



Latest News

Structural and Congenital Heart

The Centers for Medicaid and Medicare Services (CMS) recently released the revised National Coverage Determination for TAVR operators and institutions (Sept. 11, 2019). CMS was quite sensitive to the issue of access to care and has therefore made the requirements inclusive to start and maintain a TAVR program inclusive. For new programs:

- The hospital needs to do 50 aortic valve replacements in the year prior.
- The hospital needs to have done 1,000 cardiac catheterizations and 400 percutaneous coronary interventions per year;
- The program must have at least one heart surgeon with cumulative experience of at minimum 100 surgical aortic valve replacements, and 25 surgical aortic valve replacements per year;
- The program must have at least one Interventional cardiologist with at minimum 100 lifetime left-sided structural procedures, or at minimum 30 lifetime structural procedures of which 60 percent are balloon aortic valvuloplasty;
- The institution should perform at least 20 surgical aortic and 20 TAVR procedures per year.

As we all know, the COAPT study examined MitraCLIP in patients with symptomatic functional mitral regurgitation with left ventricular dysfunction on guideline directed medical therapy. Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients with Functional Mitral Regurgitation (COAPT) Trial is to confirm the safety and effectiveness of the MitraClip System for the treatment of moderate-to-severe or severe functional mitral regurgitation.

At two years there was a 32.1% reduction in hospital admissions for heart failure among patients treated with MitraCLIP, compared to those treated with medication alone. Surprisingly, there was also a 17% reduction in mortality for the MitraCLIP-treated patients as well. This was considered an extremely positive trial and has led the FDA to approve the MitraCLIP procedure for treatment of secondary mitral regurgitation on March 14, 2019. Although there is an FDA approval for use of MitraCLIP for functional there is currently not a reimbursement pathway for these patients to be treated. Current reimbursement is guided by a national coverage determination which only provides reimbursement for patients with degenerative MR who are at high risk for surgery. We are currently awaiting a revised national coverage determination with expanded coverage for patients with symptomatic functional mitral regurgitation. A multi-society document (the American College of Cardiology, Society of Thoracic Surgeons, American Association for Thoracic Surgery, Society for Cardiovascular Angiography and Interventions) with recommendations for operator and Institutional requirements for percutaneous mitral valve repair is in press and will be in print soon. It highlights the recommendations for institutions and operators who wish to perform trans-catheter mitral valve repair procedures.

For new programs the authors suggest:

- Operators should have performed at least 50 lifetime structural heart procedures, prior transcatheter mitral valve repair experience with participation in at least 20 trans-septal interventions,
 - The program should have at least one surgeon who has performed at least 20 MV surgeries in the prior year of which 50% be repairs,
 - The institution should have performed at least 40 MV surgeries in the past year of which 50% should be repairs.
- Institutions with an established trans-catheter MV program should perform at least 20 procedures per year and at least 20 MV surgeries per year, along with >300 coronary interventions.

It remains to be seen whether CMS will incorporate these recommendations into the final revised national coverage determination later this year.