CMS Manual System

Pub 100-03 Medicare National Coverage Determinations

Transmittal 50

Department of Health & Human Services (DHHS)

Centers for Medicare & Medicaid Services (CMS)

Date: MARCH 31, 2006

Change Request 4350

SUBJECT: External Counterpulsation Therapy

I. SUMMARY OF CHANGES: After a reconsideration of the NCD on external counterpulsation therapy, the decision was made to continue current coverage and not to expand coverage to additional cardiac indications. Current coverage remains in effect. This update to section 20.20 of Pub. 100-03 is a NCD made under section 1862(a)(1) of the Social Security Act. NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, health maintenance organizations, competitive medical plans, health care prepayment plans, the Medicare Appeals Council, and administrative law judges (see 42 CFR section 405.1064, effective May 1, 2005). An NCD is also binding on a Medicare advantage organization. In addition, an administrative law judge may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

NEW/REVISED MATERIAL
EFFECTIVE DATE: March 20, 2006
IMPLEMENTATION DATE: April 3, 2006

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS:
R = REVISED, N = NEW, D = DELETED

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/Table of Contents
R	1/20.20/External Counterpulsation (ECP) Therapy (Effective March 20,2006)

III. FUNDING:
No additional funding will be provided by CMS; contractor activities are to be

carried out within their FY 2006 operating budgets.

IV. ATTACHMENTS:

Manual Instruction

Unless otherwise specified, the effective date is the date of service.

Medicare National Coverage Determinations Manual

Chapter 1, Part 1 (Sections 10 – 80.12)

Coverage Determinations

Table of Contents
(Rev. 50, 03-31-06)

20.20 - External Counterpulsation (ECP) *Therapy* for Severe Angina *(Effective March 20, 2006)*

(Rev. 50, Issued: 03-31-06; Effective: 03-20-06; Implementation: 04-03-06)

A. General

External counterpulsation (ECP), commonly referred to as enhanced external counterpulsation, is a noninvasive outpatient treatment for coronary artery disease refractory to medical and/or surgical therapy. Although ECP devices are cleared by the Food and Drug Administration (FDA) for use in treating a variety of cardiac conditions, including stable or unstable angina pectoris, acute myocardial infarction and cardiogenic shock, the use of this device to treat cardiac conditions other than stable angina pectoris is not covered, since only that use has developed sufficient evidence to demonstrate its medical effectiveness. Non-coverage of hydraulic versions of these types of devices remains in force.

B. Nationally Covered Indications

Effective for services performed on or after July 1, 1999, coverage is provided for the use of ECP 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, such as PTCA or cardiac bypass, because:

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 that create excessive risk.

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 patient is placed on a treatment table where their lower trunk and lower extremities are wrapped in a series of three compressive air cuffs which inflate and deflate in synchronization with the patient's cardiac cycle.

During diastole, the three sets of air cuffs are inflated sequentially (distal to proximal) compressing the vascular beds within the muscles of the calves, lower thighs and upper thighs. This action results in an increase in diastolic pressure, generation of retrograde arterial blood flow and an increase in venous return. The cuffs are deflated simultaneously just prior to systole which produces a rapid drop in vascular impedance, a decrease in ventricular workload and an increase in cardiac output.

The augmented diastolic pressure and retrograde aortic flow appear to improve myocardial perfusion, while systolic unloading appears to reduce cardiac workload and oxygen requirements. The increased venous return coupled with enhanced systolic flow appears to increase cardiac output. As a result of this treatment, most patients experience increased time until onset of ischemia, increased exercise tolerance, and a reduction in the number and severity of anginal episodes. Evidence was presented that this effect lasted well beyond the immediate post-treatment phase, with patients symptom-free for several months to 2 years. This procedure must be done under direct supervision of a physician.

C. Nationally Non-Covered Indications

All other cardiac conditions not otherwise specified as nationally covered for the use of ECP remain nationally non-covered.

(This NCD last reviewed March 2006.)