July 18, 2024

Tamara Syrek Jensen, JD
Director, Coverage & Analysis Group
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Re: CAG-00467N Transcatheter Tricuspid Valve Replacement (TTVR) and Broader CED Policy Considerations

Dear Ms. Syrek Jensen,

As authors of "A Roadmap for Improving Medicare's Application of Coverage With Evidence Development" recently published in Value in Health[1], we are writing to comment on the National Coverage Analysis (NCA) for Transcatheter Tricuspid Valve Replacement (TTVR) and, more broadly, on the application of the Coverage with Evidence Development (CED) policy.[2] The principles outlined in the tracking sheet for this NCA align with several key recommendations we made for improving CED policy across all cases.

Clarifying the Process for Ending CED Requirements

The lack of clarity around the process and timeline for reconsidering CED requirements is a significant issue in all CED cases. The collaborative approach taken in developing the Evidence Development Plan (EDP) for TTVR, involving the sponsor, CMS, and the Agency for Healthcare Research and Quality (AHRQ), appears to address this concern. This proactive, upfront collaboration could serve as a model for all future CED implementations, providing a clear pathway for transitioning from CED coverage.

We recommend that CMS explicitly articulate how the EDP will guide the eventual reconsideration of CED requirements in all cases. This process should include:

1. Developing objective, upfront criteria or findings from the data collected—based on priorities that matter to patients—that would trigger various CED outcomes (extension of CED, removal of CED, revocation of NCD, etc.).

2. Specifying a preliminary review date—ideally within 3 years—to evaluate whether the evidence generated meets those criteria.

3. Including an option to amend the coverage decision earlier if significant new evidence arises.

[1] Darius Lakdawalla et al., "A Roadmap for Improving Medicare's Application of Coverage With Evidence Development," *Value in Health* 0, no. 0 (May 22, 2024), https://doi.org/10.1016/j.jval.2024.05.008.
[2] The opinions expressed herein represent those of the authors and do not represent the positions of any of their affiliated organizations.

4. Establishing a formal process for periodic review of evidence generated under CED, with pre-specified criteria for determining when sufficient evidence has been gathered to warrant reconsideration of the CED requirements.

Clear Criteria for Applying CED
The adoption of clear and predictable criteria for when CED should be applied is essential across all potential applications. While the TTVR NCA could serve as a model, these criteria should be consistently applied to all technologies under consideration for CED. We encourage CMS to explicitly state the rationale for applying CED in each case and how it aligns with broader CED policy goals. Possible high-level criteria for applying CED could include situations where:

1. Peer-reviewed evidence suggests an item or service offers meaningful outcomes that matter to patients or the healthcare system.

2. Significant questions exist about the items or services that can be addressed through further data collection, with the level of significance of each question (and subsequent data requirements) aligned with outcomes that are prioritized by patients.

Prioritizing Patient Preferences
Incorporating patient-centered outcomes and preferences in CED is crucial for any technology under consideration. We are pleased to see indications that patient preferences may play a role in the TTVR NCA and encourage this approach for all CED decisions. We urge CMS to use validated patient preference information throughout the CED process, from the initial application of CED to the design of evidence collection activities and the evaluation of generated evidence.

Timely and Equitable Access
A primary goal of CED is to expedite beneficiary access to promising new technologies while ensuring appropriate safeguards. This principle should be applied universally, including in the TTVR NCA. We urge CMS to carefully consider how any coverage requirements, including potential center of excellence criteria, might impact equitable access to technologies under CED. Particular attention should be paid to avoiding undue barriers for underserved populations, rural areas, and other patient groups that may face challenges in accessing care. By thoughtfully designing CED requirements, CMS can help ensure that the benefits of new technologies are accessible to all Medicare beneficiaries, regardless of their geographic location or socioeconomic status.

Minimizing Burden on Providers and Patients
CED data collection activities have sometimes placed unnecessary burdens on clinicians, facilities, and patients. In designing evidence collection requirements for all CED cases, we encourage CMS to prioritize approaches that minimize these burdens while still addressing key evidence gaps.

In conclusion, it is crucial that CMS implement an improved approach to CED that aligns with our recommendations across all cases. We recommend that CMS continue to refine and enhance its CED policy, incorporating principles such as clear criteria for application and termination, patient-centered approaches, minimized burdens, and equitable access considerations. These improvements to the CED process could not only provide timely access to promising new technologies for Medicare beneficiaries but also set a positive precedent for all future applications of CED.

As policy researchers, we appreciate the opportunity to comment on this important NCA and the broader implications for CED policy as CMS may need to apply it going forward. We would be happy to provide any additional information or clarification that might be helpful in improving the CED process across all applications.

Respectfully,

Darius Lakdawalla, PhD
Quintiles Chair in Pharmaceutical Development and Regulatory Innovation, University of Southern California Schaeffer Center for Health Policy & Economics

Sean Tunis, MD
Founder and Senior Strategic Advisor, Center for Medical Technology Policy

Peter Neumann, ScD
Director, Center for the Evaluation of Value and Risk in Health, Institute for Clinical Research and Health Policy Studies, Tufts Medical Center

Danielle Whicher, PhD
Senior Researcher, Mathematica

Emily Zeitler, MD MHS
Assistant Professor of Medicine, The Dartmouth Institute for Health Policy and Clinical Practice, Geisel School of Medicine at Dartmouth

Barry Liden, JD
Director of Public Policy, USC Schaeffer Center for Health Policy & Economics