



ACCESS TO **ALL** APPROPRIATE TREATMENTS FOR **ALL** HEART VALVE DISEASE PATIENTS

INFOGRAPHIC SOURCES

~2.9 to 5.8 million adults in the U.S. have aortic valve disease—one of the most common and serious types of heart valve disease

Alliance for Aging Research generated statistics, based on 2000 percentage prevalence estimates by Nkomo, V, J Gardin, T Skelton, J Gottiner, C Scott, and M Enriquez-Sarano 2006. Burden of Valvular Heart Diseases: A population-based study. *Lancet* 368(9540):1005-11 AND Bach, D, J Radeva, H Birnbaum, A-A- Fournier, and E Tuttle. 2007. Prevalence, Referral Patterns, Testing, and Surgery in Aortic Valve Disease: Leaving women and elderly patients behind? *J Heart Valv Dis* 16(4):362-9 AND U.S. Census Bureau. 2016. *American Fact Finder*. <http://bit.ly/2waFWma>

Medicare patients with severe symptomatic aortic stenosis have an average lifespan of 1.8 years without repair or replacement

Goel, S, N Bajaj, B Aggarwal, S Gupta, KL Poddar, et al. 2014. Prevalence and Outcomes of Unoperated Patients with Severe Symptomatic Mitral Regurgitation and Heart Failure. *J Am Coll Cardiol* 63(2):185-6.

For patients with severe symptomatic aortic stenosis without repair or replacement, only 50% survive 2 years and only 20% survive 5 years

Otto, C. 2000. Timing of Aortic Valve Surgery. *Heart* 84(2):211-8.

The increase of TAVR centers between 2014 and 2016 reduced deaths from severe symptomatic aortic stenosis by 19%

Optum EHR data cited in Leon presentation posted on CMS NCA Tracking Sheet for TAVR. Available at <https://www.cms.gov/medicare-coverage-database/details/medcac-meeting-details.aspx?MEDCACId=75>. Last accessed on 7/18/18.

Patients with symptomatic aortic stenosis ages 80+ who underwent surgical aortic valve replacement have 1-year, 2-year and 5-year survival rates of 87%, 78%, and 68% respectively—compared with 52%, 40%, and 22% for those patients who did not have surgery.

Clark, M, F Duhay, A Thompson, M Keyes, L Svensson, et al. 2012. Clinical and Economic Outcomes After Surgical Aortic Valve Replacement in Medicare Patients. *Risk Manag Healthc Policy* 2012(5):117-26.

Less than half of patients with severe aortic stenosis undergo aortic valve replacement

Charlson, E, A Legedza, and M Hamel. 2006. Decision-Making and Outcomes in Severe Symptomatic Aortic Stenosis. *J Heart Valve Dis* 15(3):312-21 AND Varadarajan, P, N Kapoor, R Bansal, and R Pai. 2006. Clinical Profile and Natural History of 453 Nonsurgically Managed Patients with Severe Aortic Stenosis. *Ann Thorac Surg* 82(6):2111-5 AND Jan, F, M Andreev, N Mori, B Janosik, and K Sagar. 2009. Abstract 3155: Unoperated Patients with Severe Symptomatic Aortic Stenosis. *Circ* 120:S753 AND Bach, D, D Siao, S Girard, C Duvernoy, B McCallister, and S Gualano. 2009. Evaluation of Patients with Severe Symptomatic Aortic Stenosis Who Do Not Undergo Aortic Valve Replacement: The potential role of subjectively overestimated operative risk. *Circ Cardiovasc Qual Outcomes* 2(6):533-9 AND Freed, B, L Sugeng, K Furlong, V Mor-Avi, J Raman, V Jeevanandam, and R Lang. 2010. Reasons for Nonadherence to Guidelines for Aortic Valve Replacement in Patients with Severe Aortic Stenosis and Potential Solutions. *Am J Cardiol* 105(9):1339-42.

TAVR is an important treatment option for inoperable, high-risk, and intermediate-risk patients that can reduce the burden on the patient: reducing hospital stays and recovery times, and producing better outcomes

Baron, S, V Thourani, S Kodali, S Arnold, K Wang, et al. 2018. Effect of SAPIEN 3 Transcatheter Valve Implantation on Health Status in Patients with Severe Aortic Stenosis at Intermediate Surgical Risk: Results from the PARTNER S3i Trial. *JACC* 11(12):1188-98.

TAVR National Coverage Determination Requirements

National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR) (20.32). Available at [https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDid=355&ncdver=1&NCAid=257&ver=4&NcaName=Transcatheter+Aortic+Valve+Replacement+\(TAVR\)&bc=ACAAAAACAAAAA%3D%3D&.%20](https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDid=355&ncdver=1&NCAid=257&ver=4&NcaName=Transcatheter+Aortic+Valve+Replacement+(TAVR)&bc=ACAAAAACAAAAA%3D%3D&.%20). Last accessed on 7/18/18.

Procedure volume was used a surrogate for outcomes to ensure quality in the absence of other evidence.

O’Riordan, M. *High-Quality TAVR: Does a Minimum Volume Requirement Still Make Sense?* tctMD. <https://www.tctmd.com/news/high-quality-tavr-does-minimum-volume-requirement-still-make-sense>

It was believed that increased experience from higher volume facilities would lead to better outcomes.

Carroll, J, S Vemulapalli, D Dai, R Matsouaka, E Blackstone, et al. 2017. Procedural Experience for Transcatheter Aortic Valve Replacement and Relation to Outcomes: The ST/ACC TVT Registry. *JACC* 70(1):29-41.

Now have a significant body of evidence on outcomes that proves safety of TAVR

Grover, F, S Vemulapalli, J Carroll, F Edwards, M Mack, et al. 2017. 2016 Annual Report of The Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry. *JACC* 69(10).

In general, recent evidence shows that TAVR outcomes have been excellent in both high- and low-volume facilities

De Biasi, A, S Paul, A Nasar, L Girardi, and A Salemi. 2016. National Analysis of Short-Term Outcomes and Volume-Outcome Relationships for Transcatheter Aortic Valve Replacement in the Era of Commercialization. *Cardiology* 133:58-68.

Enhanced technology, simplification of the procedure, widespread training, and group learning positively impacts outcomes independent of volume

Gurevich, S, R John, R Kelly, G Raveendran, G Helmer, et al. 2017. Avoiding the Learning Curve for Transcatheter Aortic Valve Replacement. *Cardiol Res Pract* 7524925.

NCD for TAVR Reopened

CMS.gov. *National Coverage Analysis (NCA) Tracking Sheet for Transcatheter Aortic Valve Replacement (TAVR) (CAG-00430-R)*. Available at <https://www.cms.gov/medicare-coverage-database/details/nca-tracking-sheet.aspx?NCAId=293&NCDId=355&IsPopup=y&bc=AAAAAAAAQAAA&>. Last accessed on 7/18/18.

MEDCAC Panel

CMS.gov. Medicare Evidence Development & Coverage Advisory Committee. Available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/MEDCAC.html>. Last access on 7/18/18.

94% of TAVR recipients are white

Grover, F, S Vemulapalli, J Carroll, F Edwards, M Mack, et al. 2017. 2016 Annual Report of The Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry. *JACC* 69(10).

>90% of TAVRs are performed in urban, teaching hospitals

Analysis performed using [HCUP Net Database](#) for 2015 Hospital Discharges.

78% of patients served by these hospitals are in higher income zip codes

Analysis performed using [HCUP Net Database](#) for 2015 Hospital Discharges.

Safety net hospitals—often providers of last resort—perform ~20% of TAVRs

Analysis performed using [HCUP Net Database](#) for 2015 Hospital Discharges.

Increasing volume requirements could further limit TAVR access and heighten disparities

Optum EHR data cited in Leon presentation posted on CMS NCA Tracking Sheet for TAVR. Available at <https://www.cms.gov/medicare-coverage-database/details/medcac-meeting-details.aspx?MEDCACId=75>. Last accessed on 7/18/18.