

Policy Number: MP.107.MPC Last Review Date: 08/26/2021 Effective Date: 10/01/2021

MP.107.MPC External Counterpulsation Therapy

Maryland Physicians Care considers an initial full course (35 one hour treatments per benefit period, which may be offered once or twice daily, usually five days per week) of **External Counterpulsation Therapy (ECP)** medically necessary for the following indications:

Members with a diagnosis of chronic disabling stable angina *Class III or IV* per New York Heart Association (NYHA) or Canadian Cardiovascular Society (CCS) refractory to maximum medical therapy and not amenable to surgical intervention (in the opinion of a cardiologist or cardiothoracic surgeon) such as percutaneous transluminal coronary angioplasty (PTA) or cardiac bypass because of one of the following:

- Their condition is inoperable or at high risk of operative complications or post-op failure; OR
- Their coronary anatomy is not amenable for such procedures; OR
- They have co-morbid states which could create excessive risk.

Repeat courses of ECP will be considered on a case by case basis for persons with chronic stable angina if all of the following criteria are met:

- Member meets medical necessity criteria for ECP; AND
- Prior ECP has resulted in a sustained improvement in symptoms, with a significant (greater than 25%) reduction in frequency of angina symptoms;
- Improvement by one or more angina classes (NYHA or CCS); AND
- Three or more months has elapsed from the prior ECP treatment.

Limitations

- This policy only addresses ECP performed in the outpatient setting
- All other cardiac conditions not otherwise specified as nationally covered for the use of ECP remain nationally non-covered
- Must be performed under the direct supervision of a physician who must be present and immediately available to provide assistance and direction during the treatment
- FDA approved ECP devices intended for the treatment of cardiac conditions
- Hydraulic versions of ECP devices will not be covered



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• ECP is not intended as a first-line therapy for angina

ECP is not covered for member with any of the following conditions:

- Arrhythmias that interfere with machine triggering
- Active thrombophlebitis
- Severe lower extremity vaso-occlusive disease
- Presence of a documented aortic aneurysm requiring surgical repair
- Pregnancy

Background

The Centers for Medicare and Medicaid Services (CMS) define external counterpulsation (ECP) as a noninvasive outpatient treatment for coronary artery disease refractory to medical and/or surgical therapy. ECP is also commonly referred to as enhanced external counterpulsation. 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.

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.

New York Heart Association Grading Scale for Heart Failure:

- Class I: No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath).
- Class II: Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea.
- Class III: Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea.
- Class IV: Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.

Canadian Cardiovascular Society Grading Scale for Angina:



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- Class I: Ordinary physical activity does not cause angina, such as walking or climbing stairs. Angina occurs with strenuous, rapid or prolonged exertion.
- Class II: Slight limitation of ordinary activity. Angina occurs only during vigorous physical activity, such as walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals in cold, wind, or under emotional stress, or only during the few hours after awakening. Walking more than two blocks on the level and climbing more than one flight of ordinary stairs at a normal pace and in normal conditions
- Class III: Marked limitation of ordinary physical activity. It is induced by walking one or two level blocks and climbing one flight of stairs in normal conditions and at a normal pace
- Class IV: Inability to carry on any physical activity without discomfort. Anginal syndrome may be present at rest.

Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes	
Code	Description
HCPCS codes covered if selection criteria are met (If Appropriate):	
G0166	External Counterpulsation, per treatment session
ICD-10 codes covered if selection criteria are met:	
120.0	Unstable angina
120.1	Angina pectoris with documented spasm
120.8	Other forms of angina pectoris
120.9	Angina pectoris, unspecified

References

- 1. American Heart Association (AHA). Classes of Heart Failure. Last reviewed 05/31/2017. <u>https://www.heart.org/en/health-topics/heart-failure/what-is-heart-failure/classes-of-heart-failure</u>
- Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) No. 20.20 - External Counterpulsation Therapy for Severe Angina. Effective Date: 03/20/2006. <u>http://www.cms.gov/medicare-coveragedatabase/details/ncd-</u> details.aspx?NCDId=97&ncdver=2&bc=AgAAgAAAAAAAAA%3d%3d&
- 3. Centers for Medicare and Medicaid Services (CMS). Decision Memo for External Counterpulsation (ECP) Therapy (CAG-00002R2). March 20, 2006.



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https://www.cms.gov/medicare-coverage-database/details/nca-decisionmemo.aspx?NCAId=162&ver=21&NcaName=External+Counterpulsation+(ECP) +Therapy+(2nd+Recon)&bc=BEAAAAAAEAAA&&fromdb=true

4. Ischemia Trial – Apendix I: New York Heart Association Grading Scale for Heart Failure and Canadian Cardiovascular Society Grading Scale for Angina. Protocol Version Date: Jan 6, 2014.

https://clinicaltrials.gov/ProvidedDocs/22/NCT01471522/Prot_001.pdf

- Jneid H, Anderson JL, Wright RS, et al. 2012 ACCF/AHA focused update incorporated into the ACCF/AHA 2007 guidelines for the management of patients with unstable angina/non-ST-elevation myocardial infarction: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2013 Jun 11;61(23):e179-347. doi: 10.1016/j.jacc.2013.01.014. Epub 2013 Apr 29. http://circ.ahajournals.org/content/early/2013/04/29/CIR.0b013e31828478ac.full. pdf
- 6. McKenna C, McDaid C, Suekarran S, et al. Enhanced external counterpulsation for the treatment of stable angina and heart failure: a systematic review and economic analysis. Health Technol Assess. 2009; 13(24): iii-iv, ix-xi, 1-90. doi: 10.3310/hta13240. <u>http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0015045/</u>
- Snow V, Barry P, Fihn SD, et al. Primary care management of chronic stable angina and asymptomatic suspected or known coronary artery disease: a clinical practice guideline from the American College of Physicians. Ann Intern Med. 2004 Oct 5;141(7):562-567. <u>http://annals.org/article.aspx?articleid=717863</u>

Archived References

1. Hayes Medical Technology Directory. External Counterpulsation. Annual Review June 25, 2012. Archived: Jul 23, 2013.

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