

Prepublication Requirements

• Issued June 18, 2021 •



Revisions to Requirements for Advanced Certification for Ventricular Assist Device

The Joint Commission has approved the following revisions for prepublication. While revised requirements are published in the semiannual updates to the print manuals (as well as in the online *E-dition*®), accredited organizations and paid subscribers can also view them in the monthly periodical *The Joint Commission Perspectives*®. To begin your subscription, call 800-746-6578 or visit <http://www.jcrinc.com>.

Please note: Where applicable, this report shows current standards and EPs first, with deleted language struck-through. Then, the revised requirement follows in bold text, with new language underlined.

APPLICABLE TO ADVANCED CERTIFICATION FOR VENTRICULAR ASSIST DEVICE

Effective January 1, 2022

Program Management (DSPR) Chapter

DSPR.1

The program defines its leadership roles.

Element(s) of Performance for DSPR.1

1. The program identifies members of its leadership team.

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Requirements Specific to Ventricular Assist Device

- a. **The program identifies a medical director who has knowledge and experience in advanced heart failure therapies and experience managing patients with ventricular assist devices (VAD).**
- b. **The program identifies a ventricular assist device (VAD) coordinator who has knowledge and experience in advanced heart failure therapies and experience managing patients with ventricular assist devices (VAD).**

4. The program leader(s) identifies, in writing, the composition of the interdisciplinary team.

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Key: **D** indicates that documentation is required;

R indicates an identified risk area;

Requirements Specific to Ventricular Assist Device Destination Therapy

a. The interdisciplinary VAD team is comprised of the following:

- One or more cardiologists trained in advanced heart failure (See also DSDF.1, EP 1a)
- One or more cardiac surgeons (See also DSDF.1, EP 1a)
- A VAD coordinator

Note: Examples of a VAD coordinator include registered nurse, perfusionist.

- A social worker
- A palliative care representative

b. Based on patient and family needs, the interdisciplinary program team also includes individuals from the following disciplines:

- Nutrition
 - Psychological services
 - Rehabilitative services
 - Financial support
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Requirements Specific to Ventricular Assist Device

a. Ventricular assist device (VAD) patients are managed by a distinctly identified interdisciplinary team of medical professionals that is based at the facility. The interdisciplinary team works collaboratively across medical specialties to offer optimal patient-centered care.

b. Members of the interdisciplinary team have appropriate qualifications, training, and experience, and the team must include individuals with experience working with patients before and after placement of a VAD. The interdisciplinary VAD team includes, but is not limited to, the following:

- One or more cardiologist(s)
 - One or more cardiothoracic surgeon(s)
 - VAD coordinator
 - Social worker
 - Palliative care representative
 - Anesthesiologist(s) or certified registered nurse anesthetist(s)
 - Advanced practice provider(s) (if utilized by the program)
 - Nursing staff
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7. The program leader(s) makes certain that practitioners practice within the scope of their licensure, certification, training, and current competency.

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Requirements Specific to Ventricular Assist Device

- a. The program makes certain that licensed practitioners who manage VAD device settings and parameters are trained, experienced, and privileged according to their scope of practice and in accordance with laws and regulations and organizational procedure(s).
- b. The cardiothoracic surgeon(s) is privileged by the organization for VAD implantation.
- c. The cardiologist(s), including the heart failure specialist, is privileged by the organization to care for the VAD patient population.

DSPR.3

The program meets the needs of the target population.

Element(s) of Performance for DSPR.3

3. The program identifies its target population.

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Requirement Specific to Ventricular Assist Device Destination Therapy

- a. ~~The program has a process to determine eligibility for VAD placement that at a minimum includes:~~
 - ~~- The use of specific criteria for determining the inclusion or exclusion of patients~~
 - ~~- An interdisciplinary approach to determining which patients are eligible for VAD placements~~

Requirement Specific to Ventricular Assist Device

- a. The program utilizes an interdisciplinary approach in determining which patients are eligible for VAD placements. The following patient criteria are included in this determination:
 - New York Heart Association (NYHA) Class IV heart failure; and
 - Left ventricular ejection fraction (LVEF) less than or equal to 25%; and
 - Inotrope dependent; or
 - Cardiac Index (CI) less than 2.2 L/min/m², while not on inotropes, and also meet one of the following:
 - Are on optimal medical management, based on current heart failure practice guidelines for least 45 out of the last 60 days and are failing to respond; or
 - Have advanced heart failure for at least 14 days and are dependent on an intraaortic balloon pump or similar temporary mechanical circulatory support for at least 7 days

4. The services provided by the program are relevant to the target population.

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Requirement Specific to Ventricular Assist Device ~~Destination Therapy~~

a. The program has a ~~relationship with a heart transplant center that provides a documented heart transplant consultation for each patient.~~

~~Note: The exception to this requirement would be those patients who are INTERMACS level 1 or 2 or too clinically unstable for an evaluation to occur.~~

Requirement Specific to Ventricular Assist Device

a. The program has a referral process to a heart transplant center, if needed.

DSPR.5

The program determines the care, treatment, and services it provides.

Element(s) of Performance for DSPR.5

4. The program complies with applicable law and regulation.

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Requirement Specific to Ventricular Assist Device

a. **The program utilizes ventricular assist devices that have received approval from the US Food and Drug Administration (FDA) and are used according to FDA-approved labeling instructions.**

6. The program has a process to provide emergency/urgent care.

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Requirements Specific to Ventricular Assist Device ~~Destination Therapy~~

a. The program provides 24 hours a day, 7 days a week support for the patient and family regarding how to handle emergency and urgent care following discharge from the hospital.

b. The ~~VAD~~ program designates practitioners to be on call to assist ~~discharged~~ patients and families after hours.

Requirements Specific to Ventricular Assist Device

- a. The program provides 24 hours a day, 7 days a week support for the patient, family, and/or caregivers, as well as other health care providers regarding how to handle emergency and urgent care following discharge from the hospital.
- b. The program designates practitioners to be on call to assist staff, patients, families, and/or caregivers, as well as other health care providers after hours with VAD support.

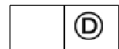
DSPR.7

The program's facilities are safe and accessible.

Note: The program may use the organization's plan and processes for safety and accessibility if they address the program's unique needs and target population.

Element(s) of Performance for DSPR.7

- 7. The program develops a medical equipment management plan.



Requirement Specific to Ventricular Assist Device ~~Destination Therapy~~

- a. The program has a process for maintaining the most up-to-date device information, including manufacturer recalls and warnings.

Requirement Specific to Ventricular Assist Device

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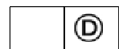
Delivering or Facilitating Clinical Care (DSDF) Chapter

DSDF.1

Practitioners are qualified and competent.

Element(s) of Performance for DSDF.1

- 1. Practitioners have education, experience, training, and/or certification consistent with the program's scope of services, goals and objectives, and the care provided.



Key: **D** indicates that documentation is required;

R indicates an identified risk area;

Requirement Specific to Ventricular Assist Device Destination Therapy

a. The interdisciplinary team has at least the following experience and expertise:

– One or more cardiologists, each of whom:

i. Is trained and experienced in advanced heart failure therapies

ii. Has recent experience managing patients who have had ventricular assist devices placed or heart transplants

iii. Has sufficient competency in evaluating patients for transplant as evidenced by having worked in or trained in a transplant center

– One or more cardiac surgeons, each of whom has successfully placed 10 ventricular assist devices in the last 36 months with current activity occurring in the last year

Note 1: Acceptable ventricular assist device procedures include placement of long-term devices and devices that are part of studies for US Food and Drug Administration approval.

Note 2: If a surgeon on the team has not placed 10 ventricular assist devices during the required time period, the volume requirement can include artificial heart placements for no more than 50% of the total volume within the 36-month period.

Note 3: The 10 ventricular assist devices implanted by a surgeon in training could have occurred during a training program if the following are met: (1) There is evidence that the surgeon in training physically implanted each ventricular assist device under the supervision of a cardiac surgeon. An example would be a procedure log with supporting documentation from the supervising surgeon. (2) The surgeon in training participated in the preoperative planning and postoperative management of the patient.

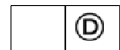
– A VAD coordinator who has experience and expertise in the complete course of treatment of a VAD patient

Note: Examples of a VAD coordinator include registered nurse, perfusionist.

– A social worker who has experience in the assessment and evaluation of a VAD patient and his or her family

– A palliative care representative who has experience with the VAD patient population

3. The program assesses practitioner competency at time of hire. This assessment is documented.



Requirements Specific to Ventricular Assist Device Destination Therapy

a. The cardiac surgeon is privileged by the organization for VAD implantation.

b. One or more cardiologists, including the heart failure specialist, are privileged by the organization to care for the VAD patient population.

DSD.F.2

The program develops a standardized process originating in clinical practice guidelines (CPGs) or evidence-based practice to deliver or facilitate the delivery of clinical care.

Element(s) of Performance for DSD.F.2

2. The selected clinical practice guidelines are based on evidence that is determined to be current by the clinical leaders.

Requirement Specific to Ventricular Assist Device

a. The program follows current clinical practice guidelines for advanced heart failure and VAD treatment such as those set forth by the American College of Cardiology (ACC), the American Heart Association (AHA), the Heart Failure Society of America (HFSA), and/or the International Society for Heart and Lung Transplantation (ISHLT).

Note: Individual patient needs or newly published evidence may warrant the use of additional clinical practice guidelines.

5. The program demonstrates evidence that it is following the clinical practice guidelines when providing care, treatment, and services.

Requirement Specific to Ventricular Assist Device Destination Therapy

a. Inclusion criteria for VAD implant are as follows:

- Patients who have an anticipated survival benefit
- Patients with New York Heart Association Functional Classification Class IV heart failure symptoms who have failed to respond to optimal medical management
- Patients with a demonstrated functional limitation with a peak oxygen consumption of less than or equal to 14 ml/kg/min
- Patients with a continued need for intravenous inotropic therapy
- Patients who have been evaluated for heart transplant and were not selected as candidates

Note: To receive CMS reimbursement, patients must meet current CMS patient selection and coverage criteria.

DSD.F.3

The program is implemented through the use of clinical practice guidelines selected to meet the patient's needs.

Element(s) of Performance for DSD.F.3

2. The assessment(s) and reassessment(s) are completed according to the patient's needs and clinical practice guidelines.

Key: **D** indicates that documentation is required;

R indicates an identified risk area;

Requirement Specific to Ventricular Assist Device ~~Destination Therapy~~

a. The VAD patient is evaluated for post-implant clinical improvement to determine further treatment options.

Requirements Specific to Ventricular Assist Device

a. Assessments and reassessments are completed in a time frame that meets the patients' needs based on current clinical practice guidelines and according to the program's policies and procedures.

b. The patient is evaluated post-implant at least annually to determine further treatment options (such as myocardial recovery or heart transplant eligibility).

3. The program implements care, treatment, and services based on the patient's assessed needs.

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Requirement Specific to Ventricular Assist Device ~~Destination Therapy~~

a. The program has the ability to perform diagnostic tests to assess the VAD patient pre-implant or post-implant. These may include electrocardiography, echocardiography with device implant, exercise testing, nuclear cardiology, electrophysiology, cardiovascular MRI, pacing, diagnostic catheterization of right- and left-sided heart, and interventional catheterization.

Requirements Specific to Ventricular Assist Device

a. The program has the ability to perform diagnostic tests to assess the VAD patient pre-implant or post-implant. These may include electrocardiography, echocardiography with device implant, exercise testing, nuclear cardiology, electrophysiology, cardiovascular MRI, pacing, diagnostic catheterization of right- and left-sided heart, and interventional catheterization.

b. Practitioners providing care within their scope of practice recognize, assess, and implement interventions to VAD program patients based on the clinical practice guidelines and evidence-based care practices followed by the program.

DSD.F.4

The program develops a plan of care that is based on the patient's assessed needs.

Element(s) of Performance for DSD.F.4

1. The plan of care is developed using an interdisciplinary approach and patient participation.

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Key: **(D)** indicates that documentation is required;

(R) indicates an identified risk area;

Requirement Specific to Ventricular Assist Device ~~Destination Therapy~~

a. The program demonstrates an interdisciplinary approach for the outpatient management of the VAD patient.

Requirement Specific to Ventricular Assist Device

a. The program demonstrates an interdisciplinary approach for the outpatient management of the VAD patient.

4. The individualized plan of care reflects coordination of care with other programs, as determined by patient comorbidities.

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Requirements Specific to Ventricular Assist Device ~~Destination Therapy~~

- a. Patients are identified for palliative care, when indicated.
- ~~b. Patients are referred to palliative care, when indicated.~~
- ~~c. Patients receive palliative care services, when indicated.~~

Requirement Specific to Ventricular Assist Device

a. **Based on prognosis and individual needs, patients are referred for palliative care when clinically indicated.**

DSD.F.5

The program manages comorbidities and concurrently occurring conditions and/or communicates the necessary information to manage these conditions to other practitioners.

Element(s) of Performance for DSD.F.5

1. The program coordinates care for patients with multiple health needs.

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Requirement Specific to Ventricular Assist Device ~~Destination Therapy~~

a. The interdisciplinary team conducts regularly scheduled VAD meetings to discuss coordination of care for VAD patients in the program.

Requirement Specific to Ventricular Assist Device

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Key: **(D)** indicates that documentation is required;

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2. Patients with comorbidities and co-occurring conditions needing clinical and/or psychosocial care, treatment, and services are managed by the program's practitioners or referred to other practitioners for care.

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Requirement Specific to Ventricular Assist Device ~~Destination Therapy~~

- a. Psychological support is available for patients and their families to help them meet the unique challenges associated with VAD implantation.

Requirement Specific to Ventricular Assist Device

- a. Psychological support is available for patients and their families to help them meet the unique challenges associated with VAD implantation.

DSD.F.6

The program initiates discharge planning and facilitates arrangements for subsequent care, treatment, and services to achieve mutually agreed upon patient goals.

Element(s) of Performance for DSD.F.6

1. In preparation for discharge, the program discusses and plans with the patient and family the care, treatment, and services that are needed in order to achieve the mutually agreed upon self-management plan and goals.

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Requirements Specific to Ventricular Assist Device ~~Destination Therapy~~

- a. Coordination of care for the VAD patient is conducted prior to discharge and includes at least the following:
- Contact information for a practitioner in the community is given to the patient to facilitate ongoing care
 - Contact information for the VAD center practitioner is given to the patient to facilitate ongoing care
- b. The program has an outpatient management plan that includes at least the following:
- A schedule for follow-up appointments
 - A schedule for device checks
 - Ongoing education based on patient and family need

Requirements Specific to Ventricular Assist Device

a. Coordination of care for the VAD patient is conducted prior to discharge and includes at least the following:

- Contact information for a practitioner in the community is given to the patient to facilitate ongoing care
- Contact information for the VAD center practitioner is given to the patient to facilitate ongoing care

b. The program has an outpatient management plan that includes at least the following:

- A schedule for follow-up appointments
 - A schedule for device checks
 - Ongoing education based on patient and family need
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2. In preparation for discharge, the program considers the patient's anticipated needs and goals when identifying the setting and practitioners for continuing care, treatment, and services.

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Requirement Specific to Ventricular Assist Device Destination Therapy

a. When the patient will not reside within a reasonable commuting distance from the facility following discharge, the program shall, at the time of discharge, arrange appropriate follow-up care with a facility and physician near the patient's residence.

Requirement Specific to Ventricular Assist Device

a. When the patient will not reside within a reasonable commuting distance from the facility following discharge, the program shall, at the time of discharge, arrange appropriate follow-up care with a facility and physician near the patient's residence.

4. The program provides education and serves as a resource, as needed, to practitioners who are assuming responsibility for the patient's continued care, treatment, and services.

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Requirements Specific to Ventricular Assist Device Destination Therapy

a. Members of the interdisciplinary team are available to other practitioners managing the patient, as needed, after discharge from the program.

b. The program has a documented plan to inform and provide education resources to first responders within the vicinity of the patient's residence.

Requirements Specific to Ventricular Assist Device

- a. Members of the interdisciplinary team are available to other practitioners managing the patient, as needed, after discharge from the program.
- b. The program documents and implements a plan to inform and provide education resources to first responders within the vicinity of the patient's residence.

Supporting Self-Management (DSSE) Chapter

DSSE.1

The program involves patients in making decisions about managing their disease or condition.

Element(s) of Performance for DSSE.1

1. The program involves patients in decisions about their care, treatment, and services.

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Requirements Specific to Ventricular Assist Device ~~Destination Therapy~~

- a. Informed surgical consent reflects the patient's understanding of the following:
 - Preoperative, intraoperative, and postoperative plan of care, treatment, and services
 - Current survival and functional expectations after VAD implant
 - Alternative courses of treatment
- b. As part of facilitating patient decision making, the interdisciplinary team members discuss the following with the patient and family:
 - Anticipated outpatient management plan
 - Quality of life factors such as physical function, psychosocial effect, symptoms, costs, caregiver burden
 - Patient expectations
 - Rehabilitation plan
- c. The informed surgical consent and all decision-making discussions are documented.

Requirements Specific to Ventricular Assist Device

- a. Informed surgical consent reflects the patient’s understanding of the following:
 - Preoperative, intraoperative, and postoperative plan of care, treatment, and services
 - Current survival and functional expectations after VAD implant
 - Alternative courses of treatment
- b. As part of facilitating patient decision making, the interdisciplinary team members discuss the following with the patient and family:
 - Anticipated outpatient management plan
 - Quality of life factors such as physical function, psychosocial effect, symptoms, costs, caregiver burden
 - Patient expectations
 - Rehabilitation plan
- c. The informed surgical consent and all decision-making discussions are documented.

DSSE.2

The program addresses the patient's self-management plan.

Element(s) of Performance for DSSE.2

- 2. The program evaluates barriers to lifestyle changes.

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Requirements Specific to Ventricular Assist Device ~~Destination Therapy~~

- a. The program determines that the patient’s home environment can support safe and reliable functioning of a VAD.
 Note: Any valid method for making a determination on the home environment can be used. The program does not have to visit the patient’s home.
- b. The program evaluates the home environment as part of its decision-making process for implantation of a VAD.

Requirements Specific to Ventricular Assist Device

- a. The program determines that the patient’s home environment can support safe and reliable functioning of a VAD.
 Note: Any valid method for making a determination on the home environment can be used. The program does not have to visit the patient’s home.
- b. The program evaluates the home environment as part of its decision-making process for implantation of a VAD.

3. The program engages family and community support structures in the patient's self-management plan, as directed by the patient.

Requirements Specific to Ventricular Assist Device Destination Therapy

- a. The hospital ascertains, through the home assessment, that the patient's home environment is satisfactory and that the patient has an adequate and reliable power supply and telephone service.
- b. Communication is sent from the hospital to the power company informing it that a ventricular assist device patient lives in the vicinity.
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Requirements Specific to Ventricular Assist Device

- a. The hospital ascertains, through the home assessment, that the patient's home environment is satisfactory and that the patient has an adequate and reliable power supply and telephone service.
- b. Communication is sent from the hospital to the power company informing it that a ventricular assist device patient lives in the vicinity.
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DSSE.3

The program addresses the patient's education needs.

Element(s) of Performance for DSSE.3

4. The program makes initial and ongoing assessments of the patient's comprehension of program-specific information.

Requirement Specific to Ventricular Assist Device Destination Therapy

- a. The program educates the patient and family on troubleshooting the VAD and responding to alarms.
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Requirement Specific to Ventricular Assist Device

- a. The program educates the patient and family on troubleshooting the VAD, responding to alarms, and when to seek medical care.
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Clinical Information Management (DSCT) Chapter

DSCT.3

Patient information is gathered from a variety of sources.

Key: **D** indicates that documentation is required; **R** indicates an identified risk area;

Element(s) of Performance for DSCT.3

2. Information is gathered from relevant practitioners and/or health care organizations.

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Requirements Specific to Ventricular Assist Device ~~Destination Therapy~~

- a. The program gathers information from all relevant practitioners or health care organizations prior to implantation of the ventricular assist device.
- b. The program gathers information from all relevant practitioners or health care organizations at least annually after implantation of the ventricular assist device to ascertain any additional needs the patient may have related to the device.

Requirements Specific to Ventricular Assist Device

- a. The program gathers information from all relevant practitioners or health care organizations prior to implantation of the ventricular assist device.
- b. The program gathers information from all relevant practitioners or health care organizations at least annually after implantation of the ventricular assist device to ascertain any additional needs the patient may have related to the device.

Performance Measurement (DSPM) Chapter

DSPM.3

The program collects measurement data to evaluate processes and outcomes.

Note: Measurement data must be internally trended over time and may be compared to an external data source for comparative purposes.

Element(s) of Performance for DSPM.3

1. The program selects valid, reliable performance measures that are relevant to the target population and based on clinical practice guidelines or other evidence-based practice.

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Requirement Specific to Ventricular Assist Device ~~Destination Therapy~~

- a. The program monitors the occurrence of the following adverse events throughout the episode of care:
 - Bleeding
 - Infection
 - Stroke
 - Readmission
 - Device malfunction

Requirement Specific to Ventricular Assist Device

a. The program monitors the occurrence of the following adverse events throughout the episode of care:

- Bleeding
- Infection
- Stroke
- Readmission
- Device malfunction

2. The program collects data related to processes and/or outcomes of care.

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Requirements Specific to Ventricular Assist Device ~~Destination Therapy~~

a. The program monitors at least the following data:

- Survival rate (all cause mortality)
- Functional capacity
- ~~- Any result provided by the national registry~~

b. The program evaluates VAD patients' perceptions of their quality of life at the following intervals: pre-implant and post-implant, at 3 months, at 6 months, then every 6 months for 2 years, and then annually.

Requirements Specific to Ventricular Assist Device

a. The program monitors at least the following data:

- Survival rate (all cause mortality)
- Functional capacity

b. The program evaluates VAD patients' perceptions of their quality of life at the following intervals: pre-implant and post-implant, at 3 months, at 6 months, then every 6 months for 2 years, and then annually.

c. The program utilizes an audited registry to monitor VAD data and measure outcomes.

Note: See the Glossary for the definition of audited registry.

DSPM.4

The program collects and analyzes data to determine variance from the clinical practice guidelines.

Element(s) of Performance for DSPM.4

2. The program evaluates variances that affect program performance and outcomes.

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Key: **(D)** indicates that documentation is required;

(R) indicates an identified risk area;

Requirement Specific to Ventricular Assist Device ~~Destination Therapy~~

a. The program analyzes its ~~VAD~~ patient data in a nationally audited registry to evaluate outcomes.

Note: ~~INTERMACS is currently the only nationally audited registry for VAD.~~

Requirement Specific to Ventricular Assist Device

a. The program analyzes the audited registry to evaluate VAD data and measure outcomes.
