



# Time to Act:

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WHAT YOU NEED TO KNOW ABOUT MEDICARE'S  
PROPOSED TAVR DECISION AND HOW TO  
LEND YOUR VOICE TO MAKE A DIFFERENCE

# Speakers

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# Introduction: Medicare National Coverage Determination for TAVR

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- In 2011, the U.S. Food and Drug Administration (FDA) approved transcatheter aortic valve replacement (TAVR) for the treatment of severe, symptomatic aortic stenosis in patients who were not eligible to have open-heart surgery.
- In 2012, the Centers for Medicare and Medicaid Services (CMS), issued a National Coverage Determination (NCD) for TAVR under Coverage with Evidence Development (CED). This allowed Medicare to cover TAVR for both non-FDA and FDA-approved uses. Hospitals had to meet these requirements using clinical trials and data collection through a registry.
- The hospitals that wanted to offer TAVR had to meet several strict conditions in order to be paid for the procedure and for Medicare patients to get coverage for it.
- Now CMS is reconsidering this decision and inviting feedback from the public, including the patient community.
- Our goal today is to go over some key issues within the current set of conditions and explain changes we would like to see that would provide greater treatment access and help more patients in the future.

# Coverage with Evidence Development (CED) is No Longer Needed

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The available evidence is more than sufficient to conclude that TAVR improves health outcomes for Medicare beneficiaries with severe symptomatic aortic stenosis for FDA-approved indications

# Replace Annual Volume Requirements with Health Outcomes

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- Hospital-based health outcomes data should be used in lieu of annual procedural volume requirements that do not ensure quality
- Such requirements place access burdens on minority and rural beneficiary populations, as well as service barriers to the smaller hospitals that serve them

# People May Die Waiting for Treatment

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If FDA approval expands to patients at low-risk for surgery, and the CED and its program maintenance requirements remain, waiting lists at larger hospitals will lengthen and patients may die due to delays

# CED Does Not Prioritize Patients

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Continuation of the CED requirement is contrary to CMS' "patients over paperwork" initiative and places unnecessary regulatory burdens and costs on providers that don't improve care for patients

# Email a Public Comment to CMS

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CMS is accepting comments until Thursday, April 25 at this link:

<http://bit.ly/SubmitTAVRComment>

Be sure to accept the posting policy on the CMS website.





# Tips for Sending in a Comment

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- The most important thing is to share is your own story, especially if you've had treatment for severe symptomatic aortic stenosis, either with surgery or TAVR. Tell CMS about your experience, and why getting good treatment was/is important to you.
- We are encouraging CMS to expand access to TAVR and remove overly strict requirements Medicare has had in place for seven years for patients to get the procedure. Put in your own words how you were, or were not, able to get the treatment you needed.
- We are also stressing how valuable it would be for patients to see how well their local hospitals are performing surgery and TAVR. Currently, this information is not available to the public. We are urging CMS to change that, so patients can make informed choices about where to get their care.

**Deadline: Next Thursday, April 25<sup>th</sup>**