



March 9, 2026

SUBMITTED ELECTRONICALLY

The Honorable Brett Guthrie
Chairman
Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
Committee on Energy & Commerce
2323 Rayburn House Office Building
Washington, DC 20515

RE: ITEM Coalition Support for H.R. 5343, the Ensuring Patient Access to Critical Breakthrough Products Act

Dear Chairman Guthrie and Ranking Member Pallone:

On behalf of the undersigned members of the Independence Through Enhancement of Medicare and Medicaid (“ITEM”) Coalition, we write to express our strong support for H.R. 5343, the *Ensuring Patient Access to Critical Breakthrough Products Act*. This bipartisan legislation would ensure that Food and Drug Administration (“FDA”)-designated breakthrough devices and technologies are covered under Medicare during a four-year transitional period, while also establishing a pathway to make a permanent coverage determination. The ITEM Coalition believes this bill would be a positive step in the right direction towards ensuring timely access to breakthrough devices and technologies for millions of Medicare beneficiaries. We respectfully urge the House Energy & Commerce Committee to hold a markup on H.R. 5343 as soon as possible in the second session of the 119th Congress.

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. This bipartisan legislation was originally introduced following the issuance of a similar regulatory coverage pathway proposed and finalized 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. The Biden administration rescinded the MCIT final rule on November 12, 2021.

In June 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 pathway, the policy 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.

H.R. 5343 recognizes that new approaches are needed to make decisions on certain innovative items and services, such as medical devices, to more quickly provide expedited access to new and emerging medical technologies, even if such coverage is initially temporary in nature. We believe the current regulatory approach is not sufficient and therefore, we support this bill which 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 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.

H.R. 5343 has strong bipartisan support as demonstrated by its 37-3 passage out of the House Ways and Means Committee in September 2025. To continue the progress made to date towards its passage in the 119th Congress, the ITEM Coalition respectfully urges the House Energy and Commerce Committee to advance H.R. 5343 to a markup hearing without delay.

Thank you for your consideration of this request. 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,

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).

The Undersigned Members of the ITEM Coalition

Access Ready, Inc.

All Wheels Up

ALS Association*

AG Bell Association for the Deaf and Hard of Hearing

Alliance of Wound Care Stakeholders

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 Music Therapy Association

Autistic Women & Nonbinary Network

Blinded Veterans Association

Center on Aging and DIS-Ability Policy

Christopher & Dana Reeve Foundation*

Clinician Task Force

CureLGMD2i

Cure SMA

3DA

Institute for Matching Person and Technology

International Registry of Rehabilitation Technology Suppliers (iNRRTS)

Lakeshore Foundation

Long Island Center for Independent Living (LICIL)

Muscular Dystrophy Association

National Association for the Advancement of Orthotics and Prosthetics

NCART

Prevent Blindness

RESNA

Rifton Equipment

Spina Bifida Association of America*

Team Gleason*

The Vision Council

United Cerebral Palsy

United Ostomy Associations of America, Inc.

United Spinal Association*

Unite2Fight Paralysis

VisionServe Alliance

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