Medicare to Pay for TAVI

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The Centers for Medicare and Medicaid Services (CMS) has decided to reimburse clinicians for transcatheter aortic valve implantation (TAVI) in patients with severe aortic stenosis.

The National Coverage Decision with evidence development was issued Tuesday and follows very closely the proposed decision memo issued by CMS in February.

Five conditions must be met for TAVI reimbursement:

- The procedure must use a device approved by the FDA. (The agency approved the Sapien valve in November to be used in patients too sick to undergo surgical repair.)
- Two cardiac surgeons must have reviewed the patient's suitability for surgery.
- The patient must be under the care of a multidisciplinary heart team, and the facility must have the appropriate infrastructure to perform TAVI.
- Interventional cardiologists and cardiac surgeons must jointly participate in the intra-operative technical aspects of the procedure.
- The hospital in which it is performed must participate in a prospective, national, audited registry that follows the patient for at least 1 year but tracks outcomes for 5 years.

In December, the American College of Cardiology and the Society of Thoracic Surgeons launched the TVT Registry to track patient, physician, and facility detail.

That registry will be linked to the Social Security Death Master File and CMS databases in order to track long-term outcomes.

In its decision, CMS said that the following outcomes must be tracked in the registry:

- Stroke
- All-cause mortality
- Transient ischemic attacks
- Major vascular events
- Acute kidney injury
- Repeat aortic valve procedures
- Quality of life

If all the above requirements are not met, CMS will still reimburse for the procedure if it is performed within a clinical study and follows certain guidelines, such as having the trial registered on the government's clinical trials website and making use of the "heart team" concept.

CMS also mandates certain qualifications for hospitals and physicians with and without TAVI experience.

For example, interventionalists without TAVI experience should have performed at least 100 structural procedures and have done at least 30 left-sided structural procedures per year, of which 60% should be balloon aortic valvuloplasty.

The surgeon without TAVI experience, on the other hand, should have performed at least 100 aortic valve repairs, at least 10 of which were high risk, and at least 20 procedures in the last year prior to beginning to perform TAVI.

New hospital TAVI programs should do at least 20 procedures a year, or 40 over 2 years. It should have two physicians with cardiac surgery privileges, and do at least 1,000 catheterizations per year, including more than 400 percutaneous coronary interventions.

The FDA approval of the Sapien valve and CMS's decision to reimburse for TAVI stem primarily from results of the PARTNER trial. Two-year results from PARTNER cohort B, published in March, showed a continued advantage for TAVI in all-cause mortality compared with medical therapy alone.

The FDA is currently considering approval of the Sapien valve for use in high-risk patients, as well as inoperable patients.