Jobst Extremity Pump is classified in the "Sleeve, Limb, Compressible" device category.[6] Note that devices with similar FDA classifications do not necessarily imply that the clinical indications of the devices are the same.

In this approval letter, the FDA listed the following indications for use of the Circulator Boot:

- Peripheral arterial disease
- Ischemic lesions
- Claudication pain
- Necrotizing cellulitis
- Venous stasis ulcers
- Stasis dermatitis
- Chronic lymphedema
- Thrombophlebitis

In addition, the Circulator Boot was described as "an end diastolic pneumatic compression device made up of several components. A double walled plastic bag is placed over the leg of the patient and then placed inside a rigid plastic boot. The boot is then attached to a valve system which is connected to an air supply. The valve is also connected to an EKG QRS monitor that times the compression cycle to occur after a variable (operator selected) delay following the QRS cycle."[7] This 510(K) clearance did not require any clinical data regarding the effectiveness of the Circulator Boot for the indications listed above.

CMS Analysis

This reconsideration does not address the potential medical benefit of the Circulator Boot or other end diastolic pneumatic compression devices intended for non-cardiac conditions, and at no time was any scientific or clinical evidence examined during the course of this review that would allow us to make such a determination.[8] The intention of this reconsideration is to review whether CIM 35-74 is relevant to other end diastolic pneumatic compression devices for the treatment of non-cardiac conditions.

The language currently used in CIM 35-74 suggests that devices similar to ECP systems but intended for non-cardiac conditions are noncovered. In evaluating this request, we examined the precedent NCDs and the information received from the public to determine whether this language needs to be revised.

We received additional information from the Circulator Boot Corporation, a letter from Vasomedical, Inc., and several letters from physicians and patients who have used the Circulator Boot for various non-cardiac indications. In summary, these letters clearly support the Circulator Boot Corporation's contention that these end diastolic pneumatic compression devices intended for the treatment of certain non-cardiac conditions are not ECP devices used for the treatment of cardiac conditions and should not be linked to the coverage requirements as stated in CIM 35-74.

We have determined that at no time during the initial coverage determination for ECP or the first reconsideration did CMS examine any scientific or clinical evidence related to end diastolic pneumatic compression devices intended for non-cardiac conditions. Furthermore, CMS did not perform any formal coverage review regarding these devices. Because CMS has not reviewed any evidence regarding the potential medical benefit of these end diastolic pneumatic compression devices intended for noncardiac conditions, we are not making any affirmative national coverage or noncoverage determination regarding these devices. Accordingly, coverage of these devices is left to Medicare contractor discretion.

Conclusion

The policy set forth in CIM section 35-74 should be limited to ECP devices intended for the treatment of cardiac conditions. Other non-cardiac conditions in which end diastolic pneumatic compression devices may be considered for coverage are not considered under this policy. Therefore, Medicare contractors continue to have discretionary authority in making reasonable and necessary coverage determinations related to other end diastolic pneumatic compression devices not related to this policy or included in any other section of the CIM.

Decision

Amend CIM 35-74 to indicate that this policy **only** pertains to ECP devices intended for the treatment of certain cardiac conditions.

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[1] The Multicenter Study of Enhanced External Counterpulsation (MUST-EECP): Effect of EECP on Exercise-Induced Myocardial Ischemia and Anginal Episodes. *Journal of the American College of Cardiology* 1999;33(7):1833-1840.

[2] See ECP Decision Memorandum (CAG #00002) dated 12/30/98.

[3] See ECP Decision Memorandum (CAG #00002) dated 11/22/99.

[4] See letter from Andrew Bloschichak, MD, to Richard Dillon, MD, June 16, 2000.

[5] See Letter from Richard Dillon, MD, to Andrew Bloschichak, MD, June 24, 2000.

[6] The Circulator Boot Corporation was the first device to receive a 510(k) classification in this category in 1978.

[7] See 510(k) summary submitted to the FDA by the Circulator Boot Corporation.

[8] See current Tracking Sheet for information about our formal coverage review related to pneumatic compression pumps for venous insufficiency.

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