

Congress of the United States
Washington, DC 20515

February 24, 2021

Ms. Liz Richter
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Acting Administrator Richter,

We write in support of the Centers for Medicare & Medicaid Services' (CMS's) recent "Medicare Coverage for Innovative Technologies" (MCIT) final rule. Similar to our bill, the Ensuring Patient Access for Critical Breakthrough Products Act (H.R. 5333, 116th Congress), the final rule builds on the bipartisan work of the 21st Century Cures Act that codified the medical device breakthrough pathway process at the Food and Drug Administration (FDA). We applaud CMS for taking a critical step to recognize the value of these technologies and the positive impact this access will have for seniors. The MCIT final rule will become effective March 15, 2021, and we urge CMS to retain the effective date without delay.

As you know, the medical technology community produces life-saving and life-enhancing medical devices, diagnostic products, and health information systems. This technology transforms health care through earlier disease detection, less invasive procedures, and more effective treatments. These advancements come from the largest to the smallest medical technology innovators and companies. Access to state-of-the-art medical technologies and diagnostic tests can enhance patient care delivery options and improve outcomes. However, even if an innovative technology meets FDA's rigorous standards for "breakthrough" designation, significant access hurdles have remained because FDA approval or clearance does not provide immediate coverage and payment under Medicare. These hurdles can translate to delayed beneficiary access to critical medical technologies and therapies.

MCIT allows for coverage of FDA-designated breakthrough devices, which treat patient populations with limited or no treatment alternatives. Delaying the effective date of the final rule risks unintended consequences for these patients, including denying MCIT coverage to technologies that would otherwise be eligible for the program under the current implementation date. For this reason, we ask that you work to ensure all breakthrough devices currently within the timeframe of the rule remain covered should any delays occur.

We appreciate your consideration as you review existing and proposed rules at this time and make determinations about moving forward. Thank you for your leadership, and we look

forward to working with you in providing seniors with timely and appropriate access to innovative medical technologies.

Sincerely,



Suzan K. DelBene
Member of Congress



Terri A. Sewell
Member of Congress



Tony Cárdenas
Member of Congress



Andy Kim
Member of Congress