

August 2025

The Honorable Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Administrator Oz,

We, the undersigned organizations, urge the Centers for Medicare & Medicaid Services (CMS) to create a timely, streamlined pathway for Medicare patients to access breakthrough medical technology. Closely aligning the efforts of the Food and Drug Administration (FDA) and CMS, the rule will streamline regulatory coordination and eliminate unnecessary obstacles standing between physicians and patients, helping to make Americans healthier.

Every day, Medicare patients across the country confront diagnoses, unexpected health emergencies, and the challenges of managing chronic conditions. Simultaneously, new and innovative medtech are continuously developed, offering profound improvements in patient care, health, and outcomes. Medtech has helped shrink the duration of hospital stays by 38%, reduce deaths from breast cancer by 43%, and decrease fatalities from heart disease and stroke by 49%. Medtech also aids in earlier identification of diseases such as Alzheimer's and Parkinson's, underscoring the critical importance of patient access to these advancements.

Despite this remarkable impact and the continuous pace of innovation, Medicare patients face a significant and unacceptable barrier to accessing innovative medical technology. A recent study alarmingly revealed that for technologies requiring a new reimbursement pathway, nearly six years passed between FDA market authorization and Medicare coverage. Patients should not be forced to wait the better part of a decade for access to safe and effective medical technology that holds the potential to meaningfully improve their health and life.

Existing programs, including the Transitional Coverage of Emerging Technologies (TCET) program, fall short of providing the consistent, timely, and predictable access that breakthrough technologies demand. Its voluntary nature and limited scope – among other issues – fall short of delivering the life-changing innovations to patients who need them most. This administration has a significant opportunity to course correct and make meaningful progress on improving American health.

We have long supported a swift and streamlined approach to Medicare coverage of innovative medical devices and diagnostics that improve health outcomes for patients with debilitating or life-threatening illnesses. We are encouraged by Administrator Oz's early focus on exploring options for a better pathway for recently approved medical devices, and we encourage CMS to take bold action. A program mirroring the core tenets of the original Medicare Coverage of Innovative Technology (MCIT) framework, embodied in legislative proposals like S. 1717, offers a superior solution. This would provide coverage for FDA-market authorized breakthrough technologies – including diagnostics – ensuring that Medicare patients and their care teams have more timely access to innovations upon FDA clearance. Crucially, it would also provide a clear, predictable roadmap for CMS to collect additional necessary evidence for making a permanent coverage decision.

This would – in addition to removing or bridging regulatory obstacles – demonstrate CMS's commitment to patient-centered care and ensure that Medicare beneficiaries can benefit from the rapid advancements in medtech without unnecessary delays, helping make for a stronger, healthier country.

Sincerely,

Access Ready, Inc

AdvaMed

All Wheels Up

Alliance for Aging Research

Alzheimer's Association

Alzheimer's Impact Movement

American Association for Homecare

American Cancer Society Cancer Action Network

American Diabetes Association

American Music Therapy Association

Arizona Bioindustry Association, Inc. (AZBio)

Arthritis Foundation

Association of Black Cardiologists

Autistic Women & Nonbinary Network

Bio Nebraska

Biocom California

BioFlorida

BioForward Wisconsin

BioUtah

Breakthrough T1D
Brem Foundation to Defeat Breast Cancer
California Life Sciences
CDx Diagnostics
Colorado BioScience Association
Conquering CHD
CureLGMD2i Foundation
Florida Medical Manufacturers Consortium (FMMC)
Georgia Life Sciences
HealthCare Institute of New Jersey (HINJ)
HealthyWomen
Heart Valve Voice US
Hydrocephalus Association
Illinois Biotechnology Innovation Organization, iBIO
Indiana Life Sciences Association
International Registry of Rehab Technology Suppliers
Life Science Oklahoma
Life Science Tennessee
Life Science Washington
Life Sciences Pennsylvania
LifeSciencesNY
Maryland Tech Council
MassMEDIC
Medical Alley
Michigan Biosciences Industry Association (MichBio)
Missouri Biotechnology Association
Montana Bioscience Alliance
National Health Council
National Psoriasis Foundation
NC Life Sciences Organization
New Mexico Biotechnology & Biomedical Association
NewYorkBIO
NH Life Sciences (NHLS)
ONE CANCER PLACE
Oregon Bioscience Association
Patients Rising

Rehabilitation Engineering and Assistive Technology Society of North America
(RESNA)

RI Bio

Right Scan Right Time

Say YES to Hope

South Dakota Biotech

Spina Bifida Association

Texas Healthcare & Bioscience Institute

The Mended Hearts, Inc.

The Ohio Life Sciences Association

Virginia Biotechnology Association

Voices of Alzheimer's

Women's Health Advocates