

The TAVR National Coverage Decision

How will this recent announcement affect your patients and practice?



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On May 1, 2012, the Centers for Medicare & Medicaid Services (CMS) announced that the agency will cover transcatheter aortic valve replacement (TAVR) for Medicare patients under certain conditions. *Cardiac Interventions Today* asked a panel of experts about the National Coverage Decision (NCD) and what it will mean for your practice.

Cardiac Interventions Today: What are your thoughts regarding the NCD?

Dr. Feldman: The fact that we have a mechanism for CMS coverage at all is a huge accomplishment. Because this is a national coverage decision, there should not be significant variation in coverage from region to region around the country, which, for a therapy of this high level of interest, is important.

Mr. Powell: One of the positives is the flexibility, in that as soon as we get broadened FDA-labeled indications, we do not have to go through the 6- to 9-month-long process to get CMS coverage expanded. I believe that is novel, and it is a positive thing.

Dr. Block: I agree that the NCD establishes a great benchmark for making decisions for how we can treat our patients with aortic stenosis. However, one practical problem is how we understand the NCD in relation to the FDA-approved labeling for the Edwards Sapien transcatheter valve (Edwards Lifesciences, Irvine, CA), which currently is the only commercially available valve. FDA labeling specifically states that it can be used via the transfemoral route, whereas the NCD states “indications,” which is “inoperable” patients with aortic stenosis. Many of us are not sure what to do with patients who might be candidates for transfemoral insertion but who are borderline as far as iliofemoral vessel size is concerned. For example, if the transfemoral route fails, will switching to an iliac conduit in the OR not be covered? Currently, I think most interventionists are being quite conservative in choosing patients for commercial valve use and are staying away from so-called off-label use.

Dr. Feldman: There’s an upcoming FDA panel review for PARTNER A. When they give a thumbs up for new indications, they will be encompassed by the NCD.

Mr. Powell: The panel meeting is scheduled for June 13, 2012. It usually takes at least 2 to 6 months for the FDA to make a decision.

Dr. Feldman: Another strong piece of the NCD is the mandate for capturing clinical data going forward in a registry. It is fair to guess that, no matter how carefully coverage is crafted based on trial results, the reality of practice in approved settings is always different. We will need to understand who it is we are treating in the commercial or Medicare setting.

One of the things we realized about the PARTNER B trial is that there was a group of patients who were so sick that they did not derive a significant benefit from TAVR—the group with an STS risk calculator score > 15.

In practice, the proportion of patients who lived more

than a couple of years after TAVR versus those who seemed to follow the natural history of aortic stenosis in spite of a valve replacement is critical for us to understand. We must learn how to select patients for the procedure out of this very sick group.

Cardiac Interventions Today: Is that sick cohort included in the FDA indications?

Dr. Feldman: The FDA labeling simply says *inoperable*, defined as turned down by two surgeons. These patients can still receive the device.

Cardiac Interventions Today: Is reimbursement precluded for those patients?

Dr. Feldman: There is no good way to define them prospectively. It would be horrible if there were some upper STS risk cutoff because the findings from PARTNER B are average numbers for groups, and that does not distinguish individuals. I think many of us in the trial had individuals with STS > 15 who did phenomenally well. This is a clinical judgment, and that is hopefully where the partnership of a heart team will be helpful. That is another positive of the NCD—the emphasis on the heart team.

Cardiac Interventions Today: What is the difference between the postmarket surveillance study, which was mandated in the FDA approval and the registry required here?

Dr. Feldman: I don't think there is a difference.

Cardiac Interventions Today: CMS is echoing what was already in place?

Dr. Feldman: I do not think there is a difference in practice. I do not know if Edwards is eventually going to create a registry in parallel with the NCDR or if Edwards is going to ultimately accept the NCDR as the postmarket registry. I do not know what the FDA requirement is in that regard.

Cardiac Interventions Today: What do you believe is going to be the position of the ACC on the registry?

Dr. Feldman: I can't speak for the ACC, but I hope they will view it as important to have a society who stands to be more objective running a registry than to have industry self-reporting a registry. Industry might say that the registry effort is more complicated than the ACC appreciates.

Dr. Block: There might be a broader use for registries. I would hope that CMS and the FDA would support a registry that also allowed us to help understand which

patients the “off-label” uses of a commercial valve might best serve. That would mean setting up a registry specifically to collect clinical data from patients who might best define for us which alternate route for insertion is best (ie, transapical or transaortic) and what problems off-label uses might produce (if any). For example, more than half of our patients who we thought would be candidates for commercial valve implantation could not be treated via the transfemoral route but still were good candidates for valve implantation. I understand that we do not have data from clinical trials to support alternate-route TAVR, but to not have an option for treating such inoperable patients would be unfair.

Mr. Powell: It would be helpful and fair if the surgical procedures were required to be in a registry so that we would have a comparison group.

Dr. Feldman: Presumably, the surgical part of it is captured in the STS registry that is now going to be coordinated with NCDR.

Mr. Powell: That is correct, but participation in that is not mandatory. I believe the two-surgeon requirement is unprecedented.

Cardiac Interventions Today: What was the surgical requirement in PARTNER?

Dr. Feldman: PARTNER required the site surgeon and an executive committee surgeon. Every patient in the actual PARTNER B trial was reviewed locally by the heart team and on a conference call with other study surgeons. To be declared inoperable from a practical standpoint required the two surgeons.

Cardiac Interventions Today: In practice, will it be significantly more burdensome to have a second surgeon or is that something that is usually readily available?

Dr. Feldman: One of the issues with the discussion leading into the CMS operator and institutional requirement was trying to ensure that TAVR programs would have real surgical support onsite. I think there are several reasons that this is important. Evaluating prospective patients with a heart team is much more than doing a TAVR procedure. There are programs around the country that do not have any surgeons in house; they have a pump team and a surgeon who comes to a hospital to do a procedure, but there is no one who really resides in the program. Having two surgeons that are primarily based in your program is one of the ways to ensure that both patient selection and postpro-

cedure care are going to be optimal for TAVR patients.

I cannot speak for CMS, of course, but I think part of the idea of having a two-surgeon review is to account for that kind of oversight and, probably even more importantly, to account for the variability in surgical opinions.

Mr. Powell: On a practical level, I am not sure that the CMS coverage staff has talked to the CMS payment policy staff. Are they going to pay for two surgeons in their evaluation?

Dr. Feldman: I do not know if that has been specifically addressed, but an outpatient visit to a surgeon for a second opinion would be a covered part of usual care because it is common for regular surgery anyway.

Mr. Powell: That is true. As long as it is considered to be medically necessary, they are pretty much boxed into covering it.

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—Dr. Block

Cardiac Interventions Today: The decision then would also cover the surgeon who has to be part of the team. Has it been addressed as to how that is going to happen with respect to the fact that there is going to be both a cardiologist and a surgeon performing this procedure?

Mr. Powell: The AMA's Relative Value Update Committee (RUC) dealt with that and SCAI, the surgeons, and ACC made recommendations and got a reasonable

CMS WILL COVER TRANSCATHETER AORTIC VALVE REPLACEMENT

According to CMS, this final national coverage decision is one of the first coverage decisions completed under a mutual memorandum of understanding between CMS and the FDA, a joint effort aimed at getting sometimes lifesaving new technology to patients sooner. The agency stated that because this technology is still relatively new, it is important that these procedures are performed by highly trained professionals in optimally equipped facilities. Therefore, this decision uses Coverage with Evidence Development as a condition of coverage, which will require certain provider, facility, and data collection criteria to be met. Such requirements are important to ensure that beneficiaries receive the safest and most appropriate care, advised CMS.

In its decision memorandum, CMS noted that the FDA approved the first TAVR device for marketing in the United States in November 2011. The Edwards Sapien transcatheter heart valve (Edwards Lifesciences, Irvine, CA) was approved "for transfemoral delivery in patients with severe symptomatic native aortic valve stenosis who have been determined by a cardiac surgeon to be inoperable for open aortic valve replacement and in whom existing comorbidities would not preclude the expected benefit from correction of the aortic stenosis."

CMS also noted that the FDA approval recommended specific training and experience for practitioners who use the device, as well as continued clinical study and data submission to the Society of Thoracic Surgery–American

College of Cardiology's Transcatheter Valve Therapy Registry.

The FDA's Circulatory System Devices Panel of the Medical Devices Advisory Committee will meet to discuss, make recommendations, and vote on information related to Edwards' premarket approval application for the Sapien device for the treatment of patients with severe, symptomatic aortic stenosis who are at high risk for surgery.

The full National Coverage Analysis is available on the CMS website.

Details of the conditions for coverage are fully outlined in the decision memo. In brief, TAVR is covered for the treatment of symptomatic aortic valve stenosis when furnished according to an FDA-approved indication and when all of the conditions outlined in Part A of the decision are met. TAVR is covered for uses that are not expressly listed as an FDA-approved indication when performed within a clinical study that fulfills all of the conditions outlined in Part B of the decision. TAVR is not covered for patients in whom existing comorbidities would preclude the expected benefit from correction of the aortic stenosis.

In Part A, the conditions outlined for TAVR coverage include:

- The procedure is furnished with a complete aortic valve and implantation system that has received FDA premarket approval for that system's FDA approved indication.
- Two cardiac surgeons have independently examined the

recommendation from the RUC. The CMS leaders who were there have repeatedly expressed concern about whether this really is a cosurgery procedure, where both the surgeon and the cardiologist are fully involved in the full procedure, and whether they should pay for this as a cosurgery procedure. A cosurgery procedure is paid at 125% of the fee schedule rate, and the revenue is then divided between the two physicians. We will not know until November whether CMS accepts the recommended value and the recommended concept of this being a cosurgeon procedure.

Cardiac Interventions Today: Thus far, CMS has not assigned a value to any of this?

Mr. Powell: They won't until the Final Payment Rule for 2012 comes out in early November and is implemented on January 1, 2013. That is for physician payments; for hospitals, their payment rates will change on October 1, 2012.

Cardiac Interventions Today: What are your thoughts on the requirements regarding operator experience level and the number of procedures?

Dr. Feldman: In one respect, the numbers are probably reasonable because everybody is equally unhappy with them.

Mr. Powell: One concern is that as this develops, we are going to have to go through the entire 6- to 9-month-long process to change anything in the CMS decision. Before that, we may have to go through the process of revising our clinical competency statement. The numbers are not going to move quickly if there is evidence to show that they should move.

Cardiac Interventions Today: Is there anything in this memo that finalizes these numbers?

Dr. Feldman: There is nothing that defines them exactly.

patient face-to-face and evaluated the patient's suitability for open AVR surgery, and both surgeons have documented the rationale for their clinical judgment and the rationale is available to the heart team.

- The patient (preoperatively and postoperatively) is under the care of a heart team: a cohesive, multidisciplinary team of medical professionals. The heart team concept embodies collaboration and dedication across medical specialties to offer optimal patient-centered care. This section also details the hospital infrastructure that must be in place for a TAVR program, as well as the conditions that need to be met for starting a TAVR program.
- The heart team's interventional cardiologist(s) and cardiac surgeon(s) must jointly participate in the intraoperative technical aspects of TAVR.
- The heart team and hospital are participating in a prospective, national, audited registry that: consecutively enrolls TAVR patients, accepts all manufactured devices, follows the patient for at least 1 year, and complies with relevant regulations relating to protecting human research subjects.
- The registry must be designed to track and permit identification and analysis of patient, practitioner, and facility-level variables that predict each of these outcomes: stroke, all-cause mortality, transient ischemic attacks, major vascular events, acute kidney injury, repeat aortic valve procedures, and quality of life.

In the final decision memo's Section B regarding CMS coverage of TAVR procedures conducted in clinical studies, a notable change from February's proposed decision memo is that the final memo has dropped the requirement that said that the study must be designed to test superiority (not noninferiority). In the final decision memo, CMS permits noninferiority study designs to qualify for coverage of TAVR.

According to CMS, during the public response period, 23 commenters disagreed with the requirement that unlabeled uses of TAVR covered in clinical studies must have superiority designs, asserting that the superiority requirement is unnecessarily restrictive and will inhibit the medical device industry from introducing next-generation devices.

In the final decision, CMS stated that superiority trial designs provide important advantages that are not completely addressed by noninferiority design, but that the agency recognizes that noninferiority trials have a place in the conduct of medical device regulatory trials and that a broad noncoverage of noninferiority trials may have unintended consequences for certain important studies.

CMS concluded that, when feasible, superiority study designs should be used to investigate nonapproved, off-indication, and off-label uses; and where a noninferiority or equivalence study design is utilized, trial sponsors should comply with the most recently published CONSORT (Consolidated Standards of Reporting Trials) checklist of items for reporting noninferiority or equivalence trials, which are further specified in the memorandum.

Mr. Powell: We have a meeting between the two primary authors of the clinical competency document and CMS staff to try to operationalize some of those numbers. We are working with them to make sure there is clarity.

Dr. Feldman: When the clinical competency document was discussed (the multisociety document that CMS used as an outline for their final recommendations, or their final requirements), some of these various procedure volume requirements were separated by the word “or.” That somehow was lost in the process of getting it to a CMS recommendation.

My understanding of the intent of the structural volume requirement was that, for example, pediatric interventionists and some adult structural interventionists do not perform a significant volume of coronary interventions. They would fail the PCI criteria, but in reality, they would be very well qualified based on the structural qualifier.

I think one of our hopes is that in determining the criteria to find people who have basic skills for entry into the field, it is important to note that trial sites are qualified already. For startup sites, achieving an annual volume that is sustainable will keep them qualified. The fundamental question is, how many sites in the United States can be sustained with the current indications for the procedure? At the extreme, it is clear that we cannot have all 1,000-plus cath and surgery programs doing TAVR and expect operators to maintain volumes that are adequate to keep them performing at a highly confident level. At the other end, we cannot have criteria that are so restrictive that the procedure is not available. This set of criteria, including the idea of having surgeons on site who are primarily attached to the hospital and these volume criteria, is part of what we all hope is going to define a balance between the two extremes.

Cardiac Interventions Today: If a new site wanted to take this on, how can they get in if it is required that the site previously performed a certain number of procedures?

Dr. Feldman: Edwards has already started up approximately 100 new commercial sites around the country. These are sites that have surgical programs, heart teams, and interventional physicians with a significant experience level so that the spirit of the NCD is already well incorporated.

A new site does not have to have a TAVR physician or a TAVR implanter; they just need to have high PCI and structural volumes.

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I think there are a lot of high-volume PCI physicians with long-term experience with structural interventions, and there are a small number of adult interventionists with substantial structural experience and some PCI experience, and they are all qualified to adopt this new technology.

Dr. Block: It appears that many new sites in the United States are enthusiastic about beginning to do transcatheter valve placement. My concern is a longer-term issue. We know little about how many cases are needed to gain competence for one or two operators at each site, and even less about what numbers are needed for maintenance of competence.

Cardiac Interventions Today: Is it a concern that there will be areas of the country where this procedure will not be available to patients because there isn't a center of excellence within their geographical range?

Dr. Feldman: If that is true, they already have a problem with access to coronary and standard surgical valve therapy. It doesn't create any new problem; that would be an existing problem. I don't know where there are real holes in existing coronary therapy in the United States, if any.

I think we know from the experience of PCI for acute MI that there are very few places in the country that are more than an hour away, by some means of medical transport, from emergency PCI. I think regarding a concern about geographic unavailability, the burden of proof would go the other way. I do not think we would assume there is an availability problem; if it happens, I would be surprised.

Cardiac Interventions Today: Does the NCD memo cover enough and is it expansive enough?

Dr. Feldman: One of the other positives of the NCD is that it clearly defines reimbursement for new indications for off-label uses, as long as they are conducted

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—Mr. Powell

in registries. I would love to see a very open indication, where off-label use was permitted because many individual patients do not fit the label and are excellent candidates for the therapy. But, given that it is restricted very specifically to the FDA labeling, we at least have the potential for treating other indications in registries.

Cardiac Interventions Today: Overall, is this a positive step forward?

Dr. Feldman: I do not think this is a matter of whether it is a positive or negative step; this is our environment.

Mr. Powell: It clearly has run more smoothly than the expansion of carotid artery stenting, in part because we have been able to work with surgical colleagues.

Dr. Feldman: For TAVR in the cohort B group, the unequivocal life-saving power of the therapy is unique among therapies in medicine. It is rare to have a clinical outcome that is so black and white.

Cardiac Interventions Today: Is there anything in the memo that addresses the incidence of stroke?

Dr. Feldman: Implicit in the whole idea of the registry is that the people will perform at benchmark levels that are coincident with the registry, with the performance of other sites. Through the societies, we have many quality initiatives to help sites monitor their own activity. This goes far beyond TAVR; this is with day-to-day coronary intervention and even diagnostic catheterization. If sites are behind the averages in our registries, we have mechanisms to, in a positive way, improve quality of care, rather than simply having cut points that are punitive.

Cardiac Interventions Today: What are some of the positive steps you can take to improve a facility's rates?

Dr. Feldman: It is often just a matter of getting a facility or a group of physicians to critically examine

their outcomes. There are PCI programs that do not have regular outcome reviews and think they are doing fine. We have a multisociety program, Accreditation for Cardiovascular Excellence (ACE), which will do a site visit and say to a site, "You are not doing quite as well as you think. You do not have, for example, monthly morbidity and mortality meetings to review complications. Your vascular complication rate may be within, but at the upper end of, the range of NCDR, and there is room for improving and developing a process to review individual cases with bleeding complications." Usually, this quickly leads to improvement in outcomes.

Cardiac Interventions Today: In the case of PCI, are most sites already reporting their data?

Dr. Feldman: Yes. A majority of the PCI programs in the country report data to the National Cardiovascular Data Registry.

Mr. Powell: That is well over 80%.

Dr. Feldman: Yes, and many, unfortunately, do not regularly look at the results.

Cardiac Interventions Today: Is there room to fudge the results when reporting data?

Dr. Feldman: One of the weaknesses of registries is that they are self-reported. There is a huge spectrum of the way that people interpret the study definitions. I think if you get into the registries, and you start reading the definitions, they are not all crystal clear. Reporting does vary depending on the way sites understand the definitions.

There is another problem in that some of the definitions are overly simple and mischaracterize procedure outcomes. For example, a patient who has a diagnostic cath before going for liver surgery and then dies after the liver surgery is considered a cath death. That is not a message that is fair, but the definition is any death after a procedure during the 30-day period. We will see the same thing with the TAVR registry; the definitions, in some respects, are arbitrary, even with some risk adjustment. We do not do a good job with risk adjusting, and all of these registries are double-edged. You get reporting and, under the best of circumstances, there is a lot of roughness in data.

Mr. Powell: Looking ahead to when there is public reporting of outcomes data, we should be concerned that more difficult patients may not receive treatment. ■