01-93000-26 Original Effective Date: 01/01/00 Reviewed: 06/27/24

Revised: 07/15/24

Subject: External Counterpulsation (ECP)

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	<u>Reimbursement</u>	Program Exceptions	Definitions	<u>Related</u> <u>Guidelines</u>
Other	<u>References</u>	Updates			

DESCRIPTION:

External counterpulsation (ECP), also known as enhanced external counterpulsation (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. The mechanism of action is the augmentation of diastolic pressure by displacement of a volume of blood backward into the coronary arteries during diastole when the heart is in a state of relaxation and resistance in the coronary arteries is at a minimum. The resulting increase in coronary artery perfusion pressure enhances coronary collateral development or increase flow through existing collaterals. In addition, when the left ventricular contracts, it faces a reduced aortic counterpressure because the counterpulsation has somewhat emptied the aorta. ECP has been primarily investigated as a treatment for chronic stable angina.

Under direct supervision of a physician, 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.

Multiple external counterpulsation devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process.

POSITION STATEMENT:

External counterpulsation (using FDA-approved external counterpulsation systems) **meets the definition of medical necessity** for members with disabling stable angina (Class III or Class IV based on the Canadian Cardiovascular Society Functional Classification scale or equivalent*) **AND** who are not amenable to surgical intervention, such as percutaneous transluminal coronary angioplasty (PTCA) or coronary artery bypass graft (CABG) due to any of the following:

- Condition is inoperable; OR
- High risk of operative complications or post-operative failure; OR
- Coronary anatomy is not readily amenable to such procedures; OR
- Co-morbid states that create excessive risk.

NOTE: This procedure must be performed under direct supervision of a physician.

Hydraulic versions of external counterpulsation devices **do not meet the definition of medical necessity**. The standard of practice for external counterpulsation does not include the use of hydraulic ECP devices.

External counterpulsation is considered **experimental or investigational** for all other indications, including but not limited to unstable angina, congestive heart failure, acute myocardial infarction and cardiogenic shock. The evidence is insufficient to determine the effects of the technology on health outcomes.

*Functional Classification Scales:

Class	Canadian Cardiovascular Society Functional	New York Heart Association (NYHA)
Class	Classification	Functional Classification
	Usual physical activity, eg walking or climbing	Cardiac disease, but no symptoms and no
I	stairs, does not cause angina; angina is evoked	limitation in ordinary physical activity, e.g.
	by strenuous and/or rapid work or recreation.	no shortness of breath when walking,
		climbing stairs etc.
	Slight limitation of ordinary activities, eg after	
П	walking 2 blocks, climbing one flight of steps,	Mild symptoms (mild shortness of breath
	under normal circumstances, after meals, in	and/or angina) and slight limitation during
	the cold, wind, in the morning, or when under	ordinary activity.
	emotional stress.	
	Marked limitation of ordinary activities, eg	Marked limitation in activity due to
111	walking 1-2 blocks or climbing stairs under	symptoms, even during less-than-ordinary
	normal circumstances.	activity, e.g. walking short distances (20–
		100 m). Comfortable only at rest.
	Inability to carry out any physical activity	Severe limitations. Experiences symptoms
IV	without discomfort-angina may be present at	even while at rest. Mostly bedbound
	rest.	patients.

BILLING/CODING INFORMATION:

HCPCS Coding:

G0166	External counterpulsation per treatment session

ICD-10 Diagnosis Codes That Support Medical Necessity:

120.81-120.9	Angina pectoris
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125.118 - 125.119	Atherosclerosis
125.708 – 125.709	
125.718 – 125.719	
125.728 – 125.729	
125.738 – 125.739	
125.758 – 125.759	
125.768 – 125.769	
125.798 – 125.799	

REIMBURSEMENT INFORMATION:

External counterpulsation (G0166) is limited to 35 sessions in a twelve (12) month period.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: The following National Coverage Determination (NCD) was reviewed on the last guideline reviewed date: External Counterpulsation (ECP) for Severe Angina (20.20) located at cms.gov.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at <u>Coverage</u> <u>Protocol Exemption Request</u>.

DEFINITIONS:

None Applicable

RELATED GUIDELINES:

Transmyocardial Revascularization (TMR), 02-33000-19

OTHER:

The following information may be required documentation to support medical necessity: Physician history and physical, attending physician treatment plan, progress or hospital notes, and treatment notes including documentation of Class III or Class IV disabling stable angina.

LOINC Codes:

Documentation	LOINC	LOINC Time Frame	LOINC Time Frame Modifier Codes
Table	Codes	Modifier Code	Narrative

Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Attending physician visit note	18733-6	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Physician Initial Assessment	18736-9	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Attending physician progress note	18741-9	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Physician hospital discharge summary	11490-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 06/27/24.

GUIDELINE UPDATE INFORMATION:

01/01/00	Medical Coverage Guideline developed.
06/15/00	Revision of guideline consisting of the addition of code G0166.
08/23/01	Review of guideline with no changes.
07/15/03	Review and revision of guideline consisting of the addition of limitation.
04/15/05	Review and revision of guideline consisting of updated references and addition of
	limitation.
03/15/06	Review and revision of guideline consisting of updated references.
03/15/07	Review and revision of guideline consisting of updated references.
06/15/07	Reformatted guideline.
03/15/08	Review and revision of guideline consisting of updated references.
02/15/09	Review and revision of guideline consisting of updated references.
12/15/09	Annual review: position statements maintained, references updated.
10/15/10	Revision; related ICD-10 codes added.
07/15/11	Revision; formatting changes.
05/11/14	Revision: Program Exceptions section updated.
10/01/15	Revision; ICD10 coding section updated.
11/01/15	Revision: ICD-9 Codes deleted.
09/15/18	Review; coverage maintained; description, position statements, program exception, and
	references updated.
08/15/20	Review; position statements maintained and references updated.
08/15/22	Review: position statements maintained; references updated.
05/22/23	Update to Program Exceptions section.
10/01/23	Annual ICD10 coding update. Codes I20.81-I20.89 added; code I20.8 deleted.
07/15/24	Review: Position statements maintained and references updated.