

**The Need for Transitional Coverage for Emerging Technologies (TCET)**  
**Stanford Byers Center for Biodesign & Duke-Margolis Center for Health Policy**

March 28th, 2022

12:00-2:00 pm ET/ 9:00 – 11:00 am PT

*Agenda*

**Objective:** Recent policy and legislative proposals have highlighted a need for a Medicare coverage pathway centered around early and sustained multi-stakeholder collaboration to ensure appropriate use for breakthrough devices. CMS is currently exploring options for a coverage pathway for breakthrough devices that strikes a balance between supporting innovation, access and Medicare beneficiary protections. This webinar will explore research findings, stakeholder perspectives, and potential policy solutions to inform CMS in their efforts for coverage reform.

**12:00 p.m. ET Welcome and Introductions**

**9:00 a.m. PT** *Josh Makower, Stanford Byers Center for Biodesign*  
*Mark McClellan, Duke-Margolis Center for Health Policy*

**12:10 p.m. ET Opening Remarks with Lee Fleisher**

**9:10 a.m. PT** Chief Medical Officer and Director of the Center for Clinical Standards and Quality,  
Centers for Medicare and Medicaid Services

**12:30 p.m. ET Session 1: Medicare Coverage of Innovative Technology Survey Results**

**9:30 a.m. PT** *Presenter: Sandra Ruggles, Stanford Byers Center for Biodesign*

Dr. Ruggles will share research findings that show that a well-designed program to accelerate coverage and advance evidence development could both benefit patients and encourage invention in areas of unmet clinical need.

**12:50 p.m. ET Session 2: Potential Path Forward for Transitional Coverage for Emerging Technologies**

**9:50 a.m. PT** *Moderator: Mark McClellan, Duke-Margolis Center for Health Policy*

Panelists will discuss key elements of a transitional coverage pathway for breakthrough devices, including overarching principles and an operational framework for the coverage pathway. This session will highlight the need for early engagement among stakeholders and increased resources at CMS to support coverage activities.

*Dirksen Lehman, Edwards Lifesciences*  
*Josh Makower, Stanford Byers Center for Biodesign*  
*Parashar Patel, ViewRay*  
*Kevin Schulman, Stanford Graduate School of Business*

**1:25 p.m. ET    Session 3: Transitional Coverage Pathway in Practice**

**10:25 a.m. PT**    *Moderator: Marianne Hamilton Lopez, Duke-Margolis Center for Health Policy*

Panelists will present examples of how previous and ongoing collaboration between CMS and stakeholders resulted in advanced evidence development and patient access for novel technologies. Panelists will discuss the provider level impact of adopting breakthrough devices as well as opportunities to leverage advancements in health technology infrastructure to support evidence generation to support stable coverage.

*Louise Guy, Argenta Advisors*

*Michael Mack, Baylor Scott and White Health*

*Joe Franklin, Verily*

**1:50 p.m. ET    Next Steps**

**10:50 a.m. PT**    *Josh Makower, Stanford Byers Center for Biodesign*

*Mark McClellan, Duke-Margolis Center for Health Policy*

**2:00 p.m. ET    Adjournment**

**11:00 a.m. PT**