As the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States, the Federation of American Hospitals (FAH) appreciates the opportunity to comment on the proposed decision memorandum reconsidering the National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR) (NCD 20.32; CAG-00430R2). Many FAH members operate TAVR programs and care for the Medicare beneficiaries with aortic stenosis who depend on access to this therapy, which is why we offer the following two comments directed at ensuring the coverage criteria remain administrable and keep pace with evolving treatment options.

Coverage Should Track FDA-Approved Indications for Aortic Stenosis

The current NCD permits coverage for symptomatic patients with "aortic valve stenosis," while the proposed update would permit coverage only for patients with "severe" aortic valve stenosis. However, to date the FDA has approved TAVR valves for severe aortic stenosis and severe aortic valve regurgitation. In addition, there are currently several clinical trials in process to determine the efficacy of TAVR for moderate-to-severe aortic stenosis. This creates conflict not only today, but also for any future additional FDA approved indications. If the FDA approves any of these valves for moderate or moderate-to-severe disease, the proposed language would preclude coverage even for an FDA-approved indication, creating a coverage gap that could persist until CMS reopened and revised the NCD.

We note that the proposed coverage criteria already tie coverage to a system "that has received Food and Drug Administration (FDA) premarket approval (PMA) for that system's FDA-approved indication." Because coverage is already limited to the FDA-approved indication, removing "severe" does not extend coverage to any indication the FDA has not approved. It simply allows coverage to follow future FDA approvals without requiring a new coverage reconsideration. To align coverage with current and future FDA approvals, we recommend that CMS revise the coverage criteria as follows:

> B. Coverage Criteria
>
> We propose that TAVR for aortic valve disease is covered when furnished with a complete aortic valve and implantation system that has received Food and Drug Administration (FDA) premarket approval (PMA) for that system's FDA-approved indication, and the following conditions are met.
>
> 1. Patient Criteria
>
> TAVR is covered for the treatment of Medicare beneficiaries with:
>
> a. Symptomatic aortic stenosis under § 1862(a)(1)(A) of the Social Security Act (the Act).
>
> b. Asymptomatic aortic stenosis under CED, § 1862(a)(1)(E) of the Act.
>
> c. Symptomatic or asymptomatic aortic regurgitation under CED, § 1862(a)(1)(E) of the Act.

The "Estimated Patient Life Expectancy" Element Should Be Removed or Clarified

The current NCD requires that the heart team's physicians have "independently examined the patient face-to-face, evaluated the patient's suitability for surgical aortic valve replacement (SAVR), TAVR or medical or palliative therapy." The proposed update expands the required elements of the patient evaluation to include several components that are, in most cases, already part of the evaluation and documentation process. We recommend that CMS clarify this requirement by replacing "estimated patient life expectancy" with an objective, established standard.

As proposed, "estimated patient life expectancy" is subjective and undefined. The proposal specifies no threshold, method, or documentation standard, which invites inconsistent application across heart teams and creates unnecessary uncertainty and audit exposure for providers acting in good faith. We recommend that CMS adopt the objective, established standard already used in the Implantable Cardioverter Defibrillators NCD (NCD 20.4), which the agency and providers have applied successfully. Under that approach, the patient evaluation provision would read as follows:

> Patient Evaluation: Suitability for surgical aortic valve replacement (SAVR), TAVR, close surveillance, and palliative care must be evaluated based on individual clinical, anatomical, and procedural characteristics, lifetime management considerations, and determination that the patient does not have any disease, other than cardiac disease (e.g., cancer, renal failure, liver failure) associated with a likelihood of survival less than 1 year. These evaluations must be documented and made available to other heart team members, the patient, and other clinicians involved in the patient's care as appropriate, prior to the day of the procedure.

This substitution preserves the “lifetime management considerations” the proposed decision relies upon while replacing an open-ended clinical estimate with a bright-line standard that is administrable and consistent with existing CMS policy.

FAH appreciates CMS’s consideration of these comments and its work to modernize the TAVR NCD. We would welcome the opportunity to provide any additional information that would be helpful.