New Century Health

Cardio Policy:

Ventricular Assist Device (VAD)- Percutaneous and Permanent

POLICY NUMBER UM CARDIO_1390	**SUBJECT** Ventricular Assist Device (VAD)- Percutaneous and Permanent	**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 4**
DATES COMMITTEE REVIEWED 02/12/20, 01/13/21, 11/09/21, 01/12/22	**APPROVAL DATE** January 12, 2022	**EFFECTIVE DATE** January 28, 2022	**COMMITTEE APPROVAL DATES** 02/12/20, 01/13/21, 11/09/21, 01/12/22
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee	
URAC STANDARDS HUM v8: UM 1-2; UM 2-1	**NCQA STANDARDS** UM 2	**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**	**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid	

I. PURPOSE

Indications for determining medical necessity for the procedure of Ventricular Assist Device (VAD).

II. DEFINITIONS

A ventricular assist device (VAD), also known as a mechanical circulatory support device, is an implantable mechanical pump that helps pump blood from the lower chambers of the heart (the ventricles) to the rest of the body. A VAD is used in people who have weakened hearts or have heart failure unresponsive to the guideline directed medical therapy.

The two basic types of VADs are: left ventricular assist device (LVAD) and a right ventricular assist device (RVAD). If both types are used at the same time, they may be called a biventricular assist device (BIVAD). The LVAD is the most common type of VAD. It helps the left ventricle pump blood to the aorta which is the main artery that carries oxygen-rich blood from the heart to your body.

RVAD usually used only for short-term support of the right ventricle after LVAD surgery or other heart surgery. An RVAD helps the right ventricle pump blood to the pulmonary artery, which carries blood to the lungs to pick up oxygen.

VADs have two basic designs. A percutaneous VAD (Impella and Tandem Heart), which is used for short-term support during or after surgery and an Implantable VAD, which is mainly used when a

patient is waiting for a heart transplant or as a long-term solution if the patient is not a transplant candidate.

Patient Selection Criteria:

The VADs are indicated for patients who have chronic end-stage heart failure (New York Heart Association Class IV end-stage left ventricular failure, Stage D Heart Failure) and are not candidates for heart transplantation at the time of VAD implant, and meet the following conditions:

- Have failed to respond to optimal medical management (including beta-blockers and ACE inhibitors if tolerated) for 45 of the last 60 days, or have been balloon pump-dependent for last 7 days, or IV inotrope-dependent for 14 days and,
- Have a left ventricular ejection fraction (LVEF) < 25%; and,
- Have demonstrated functional limitation with a peak oxygen consumption of ≤ 14 ml/kg/min unless balloon pump- or inotrope-dependent or physically unable to perform the test.

III. POLICY

Indications for Ventricular Assist Device include the following:

A. Bridge to transplantation (for patients with such severe reductions in cardiac output or noncardiac co-morbidities that survival and successful cardiac transplantation are unlikely without mechanical circulatory support) **(AUC Score 8)**

1. Impending cardiogenic shock despite inotropic support ±IABP in presence of acute renal dysfunction (creatinine>2.0) that is deemed secondary to insufficient renal blood flow and,
2. is poorly responsive to inotropic support and,
3. Pulmonary hypertension (PA systolic pressure >60) that persists despite optimal medical and inotropic therapy **(AUC Score 5)**

B. Bridge to recovery (for patients with otherwise fatal low cardiac output in situations where recovery is possible or probable) **(AUC Score 5)**

1. Acute myocardial infarction complicated by cardiogenic shock
2. Acute myocarditis with shock
3. Acute cardiac failure following cardiac surgery

C. Destination Therapy or Long-term device therapy (for patients with 1 or more major contraindications to cardiac transplantation) **(AUC Score 8)**

1. Class IV heart failure with chronic, refractory, and disabling heart failure symptoms despite optimal therapy
2. Peak oxygen consumption less than 12-14 ml/(kg·min) with cardiac limitation
3. Dependence on intravenous inotropic support
4. Class IV heart failure with expected mortality exceeding 50% in 1 year

Contraindications for VAD:

A. Absolute

1. Irreversible hepatic disease
2. Irreversible renal disease
3. Irreversible neurological disease

4. Medical nonadherence
5. Severe psychosocial limitations

B. Relative
1. Age >80 y for Destination Therapy
2. Obesity or malnutrition
3. Musculo Skeletal disease that impairs rehabilitation
4. Active systemic infection or prolonged intubation
5. Untreated malignancy
6. Severe PVD
7. Active substance abuse
8. Impaired cognitive function
9. Unmanaged psychiatric disorder Lack of social support

Limitations

A. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for New Century Health and cannot be reviewed.

IV. PROCEDURE

A. In order to review a request for medical necessity, the following items must be submitted for review
1. Cardiologist note that prompted request
2. Heart Transplant team note
3. ECHO report

B. Primary codes appropriate for this service: 33979 Insertion of ventricular assist device, implantable intracorporeal, single ventricle 33980 Removal of ventricular assist device, implantable intracorporeal, single ventricle 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

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. National Coverage Determination (NCD) for Ventricular Assist Devices (20.9.1). 9/30/2014
2. Rihal et al. 2015 SCAI/ACC/HFSA/STS Clinical Expert Consensus Statement on the Use of Percutaneous Mechanical Circulatory Support Devices in Cardiovascular Care. JACC VOL. 65, NO. 19, 2015

3. Peura JL, Colvin-Adams M, Francis GS, et al. Recommendations for the Use of Mechanical Circulatory Support: Device Strategies and Patient Selection. A Scientific Statement from the American Heart Association. Circulation. 2012; 126:2648-2667.)
4. Alba AC, Rao V, Ivanov J, Ross HJ, Delgado DH. Usefulness of the INTERMACS scale to predict outcomes after mechanical assist device implantation. J Heart Lung Transplant. 2009;28:827–833.
5. NCQA UM 2022 Standards and Elements.