curative

TITLE:	VENTRICULAR ASSIST DEVICE POLICY
POLICY #:	MM-PNP-023
VERSION #:	01
DEPARTMENT:	UTILIZATION REVIEW
ORIGINAL EFFECTIVE DATE:	12/01/2023
CURRENT REVISION DATE:	N/A

1. PURPOSE

To establish medical necessity criteria and requirements ventricular assist device requests.

2. SCOPE

For use by the Medical UM Department

3. DEFINITIONS

N/A

4. RESPONSIBILITIES

N/A

5. POLICY

Provides guidelines regarding the medical necessity review of ventricular assist devices.

Medical Necessity

Curative considers a Food and Drug Administration (FDA)-approved ventricular assist device (VAD) medically necessary for *any* of the following FDA-approved indications:

- As a bridge to transplant for members who are awaiting heart transplantation (see CPB 0586 - Heart Transplantation) and the device has received FDA approval for a bridge to transplant indication (e.g., HeartMate 3 left ventricular assist system (LVAS)); *or*
- As destination therapy when **all of the following criteria are met:**
    - The device has received FDA approval for a destination therapy indication (e.g., HeartMate II LVAD and Aries HeartMate 3 [HM3]); *and*
    - Member has New York Heart Association (NYHA) Class IV end-stage ventricular heart failure and is not a candidate for heart transplant; and
    - Member has failed to respond to optimal medical management (including beta-blockers, and angiotensin-converting enzyme (ACE) inhibitors if tolerated) for at least 45 of the last 60 days, or has been balloon pump dependent for 7 days, or has been IV inotrope dependent for 14 days; and
    - Has a left ventricular ejection fraction (LVEF) less than 25%; and
    - Has demonstrated functional limitation with a peak oxygen consumption of less than or equal to 14 ml/kg/min. Note: This criterion may be waived in persons who are balloon pump or intravenous inotrope dependent or are otherwise unable to perform exercise stress testing.

Curative considers VADs experimental and investigational for all other indications because of insufficient evidence in the peer-reviewed literature.

Curative considers a FDA-approved percutaneous left ventricular assist device (pVAD) (e.g., the TandemHeart and the Impella) medically necessary for the following indications:

- Providing short-term circulatory support in cardiogenic shock; or
- As an adjunct to percutaneous coronary intervention (PCI) in the following high-risk members:
- Members undergoing unprotected left main or last-remaining-conduit PCI with ejection fraction less than 35%; or
- Persons with three vessel disease and ejection fraction less than 30%.

Curative considers pVADs experimental and investigational for all other indications because of insufficient evidence in the peer-reviewed literature.

Curative considers FDA-approved pediatric VADs medically necessary when both of the following criteria are met:

- Child has documented end-stage left ventricular failure; and
- An age and size-appropriate VAD will be used until a donor heart can be obtained

Curative considers pediatric VADs experimental and investigational when criteria are not met.

> **Note**: Current FDA-approved pediatric VADs include the Berlin Heart EXCOR Pediatric Ventricular Assist Device (for children aged 16 years or younger) and the HeartAssist 5 Pediatric Ventricular Assist Device (for children aged 5 to 16 years). The EXCOR Pediatric VAD can be used in children up to 60 kg body weight. The HeartAssist 5 Pediatric VAD can be used in children with a BSA greater than or equal to 0.7 m^2 and less than 1.5 m^2).

Curative considers FDA-approved right ventricular assist devices (RVADs; e.g., the CentriMag Right Ventricular Assist System) medically necessary for temporary circulatory support when both of the following criteria are met:

- RVAD is used for up to 30 days for members in cardiogenic shock due to acute right ventricular failure; and
- Members are willing and able to be treated with heparin or an appropriate alternative anticoagulant.

Curative considers RVADs experimental and investigational when criteria are not met.

Curative considers the Impella RP System medically necessary for providing circulatory assistance for up to 14 days in pediatric or adult persons with a body surface area ≥ 1.5 m^2 who develop acute right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery.

Experimental and Investigational

The following procedures are considered experimental and investigational the effectiveness of these approaches have not been established:

- Concomitant mitral valve surgery with left ventricular assist device implantation for the treatment of mitral regurgitation
- Implantable aortic counterpulsation ventricular assist systems (e.g., the NuPulseCV iVAS and the Symphony Heart Assist System)
- Use of mesenchymal precursor cells as adjunctive therapy in recipients of ventricular assist devices

6. PROCEDURE

N/A

7. TRAINING REQUIREMENT

7.1. All Medical UM Associates are responsible for reading and comprehending this procedure. Employees are also responsible for contacting management or Privacy and Compliance with any questions or concerns regarding the information contained within this procedure.

8. ENFORCEMENT

Violations of this controlled document will cause the imposition of sanctions in accordance with the Curative sanctions-controlled document. This may include verbal/written warning, suspension, up to termination of employment or volunteer, intern, contractor status with Curative. Additional civil, criminal, and equitable remedies may apply.

9. DOCUMENTATION

N/A

10. REFERENCE DOCUMENTS AND MATERIALS

N/A

11. COLLABORATING DEPARTMENTS

11.1. Medical and Pharmacy UM Departments

12. DOCUMENT CONTROL

APPROVED BY:	
(Printed Name) (Date)	**(Signature)**

REVISION HISTORY			
Date	**Author**	**Version**	**Comments**
			Initial Version

APPENDICES

Any applicable attachments, resources or other materials should be included as appendices in this section. Label each appendix as follows:

Appendix A: