



Implications of the proposed memo on the national coverage decision for durable mechanical circulatory support device therapy

Recently, the Centers for Medicare and Medicaid Services (CMS) has released a proposed decision memo to revise the national coverage determination (NCD) for artificial hearts and related devices, including ventricular assist devices (VADs) for bridge-to-transplant (BTT) and destination therapy (DT).¹ To understand the impact of the proposed NCD ruling on durable mechanical circulatory support device therapy, it is important to first understand Medicare's NCD process and its impact on care. NCDs are a nationwide determination by CMS on whether Medicare will pay for an item or service and represents a form of utilization management and establishes an important medical guideline or standard for treatment. The importance of an NCD is that it creates uniform guidelines for coverage decisions by Medicare and that the coverage decisions become binding by regional Medicare Administrative Contractors (MACs).² Regional MACs can be more liberal in their coverage decisions for a covered service or device, but cannot be more restrictive than the NCD. In the absence of an NCD, a coverage determination decision is made at the discretion of the regional MAC. Importantly, local coverage determinations do not set a precedent for nationwide standards for reimbursement. Thus, Medicare's use of NCDs significantly impacts patterns of care across the country. From the perspective of policymakers, commercial payers, and medical care providers, Medicare's use of NCDs promotes evidence-based medicine, reduces geographic variations in care, and decreases the amount of money spent on unnecessary or unproven care.³ Because Medicare is the largest insurer in the United States, its actions also exert significant influence on the commercial insurance market and the commercial insurance market will typically follow suit in establishing reimbursement coverage.

The historical basis for many elements in the current NCD for VAD therapy were first incorporated in October 2003 when a NCD coverage determination recognized, for the first time, the use of durable VADs for DT indication based upon the findings of the Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) clinical trial.⁴ The patient criteria to meet DT indications in the 2003 NCD fundamentally incorporated the inclusion criteria from

the REMATCH trial. The 2003 NCD also established hospital criteria and an application process through which hospitals were required to submit information to CMS and if approved, would then be listed on the CMS web site as an approved VAD DT therapy hospital. Since the 2003 coverage determination, a number of other important changes to the NCD have been incorporated by CMS. One of the more important changes was the March 2007 ruling that established new facility criteria and required hospitals to receive certification from the Joint Commission on Accreditation of Healthcare Organizations or a similarly approved accreditation agency under the Disease-Specific Certification Program for VADs. Important changes to facility criteria were the removal of the requirement that the VAD center had to be a CMS-approved transplant center and changed volume requirements to define an experienced VAD surgeon as a surgeon implanting 10 VAD implants within the previous 3 years. Another important change to total artificial heart (TAH) reimbursement coverage occurred in May 2008 when CMS established a national coverage determination for TAHs when implanted under Coverage with Evidence Determination (CED). The CED requirement essentially limited coverage of TAH therapy within the context of a clinical study.

In the recently announced memo opening the NCD for VAD coverage,¹ CMS is proposing a number of important changes to the NCD. First and foremost is the removal of the designations of BTT or DT as indications for durable VAD therapy and establishing guidelines based upon clinical characteristics or findings that include:

- Have New York Heart Association (NYHA) Class IV heart failure;
- Have a left ventricular ejection fraction (LVEF) $\leq 25\%$;
- Are inotrope dependent *OR* have a cardiac index (CI) $< 2.2 \text{ L/min/m}^2$, while not on inotropes, and also meet one of the following:
 - Are on optimal medical management (OMM), based on current heart failure practice guidelines for at 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 intra-aortic balloon pump (IABP) or similar temporary mechanical circulatory support for at least 7 days.

Additionally, the devices used for durable VAD therapy, must be approved for short- (eg, bridge to heart transplantation) or long-term (eg, destination therapy) indications by FDA. The short-term terminology used here in the NCD is not to be confused with temporary extracorporeal devices that do not permit patient discharge. CMS has importantly removed the requirement that patients receiving devices with the intent to BTT be listed for heart transplantation at the time of VAD implantation. This important change recognizes the difficulty in identifying the intent of VAD therapy at the time of implant and acknowledges the dynamic changes in patient status, both favorable and detrimental, that can influence transplant eligibility following VAD implant.⁵ The elimination of the terms BTT and DT are consistent with findings from the recent Multicenter Study of Maglev Technology in Patients Undergoing MCS Therapy With HeartMate 3 Investigational Device Exemption Clinical Study (MOMENTUM 3) trial that demonstrated similar outcomes regardless of the intent of VAD implantation, whether it was BTT or DT.⁶ Thus, the findings from the successful MOMENTUM 3 clinical trial have driven, to a large extent, the proposed changes to the current NCD.

In addition to removing the requirement for patients being listed for transplant at the time of VAD implantation for BTT intent, CMS has additionally removed the requirement for an assessment of transplant eligibility for patients undergoing VAD implant for BTT at nontransplant VAD centers from a transplant center, prior to VAD implant. While this ruling will importantly increase access to VAD therapy for patients by facilitating nontransplant VAD centers to provide this therapy, it is important to ensure this ruling will not have an unintended consequence on reducing access to heart transplantation. This concern is obviously greatest for patients with low socioeconomic status who already suffer from disparities in heart transplant access and outcomes.⁷ It is important that CMS ensure that the elimination of this requirement does not have an adverse impact on access to heart transplant services for those with limited resources and that VAD implanting centers, regardless of whether heart transplant services are available, offer all appropriate options to their patients. Follow-up investigation on this issue should be an important initiative for CMS to consider.

Another controversial issue that was not modified by the proposed NCD was the facility criterium requiring a surgeon to have an experience of at least 10 VAD implants over a 3 year period to meet the qualifications defining a proficient VAD surgeon. There is obvious controversy over this ruling as the scientific basis for the number of 10 VADs equating

to proficiency with this procedure is not proven. Having this ruling remain in place has the potential of hindering VAD access by reducing the number of VAD centers that may initiate VAD programs. It is imperative that CMS continue to examine this issue and develop other metrics of program quality and surgeon proficiency that do not rely solely on volume.

Finally, for TAHs, CMS is proposing to eliminate the NCD for TAHs, ending the CED for TAHs and permitting Medicare coverage determinations for TAH therapy to be made by regional MACs. Essentially, this ruling would eliminate a global NCD ruling for coverage of TAH therapy and leave coverage decisions up to regional MACs. Due to the significant cost of TAH therapy, this decision will likely result in significant variation in coverage of TAH therapy in the United States and likely create significant variations and disparities in access to this therapy. A future analysis of the variations and patterns of coverage for this critical therapy are necessary.

In summary, CMS is proposing important modifications to the current NCD for durable VADs and TAH therapies by eliminating the designations of BTT and DT indications and removing the requirement for heart transplant assessment for transplant eligible patients at nontransplant VAD centers. While the majority of these important changes will likely benefit the field by increasing access and simplifying patient assessment, important questions on the subsequent impact of these rulings on heart transplant access and access to the TAH therapy remain.

DISCLOSURES

Dr. Pagani is a member of the Scientific Advisory Board for FineHeart, Inc., member of the data safety monitoring board for Carmat, Inc., member of the data safety monitoring board for the National Heart, Lung, and Blood Institute PumpKIN clinical trial, and Chair, The Society of Thoracic Surgeons Intermacs Task Force.

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