HEART VALVE DISEASE POLICY
TASK FORCE

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

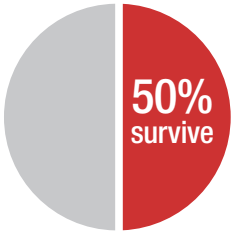
~2.9 TO 5.8 MILLION ADULTS IN THE U.S. HAVE AORTIC VALVE DISEASE–

one of the most common and serious types of heart valve disease

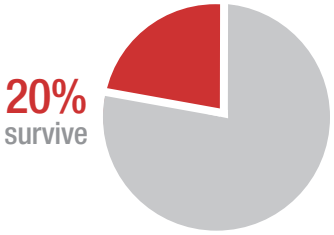
If left untreated, heart valve disease can be fatal

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

For patients with severe symptomatic aortic stenosis without repair or replacement, only



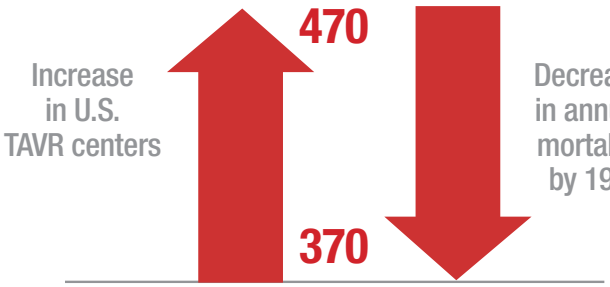
2 years



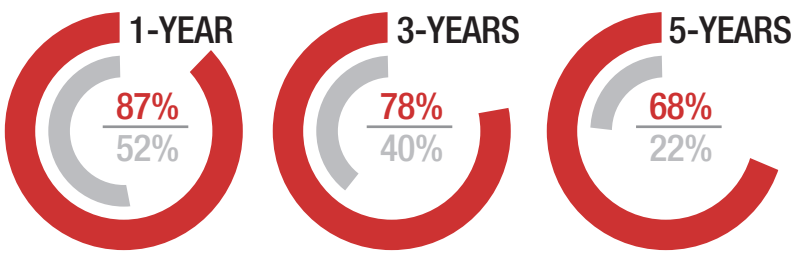
5 years

Aortic valve repair and replacement save lives

The increase of transcatheter aortic valve replacement (TAVR) centers between 2014 and 2016, reduced deaths from severe symptomatic aortic stenosis by 19%



Survival rates of symptomatic aortic stenosis patients ages 80+

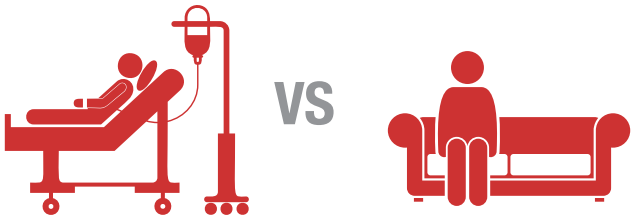


Aortic stenosis is significantly undertreated

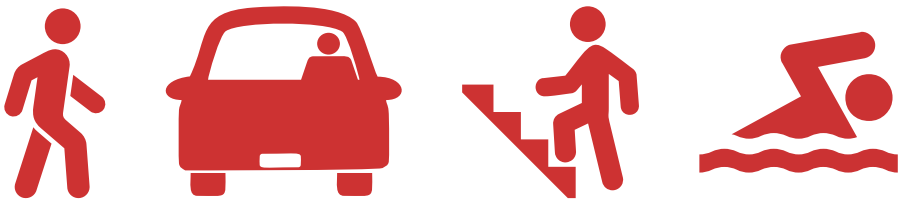
Less than half of patients with severe aortic stenosis undergo aortic valve replacement

Transcatheter aortic valve replacement (TAVR) is an important treatment option for inoperable, high-risk, and intermediate-risk patients that can reduce the burden on the patient:

Reduce hospital stays and recovery times



Produce better outcomes



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National Coverage Determination (NCD) for transcatheter aortic valve replacement (TAVR)

from Centers for Medicare and Medicaid Services (CMS) lays out requirements for Medicare coverage of TAVR procedures:

All patients must have face-to-face exams with two cardiac surgeons AND be under the care of a heart team

All TAVR patients must be entered into a qualified national registry

New and existing TAVR programs must meet the minimum number of annual surgical and interventional cardiac procedures

TO BEGIN a TAVR program, hospital must have:	TO MAINTAIN a TAVR program, hospital must have:
≥50 AVRs in yr before launch [≥10 in high-risk patients]	≥20 AVRs/yr OR ≥40 AVRs/2 yrs
≥1,000 catheterizations/yr [≥400 as percutaneous cardiac interventions]	≥1,000 catheterizations/yr [≥400 as percutaneous cardiac interventions]
Heart team with: ≥2 physicians with cardiac surgery privileges ≥1 who has done ≥100 career AVRs [≥10 in high-risk patients] OR 25 AVRs in 1 yr OR 50 AVRs in 2 yrs [20 in yr before launch] Interventional cardiologist with ≥100 career structural heart disease procedures OR ≥30 left-sided structural procedures/yr [60% as balloon aortic valvuloplasty]	**Heart team with:** ≥2 physicians with cardiac surgery privileges Cardiovascular surgeon and interventional cardiologist with combined experience that maintains: ≥20 TAVRs in previous yr OR ≥40 TAVRs in previous 2 yrs
Additional members of heart team Device-specific training required by manufacturer	Additional members of heart team

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TAVR Evidence in 2012	TAVR Evidence in 2018
Procedure volume was used as a surrogate for outcomes to ensure quality in the absence of other evidence	Now have significant body of evidence on outcomes that proves safety of TAVR
It was believed that increased experience from higher volume facilities would lead to better outcomes	In general, recent evidence shows that TAVR outcomes have been excellent in both high- and low-volume facilities Enhanced technology, simplification of the procedure, widespread training, and group learning positively impacts outcomes independent of volume

NCD for TAVR Reopened

On Wednesday, June 27, 2018 CMS reopened for reconsideration the NCD for TAVR, with an initial 30-day comment period. This means CMS is reexamining whether, and under what circumstances, Medicare will cover TAVR.

*could occur sooner

The Draft NCD will be published no later than March 27, 2019 and will be followed by an additional 30-day comment period. The Final NCD will be published no later than June 25, 2019 and could impact patient access to TAVR—potentially widening or limiting the ability of patients to get TAVR.

MEDCAC

The Medicare Evidence Development & Coverage Advisory Federal Advisory Committee (MEDCAC) provides supplemental expertise and a recommendation to CMS based on an unbiased and current review of the latest technology and scientific evidence.

The MEDCAC panel typically consists of **15 members** including:

- 1 Committee chair
- 1 patient advocate
- 1 industry representative (non-voting)
- 2 to 3 guest expert panelists (non-voting)
- Remaining members chosen from a pool of 100 approved MEDCAC members with relevant expertise
- Meetings are open to the public

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Current National Coverage Determination creates barriers and unequal access to transcatheter aortic valve replacement (TAVR)

Depending on which hospital a patient visits, their treatment can be vastly different:

94% of TAVR recipients are white

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

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

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

Minority and underserved patients receive far fewer treatments for HVD despite comparable outcomes

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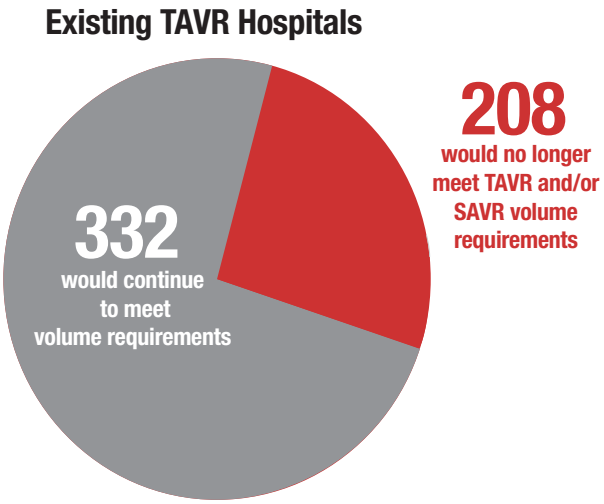
Increasing volume requirements could further limit transcatheter aortic valve replacement (TAVR) access and heighten disparities

If, for example, volume requirements were raised to 50 TAVR & 30 SAVR/year:



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The Heart Valve Disease Policy Task Force believes that ALL patients should have access to ALL appropriate treatments

- Volume is no longer a necessary surrogate for outcomes and there should be more emphasis on timely intervention and quality outcomes.
- The current 4 health outcomes measured (mortality, stroke, vascular complications, and bleeding) are medical. Other important outcomes that matter to patients that should be included in the NCD requirements include: quality of life, mobility, length of stay, new onset of AFib, staying out of the hospital, and location of discharge.
- The Task Force also believes that the two surgeon approval requirement creates unnecessary roadblocks and delays for patients. The process should instead formally incorporate a shared decision-making process where patients are free to obtain opinions and recommendations from a range of experts.
- Additionally, patients should have free or reduced-cost access to the Transcatheter Valve Therapy (TVT) Registry data and meaningful information on hospital performance.

YOUR VOICE MATTERS!

It only takes a few clicks to write to your member of Congress by going through the Heart Valve Voice website, which gives you optional language to use, finds your representatives for you, and sends the message. You can also share your thoughts on social media, contact the media, submit comments to CMS, and more. Learn more and see references for infographic statistics at www.agingresearch.org/TAVR.