Ventricular Assist Devices
Clinical Coverage Criteria

Overview
Ventricular Assist Devices (VAD) are a blood pump that is implanted during a surgical procedure and is attached to one or both ventricles. VAD’s are implanted in a weakened or damaged heart in order to assist the heart with pumping blood decreasing the work of the ventricle. VAD’s are used as both a bridge to transplantation and as destination therapy.

Policy
Fallon Health requires Prior Authorization for Ventricular Assist Devices. The below criteria must be met in order for approval. Medical records from the providers who have diagnosed or treated the symptoms prompting this request are also required.

Criteria for Destination Therapy (all criteria must be met)
1. The device has been FDA approved for Destination Therapy
2. The member has chronic end-stage heart failure as classified by New York Heart Association (NYHA) class IV (see table below) and is not a candidate for a heart-transplant
3. The member has failed to respond to maximum medical management such as:
   • Beta-blockers or Ace Inhibitors for at least 45 of the last 60 days. Or
   • Has been balloon pump dependent for the 7 days. Or
   • Has been IV inotrope dependent for 14 days.
4. Have left ventricular ejection fraction (LVEF) less than 25%
5. The member demonstrates functional limitations with peak oxygen consumption ≤ 14 ml/kg/min

Criteria for Bridge to Transplantation (all criteria must be met)
1. The device must be FDA approved
2. The member is a candidate for a heart-transplant but is not expected to survive until transplantation without a VAD

New York Heart Association (NYHA) Functional Classification:

<table>
<thead>
<tr>
<th>Class</th>
<th>Patient Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath).</td>
</tr>
<tr>
<td>II</td>
<td>Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea (shortness of breath).</td>
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<tr>
<td>III</td>
<td>Marked limitation of physical activity. Comfortable at rest. Less than ordinary</td>
</tr>
</tbody>
</table>
activity causes fatigue, palpitation, or dyspnea.

IV Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.

Exclusions
- Any use of a Ventricular Assist Device (VAD) other than outlined above.

Codes

<table>
<thead>
<tr>
<th>Code type</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>33975</td>
<td>Insertion of ventricular assist device; extracorporeal, single ventricle</td>
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<tr>
<td></td>
<td>33976</td>
<td>Insertion of ventricular assist device; extracorporeal, biventricular</td>
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<tr>
<td></td>
<td>33977</td>
<td>Removal of ventricular assist device; extracorporeal, single ventricle</td>
</tr>
<tr>
<td></td>
<td>33978</td>
<td>Removal of ventricular assist device; extracorporeal, biventricular</td>
</tr>
<tr>
<td></td>
<td>33979</td>
<td>Insertion of ventricular assist device, implantable intracorporeal, single ventricle</td>
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<tr>
<td></td>
<td>33980</td>
<td>Removal of ventricular assist device, implantable intracorporeal, single ventricle</td>
</tr>
<tr>
<td></td>
<td>33981</td>
<td>Replacement of extracorporeal ventricular assist device, single or biventricular, pump(s), single or each pump</td>
</tr>
<tr>
<td></td>
<td>33982</td>
<td>Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, without cardiopulmonary bypass</td>
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<tr>
<td></td>
<td>33983</td>
<td>Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, with cardiopulmonary bypass</td>
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<tr>
<td></td>
<td>33990</td>
<td>Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; arterial access only</td>
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<tr>
<td></td>
<td>33991</td>
<td>Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; both arterial and venous access, with transseptal puncture</td>
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<td></td>
<td>33992</td>
<td>Removal of percutaneous ventricular assist device at separate and distinct session from insertion</td>
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<tr>
<td></td>
<td>33993</td>
<td>Repositioning of percutaneous ventricular assist device with imaging guidance at separate and distinct session from insertion</td>
</tr>
<tr>
<td></td>
<td>33999</td>
<td>Unlisted procedure, cardiac surgery</td>
</tr>
</tbody>
</table>

References
1. CMS: National Coverage Determination (NCD) for Artificial Hearts and Related Devices (20.9) Last revised January 2019.


**Policy History**

Origination date: 02/01/2016

Approval(s): Technology Assessment Committee: 1/27/2016 (new policy), 01/25/2017 (updated references), 01/24/2018 (annual review), 01/23/2019 (updated references), 01/22/2020 (updated references)

*Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member’s particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product’s Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member’s benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church)*
plans. Unless otherwise specifically excluded, federal mandates will apply to all plans. For Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this policy.