SUBJECT: Temporary Ventricular Assist Devices

Prior approval is required for some or all procedure codes listed in this Corporate Medical Policy.

Definition: A temporary ventricular assist device (VAD) is intended to provide short-term circulatory support in the presence of cardiogenic shock, or severe heart failure. The devices have been evaluated for short-term use as a bridge to heart transplantation, short-term support for post-cardiotomy ventricular dysfunction, and short term use for heart decompensation. Examples of temporary ventricular assist devices approved by the U.S. Food and Drug Administration include: the TandemHeart (Cardiac Assist Inc, Pittsburg, PA) and the Impella (ABIOMED, Inc).

Medical Necessity:

The Company considers temporary ventricular support systems (i.e. Impella 2.5, 5.0, CP, LD and TandemHeart PTVA System) (CPT Codes 33990, 33991, 33993) medically necessary and eligible for reimbursement providing that one of the following medical criteria are met:

- Short term† circulatory assistance for treatment of ongoing cardiogenic shock†† that occurs less than 48 hours following:
  - Acute myocardial infarction; or
  - Open heart surgery; or
- Individual is awaiting a heart transplantation and is otherwise not expected to survive

† Impella 2.5 and Impella CP < 4 days, Impella 5.0 and Impella LD < 6 days, TandemHeart PTVA < 6 hours.

†† As a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional treatment measures including volume loading and use of vasopressors and inotropes, with or without IABP counter-pulsation. Cardiogenic Shock clinical parameters are Systolic Blood Pressure < 90 mm Hg for ≥30 min OR use of vasopressors to maintain SBP > 90 mm Hg, AND clinical pulmonary congestion, AND impaired end organ perfusion indicated by altered mental status, cold/clammy skin and extremities, urine output < 30 ml/hr, and lactate > 2.0 mmol/L.

The Company considers temporary right ventricular support (up to 14 days) ventricular assist devices (i.e. Impella RP System®) (CPT Codes 33990, 33991, 33993) medically necessary and eligible for reimbursement for providing circulatory assistance providing that all of the following medical criteria are met:
• Adult or pediatric patient
• Body surface area ≥ 1.5 m²
• Acute right heart failure or decompensation following
  o Left ventricular assist device implantation; or
  o Myocardial infarction; or
  o Heart transplant; or
  o Open-heart surgery.

The Company considers temporary ventricular assist devices for all other clinical conditions not medically necessary and not eligible for reimbursement

NOTE: Initiation of any form of mechanical circulatory assistance should at a minimum include immediate availability of interventional cardiologists, cardiovascular surgeons, cardiovascular anesthesiologists, cardiovascular imaging specialists, and staff trained in the use of approved techniques and equipment for the device used. Performance of a risk assessment, and a review of all clinical information including symptoms, clinical data, and comorbidities is appropriate.

NOTE: Place of service includes an advanced cardiac center with a mechanical circulatory assistance team and a Cardiac surgery program; and Cardiac catheterization lab or hybrid operating room; and Non-invasive imaging (i.e., echocardiography, vascular ultrasound, computed tomography, positron emission tomography and magnetic resonance); and Sufficient space in a sterile environment to accommodate necessary equipment for cases with and without complications; and Post-procedure intensive care availability is recommended.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member, and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results, and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply, and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.
Sources of Information:


Applicable Code(s):

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