External Counterpulsation (ECP)

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Approved By:	Highmark Health Options – Market Leadership
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Products:	Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 4

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

Highmark Health Options may provide coverage under medical surgical benefits of the Company's Medicaid products for medically necessary

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

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.

External counterpulsation (ECP) – Commonly referred to as enhanced external counterpulsation (EECP), is an outpatient non-invasive 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 treatment, which may be offered once or twice daily, usually five (5) days per week.

POLICY POSITION

1. Prior authorization is required.

2. 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, Canadian Cardiovascular Society Grading In Angina Pectoris Association); **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:
  - Individual is inoperable, or at high risk of operative complications or post-operative failure; or
  - Individuals' coronary anatomy is not readily amenable to such procedures; or
  - Individual has co-morbid states which create excessive risk: or
  - Individual is refractory to medical treatment

ECP procedures not meeting the criteria as indicated in this policy are considered not medically necessary, including but not limited to the following conditions: Acute myocardial infarction; or

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

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.

Canadian Cardiovascular Society Grading of Angina Pectoris:

Class	Description of Angina severity	
0	Asymptomatic Angina	Mild myocardial ischemia with no symptoms.
I	Angina only with strenuous exertion	Presence of angina during strenuous, rapid, or prolonged ordinary activity (walking or climbing the stairs).
II	Angina with moderate exertion	Slight limitation of ordinary activities when they are performed rapidly, after meals, in cold, in wind, under emotional stress, during the first few hours after waking up, but also walking uphill, climbing more than one flight of ordinary stairs at a normal pace and in normal conditions.
III	Angina with mild exertion	Having difficulties walking one or two blocks or climbing one flight of stairs at normal pace and conditions.
IV	Angina at rest	No exertion needed to trigger angina.

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
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 wavefrom 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

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.

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.

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.

US Food and Drug Administration (FDA). Cardiomedics, Inc. cardiassist counter pulsation system-series 4000. 510(k) summary. [FDA Web site]. 03/31/2005.

US Food and Drug Administration (FDA). Enhanced external counterpulsation MC-2. 510(k) summary. [FDA Web site]. 06/14/2002.

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.

Buschmann EE, Hillmeister P, Bondke Persson A, et al. Short-term external counterpulsation augments cerebral blood flow and tissue oxygenation in chronic cerebrovascular occlusive disease. Eur J Neurol. 2018;25(11):1326-1332.

POLICY UPDATE HISTORY

09/28/2022	Approved in Medical Policy Committee
10/2022	Approved in QI/UM