Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 5/1/25**
(See policy history boxes for previous effective dates)

Title: Extra-Aortic Counter-Pulsation Ventricular Assist System (E.G., C-Pulse® Heart Assist)

Description/Background

Heart failure develops when the heart fails to pump blood at a rate commensurate with the requirements of the metabolizing tissues or is able to do so only with an elevated diastolic filling pressure. Signs and symptoms of heart failure can include dyspnea, orthopnea, acute pulmonary edema, chest pressure/pain, tachycardia, fatigue and weakness, anorexia, nocturia, distended neck veins, weak/rapid or thread pulse, and rales/wheezing.

Treatment for heart failure can include pharmacologic therapy and nonpharmacologic therapy such as oxygen and noninvasive positive pressure ventilation, dietary sodium and fluid restriction, physical activity as appropriate and attention to weight gain. Surgical options may include electrophysiologic intervention, revascularization procedures, valve replacement/repair, extracorporeal membrane oxygenation, ventricular assist devices, heart transplantation and total artificial heart.

According to the manufacturer (Sunshine Heart, Inc.), the C-Pulse System is an investigational treatment option designed for patients with moderate to severe heart failure. The C-Pulse System works to assist the heart to pump blood, rather than “replacing” the heart function, and can be disconnected for short periods as required. The C-Pulse consists of a polyurethane balloon and a polyester wrap fitted to conform to the ascending aorta. The system pumps in counterpulsation to the intrinsic heartbeat. The cuff deflates prior to systole, reducing afterload. The cuff is timed to re-inflate during diastole, increasing perfusion to the coronary arteries. A bipolar epicardial ECG sensing lead is attached to the heart for timing.

The C-Pulse System “assists” the heart rather than “replacing” it, allowing the device to be turned off if needed. Patients can remain active while it is in use. Anticoagulation medications

are not required because the system is placed outside the bloodstream. It can be implanted in a minimally invasive procedure during off-pump bypass surgery.

Regulatory Status

The C-Pulse System (Sunshine Heart, Inc.) is not yet approved for use in the U.S. but according to an April 2015 press release from the manufacturer (Sunshine Heart Provides Update on U.S. Pivotal Study of C-Pulse Heart Assist System), the FDA did issue an Investigational Device Exemption to allow pivotal clinical trials to be conducted in the U.S. for the purpose of obtaining Premarket Approval (PMA). The device is available for use in Europe and the manufacturer, Sunshine Heart, Inc., is listed in the FDA Establishment Registration and Device Listing database as a "U.S. Manufacturer of Export Only Devices." The C-Pulse is a Class 3 device, Product Code **DSQ**, defined as "ventricular (assist) bypass". No other information was located for C-Pulse Heart Assist System on the FDA website.

Medical Policy Statement

The Extra-Aortic Counterpulsation Ventricular Assist System (e.g., C-Pulse Heart Assist) is experimental/investigational. It has not been scientifically demonstrated to be as safe and effective as conventional treatment.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

33999

Rationale

There is a small body of published literature pertaining to the use of percutaneous implantable extra-aortic counterpulsation (EAC) ventricular assist devices (VAD), a small subset of which is devoted to outcomes using the C-Pulse System in patients with congestive heart failure (CHF) or end-stage heart failure. The literature includes two prospective multicenter studies, one pilot study, two individual case reports and four review articles.

In a European study, Schulz and colleagues studied the C-Pulse System to treat patients with heart failure disease in NYHA functional class III or ambulatory class IV status.[1] Between May 2013 and March 2014, the C-Pulse System was implanted in eight patients (7 male) with a mean age of 61.6±9.3 years. Four had ischemic and four had non-ischemic cardiomyopathy. No stroke, myocardial infarction, major bleeding, or major infections due to the device were reported. One patient developed non-device-related refractory tachycardia with worsening heart failure 12 h after surgery and underwent left ventricular assist device implantation. Within 6 months of observation, functional status improved from NYHA III to II in five patients, and two remained in NYHA III. Mean left ventricular ejection fraction increased from 24.3±7.9% to 44.5±4.5% ($p<0.0001$). Mean Kansas City Cardiomyopathy Questionnaire overall score improved from 28.6±19.1 to 59.1±22.5 ($p=0.0183$). Six-minute walk test was performed in 6 out of 7 patients at follow-up. The mean distance improved from 252.0±85.1 m to 279.2±87.5 m ($p>0.05$). One patient was weaned off the device after 6 months of support. The authors concluded that the C-Pulse System provides a therapeutic option for patients with moderate-to-severe heart failure and seems to improve quality of life and cardiac function over time.

In another multicenter, single arm study, Abraham et al sought to assess the feasibility, safety and potential efficacy of an implantable extra-aortic counterpulsation system (C-Pulse) in functional class III and ambulatory functional class IV heart failure patients.[2] New York Heart Association (NYHA) functional class III or ambulatory functional class IV HF patients were eligible. Safety was assessed continuously through 12 months. Efficacy measurements included changes from baseline to 6 and 12 months in NYHA functional class, Minnesota Living with Heart Failure (MLWHF) and Kansas City Cardiomyopathy Questionnaire (KCCQ) scores, 6-min walk distance (6MWD), and exercise peak oxygen consumption (pVO2; 6 months only).

Twelve men and 8 women (56.7 ± 7 years, 34 to 71 years of age) with ischemic (n = 7) or nonischemic (n = 13) cardiomyopathy were implanted. There was no 30-day mortality and no neurological events or myocardial infarctions through 12 months. At 6 months, there were 3 deaths (1 device-related). One-year survival was 85%. At 6 months, C-Pulse produced improvements in NYHA functional class (3.1 ± 0.3 to 1.9 ± 0.7, p = 0.0005), MLWHF (63.6 ± 19.9 to 40.2 ± 23.2, p = 0.0005), and KCCQ scores (43.6 ± 21.1 to 65.6 ± 21.5, p = 0.0002), but not 6MWD (275.5 ± 64.0 to 296.4 ± 104.9, p = NS) or pVO2 (14.5 ± 3.6 to 13.1 ± 4.4, p = NS). Improvements continued at 12 months, with 6MWD change becoming statistically significant (336.5 ± 91.8, p = 0.0425). The authors concluded that the use of C-Pulse in this population is feasible, appears safe, and improves functional status and QoL. A prospective, multicenter, randomized controlled trial is underway.

In a pilot study, Hayward et al described a first-in-human experience with an implantable non-blood-contacting extra-ascending aortic counterpulsation heart assist system (C-Pulse) in five end-stage heart failure patients, aged 54 to 73 years.[3] All patients improved by 1 NYHA class and improvements in invasive hemodynamics were documented in 3 patients. Three of 5 patients (60%) had infectious complications. Two patients were explanted at 5 and 7 weeks, respectively, because of mediastinal infection related to the implant procedure. One patient was successfully transplanted at 1 month and 1 remained hemodynamically improved on the device at 6 months but suffered infective complications. The device and protocol have been modified because of this pilot study with a further multicenter safety study underway. Although feasibility of this device is suggested by this pilot study, the authors concluded that the safety and efficacy would need to be examined in a larger cohort with longer follow-up.

In 2017, Campos et al studied C-Pulse cardiac support device and the impact on overall hemodynamics.[10] In this study, the function of the C-Pulse heart assist system is implemented in a one-dimensional (1-D) model of the arterial tree, and central and peripheral pressure and flow waveforms with the C-Pulse turned on and off were simulated. The results were studied using wave intensity analysis and compared with in vivo data measured non-invasively in three patients with heart failure and with invasive data measured in a large animal (pig). In all cases, the activation of the C-Pulse was discernible by the presence of a diastolic augmentation in the pressure and flow waveforms. Activation of the device initiates a forward traveling compression wave, whereas a forward traveling expansion wave is associated to the device relaxation, with waves exerting an action in the coronary and the carotid vascular beds. The authors also found that the stiffness of the arterial tree is an important determinant of action of the device. In settings with reduced arterial compliance, the same level of aortic compression demands higher values of external pressure, leading to stronger hemodynamic effects and enhanced perfusion. The authors concluded that the 1-D model may be used as an efficient tool for predicting the hemodynamic impact of the C-Pulse system in the entire arterial tree, complementing in vivo observations.

SUMMARY OF EVIDENCE

The C-Pulse System is an implantable, extra-aortic, non-blood-contacting counterpulsation device, investigational in the United States and intended for use as a heart assist device for heart failure (NYHA class III-ambulatory IV) patients. The safety, efficacy and long-term effects of this implantable extra-aortic counterpulsation device on the aortic wall structure are not well established and require further study.

ONGOING AND UNPUBLISHED CLINICAL TRIALS

There are currently no ongoing trials that would impact this policy.

SUPPLEMENTAL INFORMATION

PRACTICE GUIDELINES AND POSITION STATEMENTS

American College of Cardiology/American Heart Association

The ACCF/AHA guidelines for the management of heart failure do not mention the use of extra aortic counterpulsation VADs.

European Society of Cardiology

The ESC guidelines for the management of heart failure do not mention the use of extra aortic counterpulsation VADs.

Government Regulations

National:

There is a National Coverage Determination (NCD) on the CMS website pertaining to ventricular assist devices (VADs) and a separate NCD for external counterpulsation. However, neither policy specifically addresses the use of the C-Pulse System (Sunshine Heart, Inc.) or other similar devices. In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

- National Coverage Determination (NCD) for Ventricular Assist Devices (20.9.1)
- National Coverage Determination (NCD) for External Counterpulsation (ECP) Therapy for Severe Angina (20.20)

Local:

No LCD on CMS website regarding C-Pulse System.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Total Artificial Hearts and Implantable VADs
- Enhanced External Counterpulsation (EECP)

References

1. Schulz A, Drabatsch T, Schmitto JD, et al. Preliminary results from the C-Pulse OPTIONS HF European multicenter post-market study. Med Sci Monit Basic Res. 2016: 18;22:14-9.
2. Abraham WT, Aggarwal S, Prabhu SD, et al. Ambulatory extra-aortic counterpulsation in patients with moderate to severe chronic heart failure. JACC Heart Fail. 2014; 2(5):526-533.
3. Hayward CS, Peters WS, Merry AF, et al. Chronic extra-aortic balloon counterpulsation: first in-human pilot study in end-stage heart failure. J Heart Lung Transplant. 2010; 29(12)L1427-1432.
4. Black MC, Schumer EM, Rogers M, et al. Sunshine Heart C-Pulse: device for NYHA Class III and ambulatory Class IV heart failure. Future Cardiol. 2016; 12(5):521-531.
5. Zeriouh M, Sabashnikov A, Bowles CT, et al. Full-support LVAD implantation in a C-pulse Heart Assist System recipient with deteriorating chronic heart failure: is it feasible and safe? ASAIO J. 2016; 62(6):e55-e57.
6. Capoccia M, Bowles CT, Pepper JR, et al. Evidence of clinical efficacy of counterpulsation therapy methods. Heart Fail Rev. 2015; 20(3):323-335.
7. Division of Cardiology, Rutger-New Jersy Medical School. Aortic counterpulsation: C-Pulse and other devices for cardiac support. J Cardiovasc Transl Res. 2014;7(3):292-300.
8. Cheng A, Monreal G, William ML, et al. Extended extra-aortic counterpulsation with the C-Pulse device does not alter aortic wall structure. ASAIO J. 2014;60(6):e5-e7.
9. Bluhm Cardiovascular Institute, Division of Cardiac Surgery at Northwestern University Feinberg School of Medicine and Memorial Hospital. Understanding the C-pulse device and its potential to treat heart failure. Curr Heart Fail Rep; 2010; 7(1):27-34.
10. Campos A, Londono F, Rodriguez M, et al. Hemodynamic impact of the C-Pulse cardiac support device: a one-dimensional arterial model study. Artif Organs.2017;41(10):E141-E154.
11. HAYES Search and Summary. C-Pulse Heart Assist System (Sunshine Heart, Inc.) for Congestive Heart Failure. Lansdale, PA: HAYES, Inc. published December 2016.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through January 2025, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
5/1/17	2/21/17	2/21/17	Joint policy established
5/1/18	2/20/18	2/20/18	Updated rationale, added reference #10. Policy status unchanged.
5/1/19	2/19/19		Routine policy update. No change in policy status.
5/1/20	2/18/20		Routine policy update. No change in policy status.
5/1/21	2/16/21		Routine policy update. No change in policy status.
5/1/22	2/15/22		T codes deleted and replaced by code 33999 (NOC). Routine policy maintenance, no change in status.
5/1/23	2/21/23		Updated CMS section. Routine policy maintenance, no change in policy status. (ds)
5/1/24	2/20/24		Routine policy maintenance, no change in policy status. Vendor managed: N/A (ds)
5/1/25	2/18/25		Routine policy maintenance, no change in policy status. Vendor managed: N/A (ds)

Next Review Date: 1st Qtr. 2026

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: EXTRA-AORTIC COUNTERPULSATION VENTRICULAR ASSIST SYSTEM (E.G., C-PULSE HEART ASSIST)

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	See government section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.