Global Coalition on Aging

Modernizing Medicare Coverage:
It's Time to Expand Access to TAVR for Asymptomatic Aortic Stenosis

Why Now: America is Aging and Medicare Must Adapt

By 2050, nearly 1 in 4 Americans will be over 65. This unprecedented demographic shift is reshaping the health landscape, as chronic conditions, complex care needs, and fiscal pressure on Medicare increase. Medicare must evolve with smarter, more proactive strategies to continue to meet the demands of a growing aging population.
Conditions that are more prevalent with advancing age, such as aortic stenosis, can place additional demands on the healthcare system if they are treated only in later, more advanced stages of the disease.

The only treatment shown to directly improve survival of patients with aortic stenosis is replacement of the diseased aortic valve.[1, 2, 3] Aortic valve replacement (AVR) can be performed through traditional open-heart surgery or through a minimally-invasive procedure called transcatheter AVR (TAVR).

Diagnosing and intervening earlier in disease progression is critical for both patient well-being and health system sustainability. Innovative and proven solutions like TAVR present the opportunity to ensure spending supports well-being for both individuals and the program's budget through:

- Prevention that supports healthier aging, and
- Diagnosis, proactive disease management, and earlier intervention before symptom onset, to avoid significantly worse clinical and economic outcomes

Expanding access to TAVR is a clear opportunity to modernize Medicare in response to today's aging realities and ensure the program remains sustainable for generations to come.

Key Messages

- TAVR is a proven, minimally-invasive treatment for aortic stenosis.
- Earlier intervention before symptom onset saves lives and reduces healthcare costs.
- New evidence shows clear benefits without added risk.

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[1] Schwarz, F., Baumann, P., Manthey, J., et al. (1982). The effect of aortic valve replacement on survival. *Circulation*, *66*(5), 1105–1110. https://doi.org/10.1161/01.cir.66.5.1105
[2] Thourani, V.H., Suri, R.M., Gunter R.L., et al. (2014). Contemporary Real-World Outcomes of surgical aortic valve replacement in 141,905 Low-Risk, Intermediate-Risk, and High-Risk patients. *The Annals of Thoracic Surgery*, *99*(1), 55–61. https://doi.org/10.1016/j.athoracsur.2014.06.050
[3] Leon, M.B., Smith, C.R., Mack, M., et al. (2010). Transcatheter Aortic-Valve implantation for aortic stenosis in patients who cannot undergo surgery. *New England Journal of Medicine*, *363*(17), 1597–1607. https://doi.org/10.1056/nejmoa1008232

- As the US population ages, Medicare will feel increasing strain. Expanding access to efficient, life-saving interventions like TAVR is not just clinically sound—it's economically strategic.
- CMS should update its outdated TAVR coverage policy to better align with the latest clinical evidence and practice patterns, thereby allowing appropriate access for a now proven indication.
- Ensuring a coverage policy that provides all patients with aortic stenosis access to TAVR enables patients to access the right treatment at the right time.

What is TAVR?

Transcatheter Aortic Valve Replacement (TAVR) is a minimally-invasive, non-surgical procedure to treat aortic stenosis—a serious condition in which the heart's aortic valve narrows. It can lead to heart failure, stroke, and death if left untreated.

Aortic stenosis is linked to age, making proactive, effective treatment especially important for Medicare beneficiaries.[4, 5] As the population ages, expanding access to efficient life-saving interventions like TAVR is essential to both improving patient outcomes and managing growing healthcare costs.

TAVR offers patients a minimally-invasive alternative to avoid traditional open-heart surgery, resulting in shorter hospital stays and faster post-procedure recovery. It has been approved by the FDA for asymptomatic patients with severe aortic stenosis, but CMS policy has not yet caught up.[6]

Current CMS Policy only addresses TAVR for patients with symptoms, despite evidence demonstrating improved outcomes for asymptomatic patients who receive TAVR.[7]

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[4] Bonow, R. O., & Greenland, P. (2015). Population-Wide Trends in Aortic Stenosis Incidence and Outcomes. *Circulation*, *131*(11), 969–971. https://doi.org/10.1161/circulationaha.115.014846

[5] Clark, M. A., Arnold, S. V., Duhay, F. G., et al. (2012). Five-year clinical and economic outcomes among patients with medically managed severe aortic stenosis. *Circulation Cardiovascular Quality and Outcomes*, *5*(5), 697–704. https://doi.org/10.1161/circoutcomes.112.966002

[6] TAVR procedures were first approved by the FDA in 2011 for patients with severe symptomatic aortic stenosis who were deemed inoperable. In 2012, CMS issued a National Coverage Determination (NCD), allowing Medicare coverage for TAVR under Coverage with Evidence Development (CED). By 2019, TAVR FDA approved indications had expanded to include intermediate-risk patients and TAVR procedures were considered a common, safe procedure with excellent outcomes. Most recently, in April 2025, the FDA approved the use of the SAPIEN 3 TAVR platform for asymptomatic patients with severe AS.

[7] Transcatheter Aortic Valve Replacement (TAVR). CMS. (2025). https://www.cms.gov/medicare/coverage/evidence/aortic-valve-replacement

Why it Matters: Asymptomatic Aortic Stenosis Is Not Benign

Even without symptoms, patients can be just one step away from catastrophic cardiovascular events. Waiting for symptoms to emerge puts patients at risk.

Diagnosis without symptoms is possible through echocardiographic imaging and clinical evaluation.

Additionally, age-related bias in healthcare—when symptoms are mistaken for "normal aging" or treatments are withheld based on age alone—can delay diagnosis and deny older adults access to lifesaving interventions like TAVR.

Key Data

- 1 in 4 patients with aortic stenosis develop symptoms and require AVR within 6 months.[8, 9]
- As many as 50% of asymptomatic patients with severe aortic stenosis show symptoms and require treatment within 2 years.[10]
- Once symptomatic, 1 in 10 patients may die within 5 weeks waiting for treatment.[11]
- 40% of patients with severe aortic stenosis remain untreated after 4 years.[12]

Symptoms Are Often Missed

Current treatment guidelines recommend AVR when symptoms appear or when the heart isn't functioning as it should.[13, 14] The current approach for the majority of asymptomatic patients with severe aortic stenosis is "watchful waiting," in which care teams monitor the disease without intervening. However, assessing symptoms is challenging in clinical

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[8] Gahl, B., Çelik, M., Head, S. J., et al. (2020). Natural history of asymptomatic severe aortic stenosis and the association of early intervention with outcomes. JAMA Cardiology, 5(10), 1102. https://doi.org/10.1001/jamacardio.2020.2497

[9] Genereux, P., Schwartz, A., Oldemeyer, J.B., et al. (2025). Transcatheter aortic-valve replacement for asymptomatic severe aortic stenosis. N Engl J Med, 392(3), 217–227. https://doi.org/10.1056/NEJMoa2405880

[10] Iung, B., Delgado, V., Rosenhek, R., et al. (2019). Contemporary presentation and management of valvular heart disease: The EURObservational Research Programme Valvular Heart Disease II Survey. *Circulation*, *140*(14), 1156–1169. https://doi.org/10.1161/circulationaha.119.041080

[11] Malaisrie, S.C., McDonald, E., Kruse, J., et al. (2014). Mortality while waiting for aortic valve replacement. *The Annals of Thoracic Surgery*, *98*(5), 1564–1571. https://doi.org/10.1016/j.athoracsur.2014.06.040

[12] Généreux, P., Sharma, R.P., Cubeddu, R.J., et al. (2023). The mortality burden of untreated aortic stenosis. *Journal of the American College of Cardiology*, *82*(22), 2101–2109. https://doi.org/10.1016/j.jacc.2023.09.796

[13] Otto, C.M., Nishimura, R.A., Bonow, R.O., et al. (2020). 2020 ACC/AHA Guideline for the Management of Patients with Valvular Heart Disease. *Journal of the American College of Cardiology*, *77*(4), e25–e197. https://doi.org/10.1016/j.jacc.2020.11.018

[14] Vahanian, A., Beyersdorf, F., Praz, F., et al. (2021). 2021 ESC/EACTS Guidelines for the management of valvular heart disease. *European Heart Journal*, *43*(7), 561–632. https://doi.org/10.1093/eurheartj/ehab395

practice, and patients often fail to notice or report them, which can delay referrals for treatment.[15]

Underdiagnosis adds further risk: 1 in 7 with severe aortic stenosis are never clinically diagnosed.[16]

Watchful Waiting Is No Longer Appropriate

Clinical evidence shows that waiting to intervene with AVR after symptom onset is associated with significantly worse clinical and economic outcomes.

The EARLY TAVR Trial found that intervention with TAVR prior to symptom onset significantly reduced the combined risk of death, stroke, or unplanned cardiovascular hospitalizations:[17]

Outcome	Early TAVR	Watchful Waiting
Death, stroke, or unplanned cardiovascular hospitalization	35.1%	51.2%
Mortality	8.4%	9.2%
Stroke	4.2%	6.7%

Earlier intervention with TAVR was also associated with significantly fewer hospitalizations for heart failure (5.3% vs 12.0%).

"We believe that the time has come to recommend AVR for asymptomatic patients with severe AS. This paradigm shift is anticipated to yield improved patient outcomes, public health, and resource utilization. It is time to act."[18]

Brian R. Lindman, MD, MSc, Eugene Braunwald, MD, Patricia A. Pellikka, MD

Cost Savings for Medicare and Beyond

Timely intervention reduces the total cost of care and associated healthcare burden for severe aortic stenosis. Treating asymptomatic severe aortic stenosis with AVR can **save**

[15] Tsampasian, V., Militaru, C., Parasuraman, S.K., et al. (2024). Prevalence of asymptomatic valvular heart disease in the elderly population: a community-based echocardiographic study. *European Heart Journal - Cardiovascular Imaging*, *25*(8), 1051–1058. https://doi.org/10.1093/ehjci/jeae127
[16] Crousillat, D.R., Amponsah, D.K., Camacho, A., et al. (2022). Racial and ethnic differences in the clinical diagnosis of aortic stenosis. *Journal of the American Heart Association*, *11*(24). https://doi.org/10.1161/jaha.122.025692
[17] Genereux, P., Schwartz, A., Oldemeyer, J.B., et al. (2025). Transcatheter aortic-valve replacement for asymptomatic severe aortic stenosis. N Engl J Med, 392(3), 217–227. https://doi.org/10.1056/NEJMoa2405880
[18] Lindman, B. R., Braunwald, E., & Pellikka, P. A. (2025). Aortic valve replacement for asymptomatic Severe aortic Stenosis—The time has come. *JAMA Cardiology*. https://doi.org/10.1001/jamacardio.2024.5648

up to $36,000 per patient within the first year, compared to treating after symptoms develop.[19]

Real-world data of over 24,000 patients demonstrates that a "watchful waiting" approach results in significantly higher mortality rates and increased healthcare costs:

- Greater than 2x higher risk of death,
- More than 20% higher healthcare costs, and
- More than 2x higher risk of hospitalizations for heart failure within 1 year after AVR.[20]

A major reset in the management of severe asymptomatic aortic stenosis is now recommended.

This Isn't Experimental—It's Proven

TAVR is an FDA-approved technology and is already covered by CMS for the treatment of symptomatic aortic stenosis. In 2019, CMS updated the TAVR National Coverage Determination (NCD) to better reflect evidence and clinical practice at that time to expand beneficiary access and available sites qualified to perform lifesaving TAVR procedures. Despite these efforts, patients with aortic stenosis continue to face significant delays and barriers to accessing TAVR. As a result, the disease remains largely undertreated, with less than half of indicated patients receiving AVR.[21]

Expanding access to include asymptomatic patients isn't about introducing something new—it's about removing outdated and burdensome requirements in the current policy that delay care and compromise patient outcomes.

Policy Recommendation

CMS should revise its NCD to include Medicare coverage of TAVR for **asymptomatic** patients with severe aortic stenosis. CMS should also eliminate TAVR's Coverage with Evidence Development status, recognizing the robust, cumulative evidence demonstrating TAVR is reasonable and necessary for aortic stenosis.

This change would:

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[19] Généreux, P., Giustino, G., Lindman, B.R., et al. (2025). Acute valve syndrome before aortic valve replacement: impact on clinical outcomes, health care costs, and resource use. *Journal of the American Heart Association*. https://doi.org/10.1161/jaha.125.043486
[20] Généreux, P., Giustino, G., Lindman, B. R., et al. (2025). Acute valve syndrome before aortic valve replacement: impact on clinical outcomes, health care costs, and resource use. *Journal of the American Heart Association*. https://doi.org/10.1161/jaha.125.043486
[21] Brennan, J. M., Leon, M. B., Sheridan, P., et al. (2020). Racial differences in the use of aortic valve replacement for treatment of symptomatic severe aortic valve stenosis in the transcatheter aortic valve replacement ERA. *Journal of the American Heart Association*, *9*(16). https://doi.org/10.1161/jaha.119.015879

- Align with latest clinical evidence and evolving global indications and guidelines
- Lower healthcare costs and improve patient outcomes
- Support equitable access to a life-saving technology

Conclusion: A Missed Opportunity—Until Now

As the U.S. population ages and the chronic disease burden grows, Medicare will continue to face increasing budgetary strain while meeting the needs of older Americans. For long-term sustainability, investing in earlier detection, treatment, and diagnosis can mitigate the expense of acute later-stage intervention. Watchful waiting is no longer appropriate. Diagnosis in earlier stages of disease, proactive disease management, and timely intervention with TAVR provides benefits to patients and healthcare systems.

Expanding access to TAVR will improve patient outcomes, enhance the quality of care, and reduce strain on healthcare systems—without adding risk to patients or Medicare.