Policy Number: PA.051.MPC
Last Review Date: 02/20/2025
Effective Date: 03/01/2025

PA.051.MPC Mechanical Circulatory Support (Ventricular Assist Device) – Percutaneous and Permanent

Maryland Physicians Care considers Mechanical Circulatory Support (**Ventricular Assist Device) – Percutaneous and Permanent** medically necessary for the following:

Indications for Mechanical Circulatory Support (LVAD)

Overview

Mechanical Circulatory Support (MCS) or Ventricular Assist Devices (VAD) are indicated for management of patients presenting with advanced heart failure (see Definitions) refractory to the administration of maximally tolerated Guideline Directed Medical Therapy (GDMT) when heart transplantation is not immediately available. The approach to MCS is dependent on the clinical scenario. MCS may be used as a bridge to recovery, when return of satisfactory ventricular function is anticipated; as bridge to transplantation in critically ill patients listed for heart transplantation (OHT); and as destination therapy when the patient is not a candidate for transplantation. These designations are not rigid and may change as the patient's clinical course evolves.

1. **Bridge to Recovery (AUC Score 5) [8]:**
   Potentially fatal low cardiac output in situations where recovery is possible or probable. Clinical scenarios for MCS for Bridge to Recovery include:

   a) Acute myocardial infarction complicated by cardiogenic shock
   b) Acute myocarditis with shock [7]
   c) Acute cardiac failure following cardiac surgery
   d) MCS using a nondurable (temporary) support device is recommended in patients with multiorgan failure, sepsis, or on mechanical ventilation to allow successful optimization of clinical status and neurological assessment before consideration of a long-term device [7].
   e) Dilated nonischemic cardiomyopathy of recent onset refractory to maximally tolerated GDMT [7]
   f) Post-cardiotomy shock with failure to wean from cardiopulmonary bypass [9]
   g) For patients with severe renal dysfunction, initial support and nondurable MCS (temporary device) to asses for potential of renal recovery before implanting durable MCS may be undertaken [7].

2. **Bridge-to-Transplantation (AUC Score 8)** [8]:
   a) Device must be FDA-approved for bridge to transplant use and used according to labeling instructions. These are durable devices, and include extracorporeal MCS, implantable MCS, and total artificial heart (TAH) *and*
   b) The patient must be approved and listed as a candidate for heart transplantation or be undergoing evaluation of candidacy by an interdisciplinary patient selection committee *and*
   c) NHYA class IV symptoms despite optimal GDMT or patients deemed to be dependent on IV inotropes [8].

Clinical scenarios for MCS for Bridge to Transplantation MCS include [8]:
   a) Severe reductions in cardiac output or noncardiac co-morbidities such that survival and successful cardiac transplantation are unlikely without mechanical circulatory support.
   b) Impending cardiogenic shock despite inotropic support and intra-aortic balloon pump (±IABP) in presence of acute renal dysfunction (creatinine level > 2.0) that is deemed secondary to insufficient renal blood flow and is unresponsive to inotropic support.
   c) Pulmonary hypertension (PA systolic pressure > 60) that persists despite optimal medical and inotropic therapy.
   d) In patients with treatment-refractory recurrent sustained ventricular tachycardia or ventricular fibrillation in the presence of an untreatable arrhythmogenic substrate (e.g., giant cell myocarditis, scar, sarcoidosis), biventricular support or a TAH is preferred over isolated LV support [7].

3. **Destination Therapy (DT) or Long-term Therapy** [8]**:**
   a) Device must be FDA-approved for destination therapy use and used according to labeling instructions, *and*
   b) Patients with a major contraindication to cardiac transplantation, *and*
   c) Dependence on intravenous inotropic support, or Class IV heart failure with expected mortality exceeding 50% in one yar despite maximum GDMT

4. **Indications for Right Ventricular Assist Device Implantation/Utilization** [7]
   a) Support with an RVAD should be performed in patients with medically refractory RV failure after durable LVAD implantation
   b) Patients with high-risk preoperative features for right ventricular failure may undergo planned RVAD implantation before worsening of cardiogenic shock

Contraindications for Ventricular Assist Device [6,7,10]

- Irreversible hepatic disease
- Irreversible renal disease
- Irreversible neurological disease
- Patient refusal of medical adherence that is necessary for post-operative recovery
- Severe psychosocial limitations
- Severely restricted pulmonary function
- Neuromuscular or musculoskeletal disease that impairs rehabilitation
- Active systemic infection
- Prolonged intubation
- Untreated/active malignancy with < 2 years life expectancy
- Severe peripheral vascular disease (PVD); (note: durable MCS may be used in selected patients with manageable peripheral vascular disease)
- Active substance abuse
- Impaired cognitive function
- Unstable psychiatric conditions
- Lack of social support
- DMCS is relatively contraindicated in the setting of diabetes-related proliferative retinopathy, very poor glycemic control, severe nephropathy, vasculopathy, or peripheral neuropathy
- Active pregnancy [7]

Background

Bridge to Recovery

This category of MCS includes the use of nondurable percutaneous support devices (VADs), which are used for cardiogenic shock when the risk of implantation of a durable device is prohibitive or recovery of function after short-term support is anticipated. These devices are removed once clinical recovery has occurred, or at the time of implantation of durable MCS. Under certain conditions, durable LVADs may be implanted as a bridge to recovery when the recovery period is anticipated to be prolonged.

Nondurable MCS devices include:

- Intra-Aortic Balloon Counter-Pulsation (IABP)
- Extracorporeal Membrane Oxygenation (ECMO)
- Extracorporeal MCS pump (implanted via sternotomy)
- Percutaneous MCS pump

Bridge to Transplantation
Implantation of a durable left ventricular assist device (LVAD) in patients who are eligible for cardiac transplantation but in whom a donor heart is not available in the setting of refractory Class IV heart failure requiring inotropic support despite maximally tolerated GDMT.

Destination Therapy
Implantation of a durable left ventricular assist device (LVAD) in patients who have refractory Class IV heart failure requiring inotropic support despite maximally tolerated GDMT but are not candidates for heart transplantation.

Right Ventricular Assist Devices (RVADs)
Right heart failure after DLVAD implantation may be managed medically in many cases. RVAD is indicated when hemodynamic indices fail to improve with medical therapy, and before end-organ damage is encountered. Both ECMO and RVAD have been used to support RV recovery after DLVAD implantation. Newer percutaneous RVAD devices provide hemodynamic unloading comparable to surgical devices with less morbidity and may be appropriate for selected patients. (7)

AUC Score

A reasonable diagnostic or therapeutic procedure can be defined as that for which the expected clinical benefits outweigh the associated risks, enhancing patient care and health outcomes in a cost-effective manner. (3)

- Appropriate Care- Median Score 7-9
- May be Appropriate Care- Median Score 4-6
- Rarely Appropriate Care- Median Score 1-3

All criteria are substantiated by the latest evidence-based medical literature. To enhance transparency and reference, Appropriate Use (AUC) scores, when available, are diligently listed alongside the criteria.

This Policy first defaults to AUC scores established by published, evidence-based guidance endorsed by professional medical organizations. In the absence of those scores, we adhere to a standardized practice of assigning an AUC score of 6. This score is determined by considering variables that ensure the delivery of patient-centered care in line with current guidelines, with a focus on achieving benefits that outweigh associated risks. This approach aims to maintain a robust foundation for

decision-making and underscores our commitment to upholding the highest standards of care. [1,2,3,4,5]

Definitions

Advanced Heart Failure: Consensus for this definition is difficult to achieve but is widely accepted to include: (1) Clinically significant circulatory compromise with class IV symptoms and requiring inotropic support; (2) Frequent hospitalizations for heart failure, resulting in consideration of heart transplantation or resulting in anticipated life expectancy < 2 years; and (3) Interference with activities of daily living. [6] Objective measurements may include VO_2 ≤ 14 ml/kg/min, or 6-min walk distance < 300 m. Patients may manifest intolerance to recommended heart failure therapy due to hemodynamic instability.

Clinical manifestations of advanced heart failure include, but are not limited to, the following [6]:

- Left ventricular ejection fraction (LVEF) ≤ 30%
- Inotrope dependence
- Frequent hospitalizations for HF in the past 12 months
- Refractory clinical congestion
- Progressive deterioration in renal or hepatic function
- Worsening right-sided HF or secondary pulmonary hypertension
- Low systolic blood pressure (SBP) ≤ 90 mm Hg
- Cardiac cachexia
- Persistent hyponatremia (serum sodium, < 134 mEq/L)
- Refractory or recurrent ventricular arrhythmias; frequent ICD shocks
- Increased predicted 1-year mortality (eg, > 20%) according to HF survival models (e.g., MAGGIC, SHFM) (https://www.mdcalc.com/calc/3803/maggic-risk-calculator-heart-failure)

Acronyms/Abbreviations
BTT: Bridge to Transplantation
DT: Destination Therapy
GDMT: Guideline-Directed Medical Therapy
LVEF: Left Ventricular Ejection Fraction
MAGGIC: Meta-analysis Global Group in Chronic Heart Failure
PVD: Peripheral Vascular Disease
SHFM: Seattle Heart Failure Model

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VAD: Ventricular Assist Device
TAH: Total Artificial Heart
MCS: mechanical circulatory support
DMCS: Durable Mechanical Circulatory Support

Codes

CPT Codes	
Code	Description
33975	Insertion of ventricular assist device; extracorporeal, single ventricle
33976	Insertion of ventricular assist device; extracorporeal, biventricular
33979	Insertion of ventricular assist device, implantable intracorporeal, single ventricle
33980	Removal of ventricular assist device, implantable intracorporeal, single ventricle
33981	Replacement of extracorporeal ventricular assist device, single or biventricular, pump(s), single or each pump
33982	Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, without cardiopulmonary bypass
33983	Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, with cardiopulmonary bypass
33991	Insertion of ventricular assist devices, percutaneous including radiological supervision and interpretation; arterial and venous access, with transseptal puncture
33995	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only
33997	Removal of percutaneous right heart ventricular assist device, venous cannula, at separate and distinct session from insertion

References

1. Bonow R O, Douglas P S, Buxton A E, Cohen D J, Curtis J P et al. AACCF/AHA methodology for the development of quality measures for cardiovascular technology: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. Circulation. 2011; 124: 1483-502. 10.1161/CIR.0b013e31822935fc.

2. Fitch K, Bernstein S J, Aguilar M D, Burnand B, LaCalle J R et al. The RAND/UCLA Appropriateness Method User's Manual. RAND Corporation. 2001; Accessed: 8/9/2024. https://www.rand.org/pubs/monograph_reports/MR1269.html.
3. Hendel R C, Lindsay B D, Allen J M, Brindis R G, Patel M R et al. AACC Appropriate Use Criteria Methodology: 2018 Update: A Report of the American College of Cardiology Appropriate Use Criteria Task Force. Journal of the American College of Cardiology. 2018; 71: 935-948. 10.1016/j.jacc.2018.01.007.
4. Hendel R C, Patel M R, Allen J M, Min J K, Shaw L J et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. Journal of the American College of Cardiology. 2013; 61: 1305-17. 10.1016/j.jacc.2013.01.025.
5. Patel M R, Spertus J A, Brindis R G, Hendel R C, Douglas P S et al. ACCF proposed method for evaluating the appropriateness of cardiovascular imaging. Journal of the American College of Cardiology. 2005; 46: 1606-13. 10.1016/j.jacc.2005.08.030.
6. Heidenreich P, Bozkurt B, Aguilar D, Allen L, Byun J et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2022; 145: e895-e1032. 10.1161/CIR.0000000000001063.
7. Saeed D, Feldman D, Banayosy A, Birks E, Blume E et al. The 2023 International Society for Heart and Lung Transplantation Guidelines for Mechanical Circulatory Support: A 10- Year Update. The Journal of Heart and Lung Transplantation. 2023; 42: e1-e222. 10.1016/j.healun.2022.12.004.
8. Kirklin J, Naftel D. Mechanical Circulatory Support. Circulation: Heart Failure. 2008; 1: 200-205. 10.1161/CIRCHEARTFAILURE.108.782599.
9. Peura J, Colvin-Adams M, Francis G, Grady K, Hoffman T et al. Recommendations for the Use of Mechanical Circulatory Support: Device Strategies and Patient Selection. Circulation. 2012; 126: 2648-2667. 10.1161/CIR.0b013e3182769a54.
10. Guglin M, Zucker MJ, Borlaug BA, Breen E, Cleveland J, Johnson MR, Panjrath GS, Patel JK, Starling RC, Bozkurt B; ACC Heart Failure and Transplant Member Section and Leadership Council. Evaluation for Heart Transplantation and LVAD Implantation: JACC Council Perspectives. J Am Coll Cardiol. 2020 Mar 31;75(12):1471-1487. doi: 10.1016/j.jacc.2020.01.034. PMID: 32216916.

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