August 15, 2025

SUBMITTED ELECTRONICALLY

The Honorable Mehmet Oz, M.D.
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: ITEM Coalition Support for a More Robust Pathway for Medicare Coverage of Breakthrough Technologies

Dear Administrator Oz:

On behalf of the undersigned members of the Independence Through Enhancement of Medicare and Medicaid ("ITEM") Coalition, we write to encourage the Centers for Medicare and Medicaid Services ("CMS") to initiate future rulemaking as soon as possible to create and establish a more timely and predictable pathway for Medicare coverage of Food and Drug Administration ("FDA")—designated breakthrough medical technologies. Such a policy would remove unnecessary regulatory barriers and accelerate patient access to critical innovations—supporting clinicians in delivering the best possible care and helping improve health outcomes for millions of individuals with disabilities, functional limitations, and chronic conditions.

The ITEM Coalition is a national consumer- and clinician-led coalition advocating for access to and coverage of assistive devices, technologies, and related services for persons with injuries, illnesses, disabilities, and chronic conditions of all ages. Our members represent individuals with a wide range of disabling conditions, as well as the providers who serve them, including limb loss and limb difference, multiple sclerosis, spinal cord injury, brain injury, stroke, paralysis, cerebral palsy, spina bifida, hearing, speech, and visual impairments, myositis, and other life-altering conditions. Ensuring timely access, coverage, and reimbursement for safe and effective breakthrough medical devices is a longstanding priority for the ITEM Coalition.

Access to life-saving breakthrough devices remains a critical issue across the United States, and particularly in the Medicare population. Far too often, Medicare beneficiaries—especially those living with complex medical needs—face unacceptable delays in accessing safe and effective medical technologies that have already received market authorization from the FDA. While innovation in medical technology continues to evolve rapidly, CMS's coverage pathways have not kept pace. In fact, a recent peer-reviewed study found that for novel devices requiring a new reimbursement pathway, the median time from FDA authorization to Medicare coverage was 5.7 years—a delay that leaves patients without access to life-changing care for the better part of a

decade.[1] Unless innovative companies are flush with financial resources to maintain operations throughout this lengthy delay, many breakthrough technologies cannot be sustained and wind up never gaining sufficient traction to meaningfully benefit patients.

This delay in access is especially harmful for people with serious conditions who could benefit most from earlier intervention, improved functionality, greater independence, and reduced reliance on institutional care. From technologies that enable mobility and communication to diagnostic technologies that detect neurodegenerative diseases earlier, medical innovation has the potential to dramatically improve quality of life for people with disabilities and chronic conditions.

We appreciate CMS's efforts to address this issue through the Transitional Coverage for Emerging Technologies ("TCET") pathway. However, as currently structured, the TCET program is voluntary, limited in scope, and does not ensure consistent or timely access to care for Medicare beneficiaries. With massive pressure to reduce spending, sufficient resources are simply not available at either CMS or the Agency for Healthcare Research and Quality (AHRQ) to meaningfully address the backlog of applications for Medicare coverage under the TCET program. The ITEM Coalition believes the current CMS leadership has a meaningful opportunity to bolster the resources and modernize coverage policy to reflect the rapid pace of innovation and the needs of the Medicare beneficiaries whom CMS serves.

The ITEM Coalition urges CMS to move forward with a much more robust and streamlined coverage pathway—similar to the Medicare Coverage of Innovative Technology ("MCIT") framework—providing time-limited Medicare coverage for FDA-designated breakthrough technologies upon a determination that they are safe and effective. This type of policy, as proposed in S. 1717, the Ensuring Patient Access to Critical Breakthrough Products Act of 2025, currently before the 119th Congress, would:

- Ensure Medicare beneficiaries have timely access to cutting-edge, life-enhancing medical devices and technologies;
- Provide CMS with a structured period to collect additional data necessary for longer-term coverage decisions;
- Offer greater clarity and predictability to patients, providers, and innovators; and
- Help modernize CMS coverage processes in a way that keeps pace with innovation while maintaining appropriate safeguards.

The ITEM Coalition is encouraged by the agency's ongoing work to improve access to care and modernize Medicare coverage policy, and we respectfully urge you to prioritize the development of a dedicated, timely pathway for breakthrough medical technologies. Doing so would help ensure that Medicare beneficiaries—particularly those with the greatest needs—can benefit fully from safe, effective innovations that improve health and functional outcomes, support independent living, and reduce unnecessary long-term care costs.

[1] Sexton ZA, Perl JR, Saul HR, et al. Time From Authorization by the US Food and Drug Administration to Medicare Coverage for Novel Technologies. *JAMA Health Forum.* (August 4, 2023), https://jamanetwork.com/journals/jama-health-forum/fullarticle/2807906

Thank you for your leadership and for your consideration of this important issue. We stand ready to support CMS in advancing patient-centered innovation and access. Should you have any further questions, please contact Peter Thomas or Michael Barnett, ITEM Coalition coordinators, at Peter.Thomas@PowersLaw.com and Michael.Barnett@PowersLaw.com or by phone at 202-466-6550.

Sincerely,

The Undersigned Members of the ITEM Coalition

Access Ready, Inc.
ACCSES
Alexander Graham Bell Association for the Deaf and Hard of Hearing
All Wheels Up
ALS Association*
American Academy of Physical Medicine & Rehabilitation
American Association for Homecare
American Association on Health and Disability
American Cochlear Implant Alliance
American Congress of Rehabilitation Medicine
American Council of the Blind
American Muscular Dystrophy Association
American Music Therapy Association
American Occupational Therapy Association
Amputee Coalition*
Autistic Women & Nonbinary Network
Center on Aging and DIS-Ability Policy
Christopher & Dana Reeve Foundation*
Clinician Task Force
CureLGMD2i Foundation
3DA
Institute for Matching Person and Technology
International Eye Foundation
International Registry of Rehabilitation Technology Suppliers
Lakeshore Foundation
Long Island Center for Independent Living (LICIL)
Muscular Dystrophy Association
National Association for the Advancement of Orthotics and Prosthetics
National Multiple Sclerosis Society
Perkins School for the Blind
RESNA
Rifton Equipment
Spina Bifida Association*
Team Gleason*
Unite 2 Fight Paralysis
United Cerebral Palsy

United Spinal Association*
The Viscardi Center
VisionServe Alliance

Member of the ITEM Coalition Steering Committee