VENTRICULAR ASSIST DEVICE DESTINATION THERAPY CERTIFICATION
FINAL RECOMMENDATIONS

The chart below contains existing Disease Specific Care standards and the elements of performance used to evaluate compliance with those standards. Any program applying for Disease Specific Certification must meet all the applicable standards in the program. There are nine elements of performance that have requirements specific for Ventricular Assist Device Destination Therapy Programs. These are displayed in *italicized red text.*

Standard	**Element of Performance*/ Requirement Specific to Ventricular Assist Device Destination Therapy Certification***
Eligibility Criteria	*Facilities have infrastructure to support ventricular assist device placements as evidenced by adequate staffing and facilities to perform and recover patients after cardiac surgery.* *Programs must be an active continuous member of a national, audited registry that requires submission of health data on all ventricular assist device destination[1] therapy patients from the date of implantation throughout the remainder of their lives.*
DELIVERING OR FACILITATING CLINICAL CARE (DF)	
DF.1 Practitioners are qualified and competent.	1 Practitioners have educational backgrounds, experience, training, and/or certification consistent with the program's mission, goals, and objectives. *Physicians managing the patient include but are not limited to:* • *One or more board-certified cardiologists each of whom:* o *Is trained and experienced in advanced heart failure therapies,* o *Has had recent experience managing patients who have had ventricular assist devices placed or heart transplants, and* o *Has sufficient competency in evaluating patients for transplant as evidenced by having worked in or trained in a transplant center.* • *One or more board certified cardiac surgeons each of whom:* o *Has successfully placed ten (10) ventricular assist devices[2] in the last 36 months with current activity in the last year.*
	2 Core criteria for hiring practitioners in the program include, at a minimum, current licensure, relevant education, training and experience, and current competence.
	3 Criteria for evaluating practitioners in the program include, at a minimum, current licensure and current competence.
	4 Current licensure is verified from primary sources.
	5 Orientation provides information and necessary training appropriate to program responsibilities.
	6 The competence of all practitioners is assessed when new techniques or responsibilities are introduced and periodically within the timeframes defined by the program.
	7 Ongoing in-service and other education and training activities are relevant

[1] *Programs are highly encouraged to enter patients who have a ventricular assist device as a bridge to transplant into national, audited registries. This will allow the program to easily track information for quality improvement purposes.*
[2] *Acceptable ventricular assist device procedures include placement of long-term devices (those with a FDA indication for use over 30 days) or placement of long-term devices as part of studies for FDA approval.*

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	to the program's needs.
	8 Practice, care, and/or services are analyzed for negative patterns and trends to provide feedback to practitioners and to identify and respond to their learning needs.
DF.2 A standardized process originating in clinical practice guidelines [CPGs] or evidence-based practice is used to deliver or facilitate the delivery of clinical care.	1 The CPGs used are based on evidence that has been evaluated as current by the clinical leaders.
	2 The CPGs used have been evaluated as appropriate for the target population.
	3 When the CPGs are selected by a sponsoring organization (for example, a disease management service provider uses a CPG chosen by the health plan with which it contracts), the program evaluates the CPGs to ensure that they are appropriate for their intended use.
	4 Assessment activities are consistent with CPGs. *Acceptance criteria:* • *Patients who have an anticipated survival benefit.* • *Patients with NYHA Class IV heart failure symptoms that have failed to respond to optimal medical management.* • *Patients with a demonstrated functional limitation with a peak oxygen consumption of ≤ 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*
	5 Intervention activities are consistent with CPGs.
	6 Adapted or adopted CPGs are reviewed annually or when significant changes in the field occur, to ensure their appropriateness for the program.
	7 Modifications made to CPGs are implemented.
	8 Appropriate leaders and practitioners in the program review and approve CPGs selected for implementation.
	9 Practitioners have been educated about CPGs and their use.
DF.3 The standardized process is tailored to meet the participant's needs.	1 The program defines the patient assessment process.
	2 An assessment is completed for all participants within the time frame determined by the program.
	3 The assessment is used to develop a plan of care.
	4 An explicit method of stratification exists.
	5 Stratification methods direct interventions.
	6 The standardized method or process is tailored to meet the targeted population's age and developmental needs.
	7 The plan of care is updated to meet the participant's ongoing needs.
DF.4 Concurrently occurring conditions are managed, or the information necessary for their management is communicated to the appropriate practitioner(s).	1 Care is coordinated for participants with multiple diseases and/or whom multiple disease-specific care programs manage. *Coordination of care of the patients is conducted in part at a regularly scheduled ventricular assist device meeting that is attended by the scope of disciplines involved in the care of the patients.*
	2 When concurrently occurring conditions are identified, salient information is communicated to the appropriate practitioners treating or managing the condition(s).
	3 When a concurrently occurring condition needs medical intervention, the

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	patient is either treated by the practitioners in the program or referred to an appropriate practitioner.
	4 The program has a mechanism for managing urgent health issues. *Members of the team are available to other practitioners managing the patient as needed even after discharge from the program.*
DF.5 The standardized process is revised or improved through the ongoing collection and evaluation of data regarding variance from the clinical practice guideline.	1 Variances are tracked at the individual participant level.
	2 Use of the CPGs is modified based on the analysis of outcomes.
	3 Information related to the changes made within the standardized process is communicated to all appropriate individuals.
	4 Changes in the standardized process are evaluated.
PERFORMANCE MEASUREMENT AND IMPROVEMENT (PM)	
PM.1 The program has an organized, comprehensive approach to performance improvement [PI].	1 The PI program is well designed and planned.
	2 The PI program collects relevant data.
	3 The PI program analyzes current performance.
	4 The PI program improves and sustains performance.
	5 PI activities are planned across practitioners, disciplines, and/or settings.
	6 PI activities include input from participants.
PM.2 The program uses measurement data to evaluate process and outcomes.	1 The program selects performance measures that are the following: • Based on the clinical practice guideline or other evidence • Relevant to the management of the disease • Valid • Reliable
	2 Data related to processes and/or outcomes of care are collected at the level of the individual participant.
	3 The program reports data aggregated at the program level to the Joint Commission on Accreditation of Healthcare Organizations at the defined intervals. • *Survival rate (All cause mortality)* • *Functional capacity* • *Any results provided by the national registry.*
	4 Measurement data are analyzed.
	5 Measurement data are used to improve processes and outcomes.
PM.3 Participant perception of care quality is evaluated.	1 The program evaluates participant perception of care quality.
	2 The program makes improvements based on the analysis of the feedback from participants about the perception of care quality.
PM.4 Data quality and integrity are maintained.	1 Minimum data sets, data definitions, codes, classifications, and terminology are standardized throughout the program.
	2 Data collection is timely, accurate, complete, and sufficiently discriminating for its intended use throughout the program.
	3 The program monitors data reliability (including accuracy and completeness) and validity on an ongoing basis and verifies that data bias is minimized.
	4 Sampling methodology is based on measurement principles.
	5 Appropriate data analysis tools are used.

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	6 Factors (participant and/or practitioner) that might affect the outcome(s) of the process (es) being measured have been evaluated.
SUPPORTING SELF-MANAGEMENT (SE)	
SE.1 The program involves participants in making decisions about managing their disease or condition.	1 Participants are involved in decisions about their clinical care. *Signed consent reflects the patient's awareness of preoperative, intraoperative, and postoperative plans and expectations*
	2 Participants and practitioners mutually agree upon goals.
	3 Participants are informed of their responsibilities to provide information to facilitate treatment and cooperate with health care practitioners.
	4 Participants are informed about potential consequences of not complying with a recommended treatment.
	5 The patient's readiness, willingness, and ability to provide or support self-management activities are assessed.
	6 As appropriate, the family's readiness, willingness and ability to provide or support self-management activities are assessed.
SE.2 The program addresses lifestyle changes that support self-management regimens.	1 Lifestyle changes that support self-management regimens are promoted as necessary.
	2 Support structures (family and community) are involved as necessary. • *The hospital ascertains that the patient's home situation is satisfactory and that the patient has power supply and telephone services.* • *Psychological support is available for the patient and their families to meet the unique challenges associated with destination ventricular assist device implantation.* • *Communication is sent from the hospital to the power company informing them that a ventricular assist device patient lives in the vicinity.* • *There is a mechanism to provide twenty-four hour, seven day a week support for the patient and family to handle emergency and urgent care following discharge from the hospital.*
	3 Barriers to change are evaluated as necessary.
	4 The participant's response to making the recommended lifestyle changes is assessed and documented.
	5 The effectiveness of efforts to help the participant in making lifestyle changes is assessed.
SE.3 The program addresses participants' education needs.	1 Materials comply with generally recommended elements of intervention in the literature or promoted through the CPGs.
	2 Content is presented in an understandable and culturally sensitive manner.
	3 The participant's comprehension is assessed initially and on an ongoing basis.
	4 Education needs related to lifestyle changes that support self-management regimens are addressed.
	5 Education needs related to health promotion and disease prevention are addressed.
	6 Education needs related to information about the participant's illnesses and treatments are addressed.
	7 When appropriate, participants are notified about screening recommendations

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	or lifestyle changes related to preventing the disease for their family members, that the participant could then present to the family member
PROGRAM MANAGEMENT (PR)	
PR.1 Leadership roles in the program are clearly defined.	1 The leaders involved in program development and oversight have educational backgrounds, experience, training, and/or certification consistent with the program's mission, goals, and objectives.
	2 The leaders' accountability is clearly defined.
	3 The leaders participate in designing, implementing, and evaluating care, treatment, and services.
	4 The leaders provide for the uniform performance of patient care, treatment, and services.
	5 The leaders confirm that practitioners practice only within their licensure, training, and current competency.
	6 The leaders set expectations, develop plans, and manage processes to measure, assess, and improve the quality of their leadership and the program's management, clinical, and support activities.
PR.2. The program is relevant for the targeted population and/or health care service areas.	1 The program's mission and scope of services are defined in writing and approved by the appropriate leaders.
	2 The program identifies their target population.
	3 The program ensures that the services available are relevant for its targeted population.
PR.3 The scope and level of care, treatment, and services offered by the program are provided to participants.	1 Care, treatment, and services offered are provided to the participants as planned and in a timely manner.
	2 Participants are informed of how to access care and services, including after hours (if applicable). *When the patient will not reside within a reasonable commuting distance from the facility following discharge, the program shall arrange appropriate follow-up care for them with a facility and physician near their residence at the time of discharge.*
	3 Adequate numbers and types of practitioners are available to deliver or facilitate the delivery of care, treatment, and services.
	4 The program evaluates services provided through contractual arrangement to ensure that the scope and level of care, treatment, and services are consistently provided.
	5 Documented policies, processes, and procedures support the care, treatment, and services provided.
PR.4 Eligible patients have access to the care and services provided by the program.	1 Enrollment and/or participation requirements are well defined.
	2 For programs that do not rely solely on direct referrals, a systematic method based on perceived need is used to identify potential participants.
	3 For programs that do not rely solely on direct referrals, individuals are given multiple opportunities to participate in the program.
PR. 5 The scope and level of care, treatment, and services provided are comparable for individuals with the same acuity and type of condition.	1 Individuals have access to an adequate level of resources required to meet the health care needs for the disease(s) being managed.

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PR.6. The program's leaders and, as appropriate, participants, practitioners, and community leaders collaborate to design, implement, and evaluate services.	1 All relevant individuals and/or disciplines participate in designing the program.
	2 All relevant individuals and/or disciplines participate in implementing the program.
	3 All relevant individuals and/or disciplines participate in evaluating the program.
PR.7 The program complies with applicable laws and regulations.	1 The program complies with applicable laws and regulations.
PR.8 The program follows a code of ethics.	1 The program protects the integrity of clinical decision-making, regardless of how the program compensates or shares financial risk with its leaders, managers, and practitioners.
	2 The program respects the participant's right to decline participation in the program.
	3 The program provides for receiving and resolving complaints and grievances in a timely way.
PR.9 Facilities where individuals receive care are safe and physically accessible.	1 The program has evaluated security and implemented strategies to minimize security risks.
	2 The program has developed an emergency plan and implemented strategies to minimize the risk of disruption of care due to an environmentally-related emergency.
	3 The program has evaluated risk points in fire safety and implemented strategies to minimize the risk of fire and fire safety-related issues.
	4 The program has developed and implemented a medical equipment management plan.
	5 The program has evaluated risk points in power, gas, and communication services and implemented strategies to minimize those risks.
	6 Staff has learned environment of care risk-reduction strategies.
	7 The program tracks incidents related to the environment of care and makes changes accordingly.
PR.10 The program has reference and resource materials readily available.	1 The program has reference materials (hard copy or electronic) that are easily accessible to practitioners.
	2 The resources are authoritative and current.
PR.11 The process for identifying, reporting, managing, and tracking sentinel events is defined and implemented.	1 A process exists for identifying these events if and when they occur.
	2 A process exists for internally tracking these events if and when they occur.
	3 A process exists for analyzing these events if and when they occur.
	4 Changes are made accordingly.
CLINICAL INFORMATION MANAGEMENT (CT)	
CT.1 The confidentiality and security of participant information are preserved.	1 Participant confidentiality is preserved.
	2 Records and information are safeguarded against loss, destruction, tampering, and unauthorized access or use.
	3 Participants and practitioners about whom data and information may be collected are made aware of how the information will be used.
	4 Methods for adding comments in the form of statements or addenda into the

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	formal records are defined.
	5 Individuals and/or positions that have access to information and measures compliance with access limitations are defined.
	6 How and when consent for release of information is required and defined.
	7 Process followed when confidentiality and security are violated is defined.
CT.2 The program gathers information about the participant's disease or condition from practitioners and settings across the continuum of care.	1 The program gathers information directly from the participant and/or family.
	2 Information is gathered from all relevant practitioners or health care organizations. • *The program gathers information from all relevant practitioners or health care organizations prior to implantation of the ventricular assist device.* • *The program gathers information from 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 implantation of the ventricular assist device.*
CT.3 The program shares information about the participant's disease or condition across the entire continuum of care to any relevant setting or practitioner.	1 The program shares information directly with the participant and/or family.
	2 The program shares information with other relevant practitioners or health care organizations as needed.
CT.4 Information management processes meet the program's internal and external information needs.	1 Data are easily retrieved in a timely manner without compromising security and confidentiality.
	2 The program has determined how long health records and other data and information are retained in accordance with applicable law and patient need.
	3 The program defines, captures, analyzes, transmits, and reports aggregate data and information that supports managerial decisions, operations, PI activities, and participant care.
CT.5 The program initiates, maintains, and makes accessible a health or medical record for every participant.	1 Practitioners have access to all needed participant information as necessary.
	2 The record contains sufficient information to identify the patient or the participant (if other than the patient); support the diagnosis; justify care, treatment, and services; and document the course and results of care, treatment, and services.
	3 The record contains sufficient information to track the patient's movement through the care system and facilitate continuity of care both internally and externally to the program.
	4 Records are periodically reviewed for completeness, accuracy, and timely completion of all necessary information.