VHA PROSTHETIC CLINICAL MANAGEMENT PROGRAM (PCMP) CLINICAL PRACTICE RECOMMENDATIONS ON THE USE OF LEFT VENTRICULAR ASSIST DEVICES (LVAD) FOR DESTINATION THERAPY FOR PATIENTS WITH END STAGE HEART FAILURE

I. BACKGROUND

VHA's Prosthetic and Sensory Aids Service Strategic Healthcare Group was directed by the Under Secretary for Health to establish a Prosthetic Clinical Management Program (PCMP). The objectives for the Left Ventricular Assist Devices (LVAD) PCMP workgroup are to provide VHA with clinical practice recommendations regarding patient eligibility for destination LVAD placement, infra-structure and logistic recommendations regarding designation of VA medical center as sites for providing destination LVAD therapy (or contractual agreements with local centers), costs responsibility, referral mechanism, and recommendations for outcomes tracking and management.

II. INTRODUCTION

Currently, no nationally accepted candidate eligibility or management guidelines exist for LVAD destination therapy. Professional organizations (International Society for Heart and Lung Transplantation and Heart Failure Society of America {ISHLT}) and payors (Centers for Medicare & Medicaid Services {CMS}) are currently drawing up such guidelines based on scientific evidence and the advice of experts in the field.

The VA LVAD PCMP Work Group exists to develop practice recommendations for VA for LVAD destination therapy. Herewith the Work Group proposes interim recommendations for initiation of LVAD destination therapy in the VA system. The Work Group proposes to review these recommendations annually by meeting or by teleconference consultation, to assure compliance with professional guidelines as they become available, and to incorporate evidence-based modifications in patient selection and management protocols.

The LVAD Work Group realizes that several of these recommendations are arbitrary and are based on consensus of opinion by experts in the management of end stage heart failure within the VA system. Some of these are likely to change as new knowledge and guidelines become available.

III. CLINICAL PRACTICE RECOMMENDATIONS

Currently, this treatment will only be offered to patients who are not transplant candidates. As part of determining the patient eligibility for destination LVAD, the Work Group recommends that the existing Thoracic Transplant Board also be responsible for reviewing cases for LVADs in the beginning, using the current VACO transplant program infrastructure, personnel, and referral system. If the volume demands expansion

of services in the future, a separate board for LVADs may be formed. The need for this will be reviewed on a yearly basis.

Regardless whether the veteran will receive the surgery at a VA facility or on a contractual basis in a civilian facility, a formal application, similar to the transplant applications, should be submitted to the Board for review and approval.

Patient Eligibility

A patient should be considered for destination LVAD if he or she has heart failure (HF) and meets the following criteria:

Inclusion Criteria:

1. Duration of chronic HF symptoms >3 months. In acute cases, no improvement with other HF therapies, including the use of a LVAD, as bridge to recovery.
2. In chronic cases, on intensively managed medical therapy for at least 8 weeks with continued or recurrent class IIIB-IV HF symptoms despite maximum tolerated medical therapy, or demonstrated medication intolerance, or demonstrated lack of indication for each of the following: angiotensin converting enzyme inhibitors/angiotensin receptor blockers, diuretics, beta-blockers, spironolactone, pacemaker, defibrillator, revascularization, and possibly cardiac resynchronization therapy.
3. Has clinical evidence of end stage heart failure, including either inotrope-dependency and/or documentation of severely reduced ejection fraction and cardiac index without inotropes (e.g., ejection fraction < 25% or CI<2.2 L/min without intravenous inotropic support or peak exercise oxygen consumption < 12/ml/min/kg).
4. The patient's records have been evaluated by a VA Transplant/LVAD Board, and turned down for cardiac transplantation and approved for LVAD, either in person or after reviewing the records.
5. The patient has been evaluated by a psychologist and a social worker and is felt to be appropriate from a social support, substance abuse, and psychological stability perspective, in order to make sure patient is able to understand the post-operative short and long-term course, basic device functions and care, and comply with medical recommendations. The patient is expected to have sufficient support to reliably maintain access to key resources (e.g., shelter, food, electrical supply, communication, transportation, and follow-up).
6. For the current devices, body surface area of > 1.5 m^2. As newer devices become available, this criterion may be altered.

Exclusion criteria:

Absolute exclusion criteria for LVAD destination:

1. Active systemic infection.

2. Active substance abuse, including recreational drugs and alcohol, which is likely to impact on patients' ability to comply with medical recommendations.
3. Dementia or other severe neurologic deficits, including those resulting from previous stroke.
4. Underlying condition (other than HF) that would limit life expectancy to less than 2 years.
5. Significant right ventricular dysfunction or severe fixed pulmonary hypertension, which remains unaltered after pharmacologic manipulation and optimized management.
6. Age older than 80 years.
7. Emphysema or other lung diseases severe enough to limit either life expectancy or rehabilitation potential, including patients who are oxygen dependent and those with FEV1 less than 1 liter.

Relative Contraindications to LVAD destination

1. History of drug or alcohol dependency, but with evidence of sustained adherence to a therapeutic regimen, and patient commitment to life-long substance abuse treatment.
2. Age greater than 70 years, unless the patient otherwise is "physiologically" young, i.e., optimal results of neuropsychological testing and no other significant comorbidity, including renal insufficiency, peripheral vascular disease, and emphysema.
3. Moderate right ventricular dysfunction.
4. Significantly impaired liver function (e.g., bilirubin >5 mg/dl, impaired synthetic function).
5. Chronic severe renal failure, including patients on dialysis, deemed irreversible despite optimization of hemodynamics with inotropes or other vasoactive medication.
6. Nutritional depletion (e.g., albumin <2.5 g/l; low pre-albumin).
7. Obesity with a body mass index of > 40 kg/m^2.
8. Active tobacco use. Patients with chronic HF should have documented negative urine cotinine twice at least one month apart. In acute cases, this will be reviewed on an individual case basis.
9. Peripheral and cerebral vascular disease, including past strokes, that is likely to reduce the chances of meaningful rehabilitation.

IV. INFRASTRUCTURE AND LOGISTIC RECOMMENDATIONS

The LVAD Work Group expects that either the destination LVADs will be implanted at a Medicare designated destination LVAD center, or if it is implanted at a VA facility, such VA implant centers will meet Medicare guidelines for LVAD destination therapy center requirements. Such VA programs should demonstrate administrative and professional commitment to a realistic plan likely to result in compliance with Medicare guidelines. Implicit in program development is financial commitment to attract and retain expert personnel and to commit institutional

resources to sustain the program. Before implanting destination LVADs within the VA system, a formal application of approval detailing the infrastructure and logistics details of the facility and adherence with the Medicare guidelines should be submitted by the VA facility to the Thoracic Transplant Board for review and approval. This should include information on both personnel and their experience, including cardiothoracic surgeon, cardiologist with heart failure expertise, dedicated LVAD coordinator, and complete service medical and surgical services.

Currently the Medicare requirements for a LVAD center include the following, (accessed on 12/12/03 at http://www.cignamedicare.com/articles/oct03/cope211.html)

> *In addition, the Centers for Medicare & Medicaid Services (CMS) has determined that VAD implantation as destination therapy is reasonable and necessary only when the procedure is performed in a Medicare-approved heart transplant facility that, between January 1, 2001, and September 30, 2003, implanted at least 15 VADs as a bridge-to-transplant or as destination therapy. These devices must have been approved by the FDA for destination therapy or as a bridge-to-transplant, or have been implanted as part of an FDA investigational device exemption (IDE) trial for one of these two indications. VADs implanted for other investigational indications or for support of blood circulation post-cardiotomy do not satisfy the volume requirement for this purpose. Since the relationship between volume and outcomes has not been well established for VAD use, facilities that have minimal deficiencies in meeting this standard may apply and include a request for an exception based upon additional factors. Some of the factors CMS will consider are geographic location of the center, number of destination procedures performed, and patient outcomes from VAD procedures completed.*
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> *Also, this facility must be an active, continuous member of a national, audited registry that requires submission of health data on all VAD destination therapy patients from the date of implantation throughout the remainder of their lives. This registry must have the ability to accommodate data related to any device approved by the FDA for destination therapy regardless of manufacturer. The registry must also provide such routine reports as may be specified by CMS, and must have standards for data quality and timeliness of data submissions, such that hospitals failing to meet them will be removed from membership. CMS believes that the registry sponsored by the International Society for Heart and Lung Transplantation is an example of a registry that meets these characteristics.*
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> *Hospitals also must have in place staff and procedures that ensure that prospective VAD recipients receive all information necessary to assist them in giving appropriate informed consent for the procedure so that they and their families are fully aware of the aftercare requirements and potential limitations, as well as benefits, following VAD implantation.*
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> *CMS plans to develop accreditation standards for facilities that implant VADs and, when implemented, VAD implantation will be considered reasonable and necessary only at accredited facilities.*

Based on periodic review, the Thoracic Transplant Board will define the requirements that need to be fulfilled by individual centers prior to being designated as a VA LVAD destination therapy center. These recommendations are expected to reflect closely the CMS guidelines stated above and the recent International Society for Heart

and Lung Transplantation (ISHLT) recommendations highlighted below (*Destination mechanical circulatory support: proposal for clinical standards. Journal of Heart and Lung Transplantation: April 2003, Pages 365-369).*

- *Mechanical Circulatory Support Device (MCSD) center should have an established heart failure program directed by specialized heart failure cardiologists who have extensive experience in advanced heart medical therapy, the care of patients after heart transplantation, and in the care of patients receiving mechanical circulatory support as a bridge to transplantation with a potential for long-term use. At least one heart failure cardiologist must have expertise in managing all of these modalities and in appropriate allocation of specific therapies to individual patients, as determined by severity of heart failure and response to alternative therapies. Her/his experience must have been obtained at a heart failure, transplant, and ventricular assist-device bridging center in which the cardiologist had personal experience caring for 10 or more patients receiving MCSD support with the potential for therapy, including out-of hospital care chronic (>2 months) support and patient ambulation.*

- *The MCSD center must have established surgeons who are personally experienced and expert in implanting and managing MCSD devices with the potential for destination therapy. At least one surgeon in the MCSD center must work or have worked at a heart transplant, heart failure, or MCSD-bridging center and should have documented expertise in implantation, in peri-operative and post-operative management, and in removal of such devices. Her/his experience must include being the primary implanting surgeon of at least 10 MCSDs, which have the potential for chronic (>2 months) support and patient ambulation. (VA LVAD Workgroup also recommends that the surgical expert should also have had experience with management of at least 10 LVADs in the outpatient arena).*

- *Other participating physicians, surgeons, and non-physician staff and faculty should have adequate training through educational fellowships and programs conducted at established long-term or bridge-to-transplant MCSD centers.*

- *The center should have an established infrastructure for infectious disease management, post-MCSD nursing, and post-MCSD social work, with written protocols for pre-, intra-, and post-operative MCSD management, including end-of-life situations.*

- *The center must report volumes for the long-term mechanical support program and must report outcomes at 1 month, 6 months, and 12 months that meet or exceed previously established target volumes and outcomes for all such programs.*

- *The MCSD center should have a quality-assurance program that includes participation in a national or international MCSD database such as the ISHLT-MCSD database.*

- *The center should have an acute heart failure-related research and teaching program.*

Conclusions and Recommendations

As the field matures, it will probably not be appropriate to restrict destination LVAD implant therapy to a few regional centers like the transplant model. Developing a major infrastructure within the VA system with multiple sites is likely to be difficult and cost-ineffective, since the projected numbers of patients receiving these devices are likely to be small, at least in the beginning. Transferring the patients to a distant VA hospital for surgery, followed by patients returning back home for long-term care, is likely to fail as not many VA and non-VA hospitals will have the required expertise to manage patients with these devices. Development of a standard contract is therefore recommended, to articulate system requirements and assure access for veterans to high-quality providers, facilitate planning, and cost management (including not only costs and care issues, but also center requirements) that several VAs, at a regional or VISN level, can then negotiate with their local private or university affiliated hospital. Separate contract for management of implanted patients long term at a non-VA hospital may be required if, after implantation, the primary responsible VA hospital is unable to provide expertise for subsequent management of the patients.

If a particular VA hospital wants to initiate an in-house program, the hospital should provide evidence in an application to VACO that suitable infrastructure and personnel are available and the hospital has administrative support to initiate such a program.

VACO may wish to assign the Thoracic Transplant Board to review the VA centers that wish to develop in-house destination LVAD programs and the Work Group strongly recommends that only those non-VA hospitals should implant destination LVADs that are approved by Medicare. The Work Group recommends that the LVAD centers should have considerable experience with LVADs as bridge to transplant, have full range of other cardiovascular medical and surgical services, and should have an active transplant program.

Outcomes Measurement

The Work Group strongly recommends the necessity of reporting outcomes to both a centralized registry for outcomes tracking and quality assurance (e.g., ISHLT MCSD database), and to review veterans' specific data, regardless of whether the device was implanted at a VA facility or a civilian hospital, on a yearly basis by the Thoracic Transplant Board. All VA implanting programs will require regular review of results to maintain their certification from VACO. Each approved center is required to participate in the designated database. Veteran specific data will need to be submitted by the primary VA, regardless if the LVAD was implanted at a VA or non-VA hospital, for review by the Thoracic Transplant Board annually. These data should include statistics on survival, hospitalizations, infectious and neurologic complication, and device failures and problems. The Work Group also recommends that VACO fund the individual centers

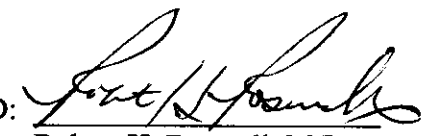
with the costs of participating in such databases for the VA centers that wish to develop in-house programs.

VI. REFERENCES

1. Deng, MC; Young, JB; Stevenson, LW; Oz, MC; Rose, EA; Hunt, SA; Kirklin, JK; Kobashigawa, J; Miller, L; Saltzberg, M; Konstam, M; Portner, PM; Kormos, R; and International Society for Heart and Long Transplantation. Destination mechanical circulatory support: Proposal for Clinical Standards. Journal of Heart and Lung Transplantation 2003, 22:365-369.

2. Rose, EA; Gelijns, AC; Moskowitz, AJ; Levitan, RG; Watson, JT; Meier, P; Ronan, NS; Shapiro, PA; Lazar, RM; Miller, LW; Gupta, L; Frazier, OH; Desvigne-Nickens, P.; Oz, MC; Poirier, VL. Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) Study Group. Long-term mechanical left ventricular assistance for end-state heart failure. New England Journal of Medicine November 15, 2001, 345(20); 1435-43.

3. Goldstein, DJ; Oz, MC; Rose, EA. Implantable left ventricular assist devices. New England Journal of Medicine. 1998, 339(21): 522-533.

(APPROVED)/DISAPPROVED:  3-25-04

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