

External Counterpulsation (ECP)

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Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

External counterpulsation (ECP), commonly referred to as enhanced external counterpulsation (EECP), is an outpatient noninvasive circulatory assist treatment for coronary artery disease refractory to medical and/or surgical therapy. A full course of therapy usually consists of up to 35 one (1) hour treatments, which may be offered once or twice daily, usually five (5) days per week.

DEFINITIONS

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan Plus members.

POLICY POSITION

- ECP may be considered medically necessary using a United States Food and Drug Administration (U.S. FDA) approved device when **BOTH** of the following are met:
 - The individual has been diagnosed with disabling chronic stable angina (Class III or Class IV, New York Heart Association Functional Classification of Cardiac Disability); and
 - A cardiologist or cardiothoracic surgeon, documented that the individual is not a candidate for surgical intervention, such as percutaneous coronary intervention (PCI) or cardiac bypass because:
 - Their condition is inoperable, or at high risk of operative complications or post-operative failure; or
 - Their coronary anatomy is not readily amenable to such procedures; or
 - They have comorbid states which create excessive risk.

ECP for any other indication including, but not limited to, ANY of the following is considered not medically necessary:

- Acute myocardial infarction; or
- Cardiogenic shock; or
- Erectile dysfunction; or
- Ischemic stroke; or
- Unstable angina.

Documentation in the medical record must contain a history and physical pertinent to the indications of this policy, and be available upon request.

Repeat courses of ECP will be considered medically necessary for individuals with chronic stable angina if **ALL** of the following criteria are met:

- Individual 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; or
 - Improvement by one or more angina classes; and
 - Three (3) or more months has elapsed from the prior ECP treatment; and
 - Individual has shown documented compliance with treatment in the past.

Repeat courses of ECP not meeting the criteria as indicated in this policy is considered not medically necessary.

Hydraulic versions of ECP devices are noncovered due to the limited use of the device.

NEW YORK HEART ASSOCIATION FUNCTIONAL CLASSIFICATION OF CARDIAC DISABILITY

| Class | Description |
|--------------|--|
| Class I | Patients with cardiac disease but without resulting limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain. |
| Class II | Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, or anginal pain. |
| Class III | Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary physical activity causes fatigue, palpitation, dyspnea, or anginal pain. |
| Class IV | Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency or of the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increase. |

Source: American Heart Association, Classes of Heart Failure. 2017.

External cardiac assist (92971), ECG rhythm strip and report (93040 or 93041), and plethysmography (93922 or 93923), or other monitoring tests for examining the effects of this treatment are not separately reimbursable on the same day as ECP, unless they occur in a clinical setting not connected with the delivery of the ECP service.

PROFESSIONAL STATEMENTS AND SOCIETAL POSITIONS GUIDELINES

American College of Cardiology Foundation / American Heart Association – 2013.

The most recent guidelines of the American College of Cardiology Foundation (ACCF) and American Heart Association (AHA) include the following recommendations for the treatment of CS:

- Class I

- Emergency revascularization with either PCI or CABG is recommended in suitable patients with CS due to pump failure after STEMI irrespective of the time delay from MI onset. (Level of Evidence: B).
- Cardiac catheterization and coronary angiography with intent to perform revascularization should be performed after STEMI in patients with CS that develops after initial presentation. (Level of Evidence: B).
- PCI of an anatomically significant stenosis in the infarct artery should be performed in patients with suitable anatomy and CS. (Level of Evidence: B)
- Urgent CABG is indicated in patients with STEMI and coronary anatomy amenable to PCI who have ongoing or recurrent CS. (Level of Evidence: B).
- In the absence of contraindications, fibrinolytic therapy should be administered to patients with STEMI and CS who are unsuitable candidates for either PCI or CABG. (Level of Evidence: B).
- Class IIa
 - The use of IABP counterpulsation can be useful for patients with CS after STEMI who do not quickly stabilize with pharmacologic therapy. (Level of Evidence: B).
- Class IIb
 - Alternative LVADs for circulatory support may be considered in patients with refractory CS. (Level of Evidence: C).

AACF/AHA-2013

Guidelines for the management of heart failure state that nondurable mechanical circulatory support with percutaneous and extracorporeal VADs is reasonable as a bridge to recovery or bridge to decision for carefully selected patients with heart failure with reduced ejection fraction who have acute, profound hemodynamic compromise (Level of Evidence: B).

ELIGIBLE PROCEDURE CODES

| CPT Codes | Description |
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| 92971 | Cardio assist method of circulatory assist; external. |
| 93040 | Rhythm ECG, one to three leads; with interpretation and report. |
| 93041 | Rhythm ECG, one to three leads; tracing only without interpretation and report. |
| 93922 | Limited bilateral noninvasive physiologic studies of upper or lower extremity: ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus bidirectional, doppler waveform recording and analysis at 1-2 levels, or ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus volume plethysmography at 1-2 levels or ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries with transcutaneous oxygen tension. |
| 93923 | Complete bilateral noninvasive physiologic studies of upper or lower extremity arteries, 3 or more levels (e.g., for lower extremity: ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus segmental blood pressure measurements with bidirectional doppler waveform recording and analysis at 3 or more levels, or ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus segmental volume plethysmography at 3 or more levels, or ankle/brachial indices at distal posterior tibial). |

References

Barghash MH, Reyentovich A. The use of implantable HF monitoring systems and the CHAMPION Trial. J Am Coll Cardiol. 2016.

Bozhurt B, Butler J, et al. 2016 ACCF/AHA Focused Update on New Pharmacological Therapy for Heart Failure: An Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure. a report of the American College of Cardiology Foundation/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. *Circ.* 2016;134.

Lounsbury P, Elokda A, Sitzmann J, et al. Efficacy of external counterpulsation enhanced with outpatient cardiac rehabilitation. *Eur. J. Physiother.* 2016;18(1): 27-33.

National Institute for Health and Clinical Excellence (NICE) quality standards. Chronic Heart Failure in Adults. Last updated February 2016.

Qin X. Does enhanced external counterpulsation (EECP) significantly affect myocardial perfusion?: A systematic review & meta- analysis. *Plos One.* 2016:1-11.

Raeissadat SA, Javadi A, Allameh F. Enhanced external counterpulsation in rehabilitation of erectile dysfunction: a narrative literature review. *Vasc Health Risk Manag.* 2018;14:393-399.

Sardina PD, Martin JS, Avery JC, et al. Enhanced external counterpulsation (EECP) improves biomarkers of glycemic control in patients with noninsulin-dependent type II diabetes mellitus for up to 3 months following treatment. *Acta Diabetol.* 2016;53(5):745-52.

Singh V, Kumari G, Chhajer B, et al. Effectiveness of enhanced external counter pulsation on clinical profile and health-related quality of life in patients with coronary heart disease: A systematic review. *Acta Angiologica.* 2018; 24(4):105-22.

US Food and Drug Administration (FDA). Cardiomedics, Inc. cardiassist counter pulsation system-series 4000. 510(k) summary. [FDA Web site]. 03/31/2005. Available at:http://www.accessdata.fda.gov/cdrh_docs/pdf5/k050172.pdf. Accessed April, 01 2021.

US Food and Drug Administration (FDA). Enhanced external counterpulsation MC-2. 510(k) summary. [FDA Web site]. 06/14/2002. Available at:http://www.accessdata.fda.gov/cdrh_docs/pdf2/K020857.pdf. Accessed April, 01 2021.

Xu L, Chen X, Cui M, et al. The improvement of the shear stress and oscillatory shear index of coronary arteries during enhanced external counterpulsation in patients with coronary heart disease. *PLoS One.* 2020;15(3):e0230144. doi: 10.1371/journal.pone.0230144. eCollection 2020. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7082042/pdf/pone.0230144.pdf2>. Accessed April 01, 2021.

Yancy CW, Jessup M, Bozkurt B, et al. 2017 ACC/AHA/HFSA Focused update of the 2013 ACCF/AHA guideline for the management of heart failure: A report of the American College of Cardiology/American Heart Association task force on clinical practice guidelines and the heart failure Society of America. *Circ.* 2017;136(6):e137-e161. Accessed on April 02, 2021.

POLICY UPDATE HISTORY

| <Date> | <Event> |
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