American Society of Transplant Surgeons
Statement before the Medicare Coverage Advisory Committee, Centers for Medicare and Medicaid Services regarding
Medicare Coverage of VADs as Destination Therapy

The American Society of Transplant Surgeons (ASTS) is delighted to have this opportunity to comment on Medicare coverage of Ventricular Assist Devices (VADs) as destination therapy. ASTS was founded in 1974 to foster and advance the practice and science of transplantation; provide clinical guidance to those who make policy decisions that influence the practice and science of transplantation; increase organ donation; and define and promote training programs and continuing education of transplant surgeons, scientists and physicians.

ASTS strongly supports Medicare coverage for the services associated with the implantation of VADs as destination therapy and the provision of appropriate post-surgical care. We believe that the results of the Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) unequivocally support extension of Medicare coverage of VADs as destination therapy **for those who are not eligible for transplantation.**

We wish to emphasize, however, that the criteria for participation in the REMATCH study excluded those who are candidates for transplantation, and we caution against the establishment of a coverage policy that essentially encourages the use of VADs as destination therapy in lieu of transplantation, in patients for whom transplantation would be a more appropriate treatment option. While the REMATCH trials clearly and unequivocally establish that the implantation of a VAD, in conjunction with appropriate medical management, has clear advantages over medical management alone for those patients who are ineligible for transplantation, the use of VADs as destination therapy is not without risk. In fact, while the one year survival rates and quality of life of the medical device group in the REMATCH study surpassed the survival rates and quality of life of those treated using medical management alone, the frequency of serious adverse effects in the device group-- including infection, bleeding, and device malfunction--were not insignificant. Improvement in these outcomes can only occur by utilizing a controlled dissemination of technology in centers experienced with the use of ventricular assist devices as either a bridge to transplantation or as destination therapy.

We also note that of three criteria established by the FDA for use of VADs as destination therapy, two are subject to interpretation by centers with less experience in the field of organ replacement: The FDA has indicated that a VAD should be used as destination therapy only in patients who:

- have severe end stage congestive heart failure;
- are not eligible for heart transplants;
- have a body surface area (BSA) greater than 1.5 square meters. (BSA depends on height and weight.)

An assessment of the severity of a patient's end stage congestive heart failure is most appropriately made by a multidisciplinary team of cardiologists and cardiac surgeons who can make discriminating distinctions regarding extended medical or surgical therapy in lieu of a ventricular assist device or transplant.

Likewise, an assessment of whether a particular patient is eligible for heart transplantation is dependent to some degree on the clinical judgment and experience of the cardiac transplant team that does the assessment. Prior to being accepted as a candidate for a heart transplant, a patient must undergo a comprehensive medical and psycho-social evaluation by a multi-disciplinary team made up of cardiologists, surgeons, other physician specialists, transplant nurse coordinators, social workers and dietitians. This evaluation determines the cause of heart failure and also provides assurance that the patient does not have a condition warranting his or her disqualification for a heart transplant. Determining a patient's eligibility for a heart transplant involves a number of complex clinical judgments that are best made by an experienced cardiac transplant team operating in a Medicare certified transplant center. **We urge CMS to require that a patient be evaluated by a qualified cardiac transplant program to determine whether, in fact, the patient is ineligible for transplantation. This determination should be made as a condition of coverage of the implantation of a VAD as destination therapy.**

We also wish to emphasize that the successful implantation of a VAD as destination therapy depends to a great extent on the experience and expertise of the team of health care professionals involved and on the institutional capabilities of the center where the procedure is performed. It has been our experience that, due to the scarcity of implantable organs, an increasing number of patients undergoing heart transplantation have previously undergone the implantation of a VAD as a bridge to transplantation, and often the implantation of a VAD for these patients is an extremely challenging surgical procedure, since many of these patients are extremely sick by the time the procedure is performed. Currently, VADs are generally implanted in Medicare-certified transplantation centers and all of the institutions that participated in the REMATCH trial were in fact certified cardiac transplant centers. We caution that, under these circumstances, if the Medicare Program determines that these procedures are eligible for coverage in institutions that are not Medicare-certified Cardiac Transplant Centers, CMS should establish criteria that must be met by both the surgical team and the institution to assure the quality of care provided. We would be delighted to work with CMS to establish such criteria, if coverage is approved for procedures performed outside of Medicare-certified Cardiac Transplant Centers.

Finally, we note the importance of adequate post-surgical care. The incidence of complications reported in the REMATCH trial suggests that CMS should establish liberal coverage for post-operative services to ensure that those who undergo this extensive surgery do not succumb to post-operative complications and should include appropriate coverage for the monitoring of these patients, including the costs of administrative filings and record-keeping. Such costs are routinely deemed to be ineligible for coverage; yet,

the provision of these services in necessary to assure the desired health outcomes for the patients involved and for patients who may undergo these procedures in the future.