

**The Need for Transitional Coverage for Emerging Technologies Public Webinar**

March 28, 2022

*Meeting Summary*

The Duke-Margolis Center for Health Policy and the Stanford Byers Center for Biodesign co-hosted a public webinar on March 28, 2022, that focused on the need for a well-designed coverage program that could accelerate patient access to critical new medical innovations. The webinar highlighted stakeholder perspectives, including those of CMS, innovators, and policymakers. Throughout four sessions, meeting participants learned about CMS objectives in providing access to emerging technologies, considerations from the innovator community on how to reduce uncertainties inherent in developing innovative products, operational frameworks for an expedited coverage pathway, and implementation considerations to ensure stable and long-term coverage and access.

The webinar began with opening remarks by Josh Makower, MD and Mark McClellan, MD, to frame some of the key issues that impact patient access to emerging technologies, such as coding, coverage, payment, evidence generation, confidence, appropriateness, and value. While an expedited coverage pathway would not address all these issues, it can be a critical factor in investment and subsequent development decisions.

Following this introduction, Lee Fleisher, MD, CMO and Director, Center for Clinical Standards and Quality, Centers for Medicare and Medicaid Services, presented current coverage processes for emerging technologies and ongoing considerations for expedited coverage. Current coverage processes with emerging technologies involve benefit category determinations, evidence assessments of clinical benefit relative to the strength of the evidence available, and an assessment of risk of harm for Medicare beneficiaries. He then presented current considerations for a new expedited pathway that, based upon stakeholder feedback, focuses on FDA and CMS collaboration, manufacturer engagement, coverage to class, and predictable evidence reviews. Dr. Fleisher highlighted a commitment to early CMS and FDA collaboration underscoring the need for alignment on post-market evidence needs. He shared CMS' call for public feedback on a potential transitional coverage pathway for emerging technologies, with the hopes of releasing an initial pathway framework by the end of 2022.

Sandra Ruggles, PhD, then presented findings from a study of 253 healthcare innovators and 83 investors that highlight the need for a redesigned, streamlined pathway to reimbursement for novel medical technologies, to include an expedited coverage pathway. Study respondents reported it takes on average 4.7 years after FDA authorization or approval to achieve nationwide coverage and as a result reimbursement (e.g., coding, broad public and private coverage, and payment) was a top factor for investment decisions driving innovation. Respondents indicated that a new transitional coverage pathway will stimulate investment and development of innovative healthcare innovations in areas important for Medicare beneficiaries.

In the first of two panel sessions, panelists discussed potential frameworks to achieve timely coverage for emerging medical technologies. The panelists, including Dirksen Lehman, Josh Makower, Parashar Patel, and Kevin Schulman, presented elements of an operational framework for expedited coverage. Early engagement among stakeholders, including CMS, FDA, and manufacturers, aligned guidance from CMS and FDA on pre- and post-market evidence generation, and assistance from CMS on coding and payment

processes were underscored as keys to a successful program. Panelists agreed that any potential framework should be voluntary for manufacturers. Manufacturers that opt into the pathway would be required to engage with CMS as early as prior to the pivotal trial stage to identify key gaps in evidence and align on a fit-for-purpose evidence generation plan to address these gaps. Data could then be collected from different sources as appropriate for each individual medical technology. These elements in a framework for transitional coverage could encourage greater efficiency in the pre-clinical stage and provide important evidence for FDA, CMS, and Medicare beneficiaries.

The second panel session focused on implementation considerations of expedited coverage. Panelists included Louise Guy, Michael Mack, and Joe Franklin, who shared feedback on mechanisms to improve processes for reimbursement, post-market data collection, real-world evidence generation, and stakeholder engagement and alignment. They discussed how manufacturers and device sponsors can connect with CMS during the clinical trial process to align on coding and payment and understand potential post-approval evidence questions. They also discussed how establishing specific codes prior to approval better supports adequate reimbursement for the technology, as well as tracking to enable product differentiation. They shared ideas on mechanisms to address the burden of post-market evidence generation, such as utilizing electronic health records to source information. Finally, panelists highlighted that collecting real-world data from patients using multiple sources during the pre- and post-approval periods can better inform how emerging medical technologies work in real-world practice for the indicated population.

Closing remarks for the meeting included Dr. Fleisher reiterating CMS' commitment to providing Medicare beneficiaries better access to emerging medical technologies, and highlighting the need for a future pathway to have defined touchpoints of engagement across stakeholders.

Materials including the Meeting Recording, Meeting Slides, and the Discussion Guide are available in the Duke-Margolis website at <https://healthpolicy.duke.edu/events/need-transitional-coverage-emerging-technologies>.