

Questions for the Record

U.S. House Committee on Energy & Commerce, Health Subcommittee Hearing, “Examining Policies to Enhance Seniors’ Access to Breakthrough Medical Technologies”

September 18, 2025

Dr. Todd Brinton

The Honorable Mariannette Miller-Meeks (R-IA)

1. Even when a breakthrough medical technology is FDA-cleared or approved, patients in rural communities often wait years for coverage and access — especially when those technologies are not traditional drugs or devices, but software-driven innovations like autonomous artificial intelligence systems that bring specialist-level diagnostic care directly into primary care and other frontline settings.

a. What do you believe are the most effective steps Congress and CMS can take to ensure that these kinds of diagnostic and preventive innovations reach rural and aging populations more quickly — particularly when they improve chronic disease management, close care gaps, support earlier detection of disease, and reduce pressure on limited specialist capacity?

Answer:

Thank you for the opportunity to respond to your question. Edwards supports a legislative approach to establish a clear and reliable transitional coverage pathway for breakthrough designated devices. To achieve our shared goals of ensuring beneficiary access to the most transformative innovation and based on our experience as a TCET pilot, Edwards supports a break-through coverage pathway that incorporates the following features:

- Extends coverage to breakthrough designated and FDA authorized devices at the time of FDA authorization that are within an existing Medicare benefit category.
- Includes breakthrough designated technologies that received FDA authorization within the past two years preceding the implementation of the breakthrough coverage pathway.
- Implements a robust enforcement mechanism to ensure Medicare Advantage plans provide consistent coverage of breakthrough technologies.
- Prioritizes resources through increased funding and additional personnel within the Coverage and Analysis Group at CMS to enable access to technologies eligible for transitional coverage.