



December 12, 2023

SUBMITTED ELECTRONICALLY

The Honorable Cathy McMorris Rodgers
Chairwoman
Energy & Commerce Committee
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
Energy & Commerce Committee
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Brett Guthrie
Chairman
Energy & Commerce Committee
Health Subcommittee
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Anna Eshoo
Ranking Member
Energy & Commerce Committee
Health Subcommittee
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

RE: ITEM Coalition Support for the Ensuring Patient Access to Critical Breakthrough Products Act of 2023

Dear Chairwoman McMorris Rodgers, Ranking Member Pallone, Chairman Guthrie, and Ranking Member Eshoo:

On behalf of the undersigned members of the Independence Through Enhancement of Medicare and Medicaid (“ITEM”) Coalition, we write to express our support for the Ensuring Patient Access to Critical Breakthrough Products Act of 2023 (H.R. 1691), which was introduced by Representatives Brad Wenstrup (R-OH), Suzan DelBene (D-WA), Gus Bilirakis (R-FL), Tony Cárdenas (D-CA), Blake Moore (R-UT), Terri Sewell (D-AL), Brett Guthrie (R-KY), and Anna Eshoo (D-CA). Understanding that this bill was ultimately not marked up by the full Energy and Commerce Committee, it is our hope that Congress will act on this bill during the second session of the 118th Congress. This bipartisan legislation would ensure that Food and Drug Administration (“FDA”)-designated breakthrough technologies are temporarily covered under Medicare during a four-year transitional period, while also establishing a pathway to make a permanent coverage determination. While not perfect, the ITEM Coalition believes that this bill would be a positive step in the right direction towards ensuring timely access to breakthrough devices for millions of Medicare beneficiaries.

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 to, through coverage of and reimbursement for, safe and effective breakthrough 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. We applaud the sponsors of this bipartisan legislation for recognizing the need to establish processes to expedite Medicare coverage of certain breakthrough devices. The introduction of this bill follows issuance and repeal of a similar proposal by the Centers for Medicare and Medicaid Services (“CMS”) to provide Medicare Coverage of Innovative Technologies (“MCIT”).¹ The ITEM Coalition supported MCIT but recognized that the FDA standard for safety and effectiveness is different from the reasonable and necessary standard under the Medicare program.

Moreover, on June 27, 2023, CMS published a notice with comment period outlining a new Medicare coverage pathway purportedly designed to achieve more timely and predictable access to breakthrough technologies for Medicare beneficiaries.² The new pathway, referred to as Transitional Coverage for Emerging Technologies (“TCET”), uses current national coverage determination (“NCD”) and coverage with evidence development (“CED”) processes to expedite Medicare coverage of certain “breakthrough devices,” deemed as such by the FDA. While the ITEM Coalition is supportive of the overall TCET proposal, the process proposed by CMS must be considerably improved to streamline, expedite, and make as transparent as possible the process in order to meet the demand for coverage of new technologies and medical devices that can truly transform care to Medicare beneficiaries with injuries, illnesses, disabilities, and chronic conditions.

Accordingly, we appreciate that this bill recognizes that new approaches are needed to make decisions on certain innovative items and services, such as medical devices, more quickly to provide expedited access to new and emerging medical technologies, even if such coverage is initially temporary in nature. We believe this bill has the potential to encourage investment in innovative technologies as innovators and manufacturers will be able to anticipate their reasonable return on investment more confidently. This bill would also allow manufacturers and providers to track data and develop additional evidence regarding the clinical benefit of their devices specific to the Medicare population while coverage is provided. While the ITEM Coalition remains supportive of this bill as written for purposes of greater access, we do plan to work with Congress to ensure there is clarity with respect to the standard of coverage used by the Medicare program under this important legislation.

¹ Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of “Reasonable and Necessary”; 84 Fed. Reg. 54,327 (Sept. 1, 2020); *see also*, Medicare Program; Coverage of Innovative Technology (MCIT) and Definition of “Reasonable and Necessary”; 86 Fed. Reg. 51,326 (Sept. 15, 2021).

² Medicare Program; Transitional Coverage for Emerging Technologies, 88 Fed. Reg. 41,633 (June 27, 2023), <https://www.federalregister.gov/documents/2023/06/27/2023-13544/medicare-program-transitional-coverage-for-emerging-technologies>.

We look forward to working with you and your colleagues in the House to pass this important piece of legislation into law. 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
Allies for Independence
ALS Association*
American Association for Homecare
American Association on Health and Disability
American Cochlear Implant Alliance
American Congress of Rehabilitation Medicine
American Macular Degeneration Foundation
American Music Therapy Association
American Occupational Therapy Association
American Therapeutic Recreation Association
Association of Assistive Technology Act Programs
Association of Rehabilitation Nurses
Autistic Women & Nonbinary Network
Blinded Veterans Association
Buoniconti Fund to Cure Paralysis
Christopher & Dana Reeve Foundation*
Clinician Task Force
Council of State Administrators of Vocational Rehabilitation (CSAVR)
Cure SMA
Epilepsy Foundation
Institute for Matching Person and Technology
International Eye Foundation
Lakeshore Foundation
Long Island Center for Independent Living, Inc.
Muscular Dystrophy Association
National Association for the Advancement of Orthotics and Prosthetics
National Association of Councils on Developmental Disabilities
National Disability Rights Network (NDRN)
National Multiple Sclerosis Society
National Registry of Rehabilitation Technology Suppliers
Prevent Blindness
Prevention of Blindness Society of Metropolitan Washington
RESNA
Simon Foundation for Continence

Spina Bifida Association*

Team Gleason*

The Miami Project To Cure Paralysis

The Support Sight Foundation

The Vision Council

Unite 2 Fight Paralysis

United Cerebral Palsy

United Spinal Association*

VisionServe Alliance

***Member of the ITEM Coalition Steering Committee**

CC:

Rep. Brad Wenstrup (OH-02)

Rep. Suzan DelBene (WA-01)

Rep. Gus Bilirakis (FL-12)

Rep. Tony Cardenas (CA-29)

Rep. Blake Moore (UT-01)

Rep. Terri Sewell (AL-07)