



August 28, 2023

**SUBMITTED ELECTRONICALLY**

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

**Re: File Code: CMS-3421-NC: Medicare Program; Transitional Coverage for Emerging Technologies**

Dear Administrator Brooks-LaSure:

The undersigned members of the Independence Through Enhancement of Medicare and Medicaid (“ITEM”) Coalition appreciate the opportunity to provide comments on the Transitional Coverage for Emerging Technologies (“TCET”) Notice.<sup>1</sup> This letter focuses on the following:

- (1) The newly proposed TCET Medicare coverage pathway and concerns that it will not meaningfully address the problem;
- (2) The need to improve coverage, coding, and payment processes for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (“DMEPOS”) that are *not* deemed “breakthrough devices or technologies” but are still important to beneficiaries; and,
- (3) Acknowledgement of CMS’ recent improvements in this area that should serve as a platform for additional reforms.

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.

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<sup>1</sup> 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>

On June 27, 2023, the Centers for Medicare and Medicaid Services (“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.<sup>2</sup> The new TCET pathway 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 Food and Drug Administration (“FDA”). Publication of this proposed notice follows issuance and repeal over the past three years of a similar proposal to provide Medicare Coverage of Innovative Technologies (“MCIT”). The ITEM Coalition supported MCIT but recognized that the FDA standard for safety and effectiveness is fundamentally different from the reasonable and necessary standard under the Medicare program.

The ITEM Coalition has high expectations for the TCET proposal. While we are pleased that CMS has issued this proposed notice on a TCET coverage pathway, considering the existing shortcomings of the NCD and CED processes, it is unclear whether this pathway will provide the streamlined access to innovative medical devices which it is intended to accomplish. We urge CMS to thoroughly examine our comments and those submitted by other stakeholders to further strengthen and streamline coverage of breakthrough and other devices and technologies on which beneficiaries with injuries, illnesses, disabilities, and chronic conditions rely.

## **I. Background on Medicare Coverage and TCET**

In order for an item or service to be covered under Medicare, it must be “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”<sup>3</sup> Under current policies, CMS determines whether specific devices and technologies are reasonable and necessary through various pathways (e.g., NCDs, local coverage determinations (“LCDs”), claim-by-claim adjudication, CED, etc.). We appreciate that CMS 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. This proposed TCET pathway is a positive step forward and intended to support manufacturers that are interested in working with the agency to generate additional evidence to eventually secure permanent Medicare coverage.

The proposed TCET coverage pathway recognizes that many innovative technologies that receive market authorization are likely to have limited or developing bodies of clinical evidence. The evidence base for some devices and technologies may not have included the Medicare population in important clinical trials or sample sizes may be too small to reliably extrapolate study findings. To the extent that the proposed TCET coverage pathway utilizes the existing NCD process, we describe below key areas in need of improvement for the TCET pathway to work effectively. CMS anticipates that many of the NCDs published under the TCET pathway will use the CED decision process. Currently, the Agency for Healthcare Research and Quality

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<sup>2</sup> 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>.

<sup>3</sup> Social Security Act, 42 U.S.C. 1395y(1)(A)

(“AHRQ”) reviews all CED NCDs, and the proposed rule would continue to rely on this same agency for review of all CED NCDs in the future.

As CMS states in the proposed notice, the agency’s goal is to finalize a TCET NCD within six months after FDA market authorization as a “breakthrough” technology. If the evidence supports a favorable coverage decision under CED, coverage will ensue but will be temporary as further evidence is developed. Coverage will not last indefinitely. Instead, a NCD that requires CED as a condition of coverage will be time-limited to facilitate the generation of sufficient evidence to support a permanent Medicare coverage determination under the reasonable and necessary standard. Given the expansiveness of the earlier—but repealed—iterations of this accelerated coverage system for breakthrough devices, coupled with a relatively poor track record of the existing CED process described below, the new proposal has received a muted response from ITEM Coalition members and other stakeholders as we analyze this proposal to assess how the system will function, and whether it will meaningfully achieve the intended goals of the program.

***Existing CED Pathway:*** Since 2005, CED has been used to support evidence development for certain innovative technologies that lack sufficient evidence to demonstrate that the item or service is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Under the CED pathway, Medicare covers items and services on the condition that they are provided in connection with approved clinical studies or the collection of additional clinical data. This pathway has been subject to considerable criticism, and it has historically been utilized with minimal success. Johns Hopkins University’s Evidence-based Practice Center recently published an [analysis](#) of CED, stating:

A recent review described 27 CED determinations from 2005 to 2022 in eight therapeutic areas. The duration of these CED activities ranged from 1 to 16 years. Only four of these CEDs led to a NCD for continued coverage, and two CEDs led to coverage revocation and deferral to local coverage decisions.

This woefully inadequate track record for CED suggests that CMS’s proposal may be less effective than the notice makes it sound, unless significant resources are applied to improve and streamline the CED (and NCD) process. CMS’s own estimate that only five breakthrough technologies annually will be subject to this new process demonstrates that, as proposed, it will not materially resolve the problem of lengthy delays in coverage of breakthrough technologies under the Medicare program. The ITEM Coalition is disappointed in the agency’s estimate of this proposal’s impact and finds it severely lacking. Hence, the ITEM Coalition believes that CMS must work with Congress to prioritize this process and ensure that the agency devotes additional resources to strengthen and dramatically increase the flow of coverage decisions through the NCD and CED processes.

Additionally, the ITEM Coalition also has concerns that CMS may not effectively eliminate Quality-Adjusted Life Years (“QALYs”) from CED and NCD analyses. QALYs, and the similarly flawed equal value of life-years gained (“evLYG”) are value assessments that, according to a 2019 report from the National Council on Disability, discriminate against people with disabilities by placing a lower value on their lives and insufficiently accounting for

outcomes that they value.<sup>4</sup> The use of these measures in utilization management tools restricts patient access, thereby limiting the ability of patients and their providers to make decisions about the best treatment path. Unfortunately, the use of these measures places the most vulnerable patients, especially people with disabilities and other chronic conditions, at increased risk of adverse health outcomes and increases out-of-pocket costs associated with their care and need for medically necessary DMEPOS.

The ITEM Coalition requests that CMS offer more clarity into exactly how the agency will exclude QALY-based metrics from analysis of clinical evidence. We also request that CMS publicly report when and how the agency removes QALY-based metrics from consideration in CED and NCD analysis. Greater transparency is needed in prohibiting the use of QALYs and or referencing other metrics or studies that included QALYs from clinical evidence reviews.

In addition, the proposed notice on breakthrough technologies is not available to new technologies that have not received a benefit category determination (“BCD”) from CMS. This is particularly problematic for DMEPOS, especially when a new type of device could arguably fit in multiple benefit categories. CMS has been known to take months, and in many cases, years, to make a determination as to whether a particular device is either DME, prosthetics, or orthotics. These three benefits have different restrictions and rules that turn on the BCD decision. The ITEM Coalition, therefore, is concerned that the lack of an integrated, transparent, and expedited BCD process will effectively limit the impact of the proposed rule in the area of DMEPOS in particular.

While the ITEM Coalition is supportive of the overall proposal and CMS’s intent in issuing this proposed regulation, the process proposed by CMS must be considerably improved. If CMS presses forward with greater reliance on the CED process to address coverage of breakthrough technologies, it must work with Congress to provide the resources necessary 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.

## **II. The Need to Improve Coding, Coverage, and Payment Processes Applicable to DMEPOS Not Otherwise Designated as Breakthrough Devices**

While the focus of CMS on breakthrough devices is well placed, even an efficient and effective system to consider coverage of these devices will not solve key barriers to DMEPOS coverage under the program. In order to better serve beneficiaries with disabilities and chronic conditions enrolled in the Medicare program, CMS must continue to improve its processes to determine specific coding, appropriate coverage, and adequate pricing of new and innovative durable medical equipment, prosthetics, orthotics, and supplies. This includes improvements to the Level II Healthcare Common Procedure Coding System (“HCPCS”), the antiquated and imprecise method of determining pricing levels for new devices and technologies, the determination of specific benefit categories for new innovations, and the NCD process itself.

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<sup>4</sup> National Council on Disability, Quality-adjusted Life Years and the Devaluation of Life with Disability, 2019. [https://ncd.gov/sites/default/files/NCD\\_Quality\\_Adjusted\\_Life\\_Report\\_508.pdf](https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf)

## **A. Improving the NCD Process**

There is a growing chorus of stakeholders and Members of Congress that recognize that the NCD process needs reform and improvement, particularly with respect to timeliness and transparency of decision-making. The NCD regulations set specific timeframes for NCD consideration which typically means that from the time an NCD is formally “opened” to the time a final decision is made, approximately nine months elapse. Considering the detailed review of the evidence base that CMS staff must undergo, this timeframe seems reasonable.

But CMS has wide discretion to hold NCD requests indefinitely after the agency determines that a submitted NCD Request is “complete” and ready to be formally considered. This delay can be months or even years, which constitutes a disservice to Medicare beneficiaries who are affected by the NCD at issue. For instance, the recently announced NCD granting coverage for seat elevation in power wheelchairs took almost two years to open for public comment. Another NCD request pertaining to an expansion of coverage of cochlear implants took eight years from the time the request was submitted to CMS until the time a final decision was made. While we understand that part of the reason for this considerably lengthy delay was due to a prospective study that was required to be undertaken as part of the submission, we still feel that this eight-year period is too long and must be improved.

Other than the regulatory timelines that apply once an NCD request is officially opened, there are very few requirements that CMS must follow with respect to transparency and accountability. There is no mechanism to publicly track NCD requests throughout the process of consideration, making it difficult for requestors to understand the status of NCDs once they are submitted. CMS is typically willing to meet with requestors to discuss new evidence while an NCD is pending but not yet formally opened, but CMS staff will not typically engage in any meaningful dialogue with requestors. CMS tends to be in listening mode only, limiting the value of these interactions. Once an NCD request is opened for public comment, the rules surrounding CMS’s ability to meet with requestors to discuss the evidence base is largely undefined and confusing. CMS should implement new rules to improve timeliness, transparency, and accountability in the NCD process so that requestors have a more predictable pathway toward coverage, and beneficiaries know when new devices and technologies may become accessible to them.

## **B. HCPCS Coding Process**

While CMS has taken steps in recent years to improve and refine the HCPCS uniform code set and the process used by CMS and its contractors to create new HCPCS codes and verify the use of existing codes, additional reforms in this area are needed. For over two decades, CMS has been reluctant to create new HCPCS codes for various reasons and this has been detrimental for providers and beneficiaries, and in particular, individuals with disabilities and chronic conditions. As the ICD-10 and CPT code sets in recent years have become more and more granular and detailed, the large categories that comprise the HCPCS codes have become more misaligned and difficult to utilize. This compromises beneficiaries’ access to care, risks program integrity, limits analysis of claims data to improve coverage policies and outcomes, and disincentivizes investments in innovative assistive devices and technologies due to the unpredictability of the coding system. For instance, coding reform of the intermittent catheter

benefit is a prime example of CMS' intransigence to reform outdated coding constructions to reflect advances in technology.

***Access to Intermittent Catheters:*** An intermittent catheter is a medical device that is prescribed when an individual is unable to empty their bladder or adequately control the process of urination. Intermittent catheters drain the bladder through the use of a tube that is inserted into the urethra and removed after the urine is drained. Individuals with bladder dysfunction due to disabilities and chronic conditions such as spinal cord injury (SCI), Parkinson's disease, Spina Bifida, and Multiple Sclerosis rely on intermittent catheters to void urine and maintain urological health.

In determining the intermittent catheter that most appropriately meets the unique medical and functional needs of each patient, the prescribing practitioner must evaluate numerous clinical factors, including the patient's diagnosis, comorbidities, internal clinical anomalies, dexterity, history of urinary tract infections, cognitive status, mobility, level of immunity, ability to perform activities of daily living, gender, and setting of care. These factors influence the selection of catheter features needed to ensure successful catheterizations without medical complications or pain. These features include protective elements (sleeve, protective grip, etc.), hydrophilic technology, pre-coated with gel-lubrication, various shaped tips, firmness, compact size, and packaging considerations. It is critically important that features of prescribed intermittent catheters align with the clinical and functional needs of patients. This clinical alignment is recognized in clinical literature and forms the standard of care for treating patients with urinary tract dysfunction.

Despite this wide variety of intermittent catheter features, only three HCPCS codes (A4351, A4352 and A4353) exist to describe over 1,300 intermittent urinary catheters. Without more specific product identifiers, it is exceedingly difficult to appropriately describe the unique features of catheters that are required for proper catheterization. The lack of nuance in the code set hinders prescribing practices, which leads to patients receiving catheters that do not meet their needs. This overly broad code set also undermines efforts to develop evidence-based treatment and complicates research involving intermittent catheters. The poorly articulated HCPCS code set describing intermittent catheters also leads to payers not being able to properly identify exactly what products are being billed under each code. As a result, certain commercial payers and Medicaid programs have been forced to develop additional coding policies to better identify different types of intermittent catheters. The lack of specificity in the code set renders payers largely unable to know exactly what they are paying for, raising program integrity concerns.

A proposal to convert the existing three HCPCS codes for intermittent catheters into a more refined set of 19 HCPCS codes was submitted to the CMS HCPCS Workgroup last fall. This proposal was submitted by AAHomecare, an ITEM Coalition member, and supported by numerous disability organizations who are key leaders in the ITEM Coalition. Thus far, CMS has not appeared to seriously consider this common sense coding reform proposal, to the detriment of patients and the providers who serve them.

The problem with intermittent catheter coding is just one example of shortcomings in the HCPCS uniform code set, which by law, is supposed to be used by all payers. To its credit,

CMS has recently made some improvements to the coding system and the process is running more smoothly in recent years, but there are several reforms that could improve the system further. CMS must reform the current HCPCS code set to better reflect advancements in technology design, facilitate improved access to new devices and technologies, promote the agency's goal of increasing health equity, facilitate the development of research and evidence-based guidance, and provide greater accountability in claims processing.

### **C. Appropriate Coverage**

While advances in surgical equipment, medications, and other treatments have been routinely covered by the Medicare program over the past several decades, CMS has been slow to grant coverage of new and innovative DMEPOS that Medicare beneficiaries with disabilities routinely rely upon to be functional and independent. We believe the NCD process works; however, it is very time and resource intensive and lacks transparency. The extensive amount of time the NCD process takes, and the lack of overall transparency and predictability, is of utmost concern to the ITEM Coalition. We witnessed this over the past three years after submitting a comprehensive [NCD Request for Reconsideration of Seat Elevation and Standing Systems in power wheelchairs](#). We strongly encourage CMS to seriously address the deficiencies in the current coverage process.

***Medicare Coverage of Seat Elevation:*** The ITEM Coalition submitted in September 2020 a joint NCD Reconsideration Request to cover both seat elevation and standing systems in complex rehabilitation technology (“CRT”) power wheelchairs. Despite the fact that CMS accepted and deemed “complete” this joint request in November 2020, the agency bifurcated the NCD Reconsideration Request for seat elevation and standing systems into two separate NCDs. The seat elevation NCD was “opened” in August 2022, two years after CMS submission, and finalized in May 2023. Despite this lengthy delay in consideration, we applaud CMS for this final coverage determination, which will grant meaningful access to seat elevation for beneficiaries in power wheelchairs. The decision will assist Medicare beneficiaries with mobility impairments in transferring from one surface to another and in reaching objects from a seated position, both functions that will assist in the performance of mobility activities of daily living (MRADLs).

Unfortunately, CMS has still not opened the NCD Request for coverage of standing systems in CRT power wheelchairs, nor has it announced any timeline for action a full three years after the request was submitted. Standing systems in power wheelchairs serve a critical function for people with mobility disabilities that would highly complement seat elevation coverage. The medical and functional benefits of a non-ambulatory individual placing body weight on his or her legs is well documented in the clinical literature.

We reiterate our often-stated concern that CMS often omits consideration of the evidence base when studies do not focus solely on individuals over the age of 65, the age-based eligibility criterion for Medicare beneficiaries. We urge CMS to continually consider that 8 million Medicare beneficiaries under the age of 65 qualify for Medicare coverage based on disability status, not age. Therefore, to focus primarily on research studies of over age 65 cohorts omits consideration of an entire sector of the Medicare beneficiary population. In addition, it is not just the Medicare population that is impacted by the decisions CMS makes in the coverage area.

Commercial insurers often defer to the coverage decisions made by CMS which creates a ripple effect throughout the U.S. health care system.

Unless CMS works with stakeholders to revise and enhance its policies with an emphasis on timeliness, transparency, and efficiency, many Medicare beneficiaries will continue to live without the assistive devices and technologies they need. Without the ability of innovators to bring to market new technologies and reasonably anticipate a path to coverage and adequate payment, beneficiaries who rely on these assistive devices and technologies will continue to be inequitably served. The ITEM Coalition welcomes the opportunity to engage in further dialogue with CMS on this important and complex issue in the future.

#### **D. Adequate Payment**

As was reflected in the ITEM Coalition's public comments at the time, the DMEPOS payment regulation finalized in December 2021 is fundamentally flawed and Congress must act to address these insufficiencies to ensure that Medicare beneficiaries have meaningful access to new devices and technologies that are accurately priced. The DMEPOS payment policy includes a gap filling process that allows CMS to use retail prices found online and in catalogs (without consideration of any related clinical services provided to the patient) and comparative analysis of existing technology to new technology to establish baseline pricing. This reference price is then deflated back to 1986 prices and re-inflated to current day prices using the Consumer Price Index for all Urban Consumers (CPI-U).

This antiquated, opaque, and unpredictable policy can result in highly inappropriate price calculations that do not allow patients to access new devices and technologies. It also serves as a major disincentive for innovators to invest the resources necessary to bring a new device or technology to market, only to receive a reimbursement level that renders that device inaccessible to Medicare beneficiaries. In some instances, suppliers simply cannot make ends meet based on the reimbursement levels assigned through the current system. Congress and CMS can and must address this issue. When adequate payment for DMEPOS services is unavailable, inequities become even more apparent; those who have the means to pay out-of-pocket for medically necessary devices are able to harness their benefits, while those who cannot afford to purchase these devices and technologies out-of-pocket are often left without access.

### **III. Recent CMS Improvements to Coding, Coverage, and Payment**

The ITEM Coalition's comments are not meant to disparage the important work that CMS is doing today to improve and provide greater access to quality care. In fact, CMS is doing a better job in recent years than it has historically and is certainly on the right track for greater access. For this, the ITEM Coalition applauds the Agency for its recent work on this front. The recently-finalized NCD on seat elevation systems in power wheelchairs, CMS contractors' retirement of the flawed upper-limb prosthetic coding guidance, and the recent regulatory proposal contained in the CY 2024 Home Health payment rule to codify the definition of orthotics and grant coverage for powered orthoses are excellent examples of the positive shift CMS has taken towards providing greater access to quality care for people with disabilities. We elaborate on these issues below.



### **A. Final NCD on Seat Elevation Systems in Power Wheelchairs**

Aside from our concerns expressed above with the lack of timeliness and transparency of the NCD process, the ITEM Coalition is thrilled with the final NCD and we commend CMS for recognizing the significant clinical evidence and overwhelming public support for covering seat elevation in Groups 2, 3 and 5 Complex Rehabilitative Technology (“CRT”) power wheelchairs. CMS determined that coverage will ensue when a patient needs seat elevation to transfer from one surface to another—with or without caregiver assistance, assistive devices, or lift equipment—or to improve one’s reach in order to perform mobility related activities of daily living (“MRADLs”). We also greatly appreciate CMS covering seat elevation systems in non-CRT power wheelchairs when determined by Medicare contractors to be reasonable and necessary. This result exceeds our expectations and is being warmly embraced by the disability and rehabilitation communities. The next step is to secure appropriate HCPCS coding and pricing to effectuate this coverage policy and ensure that beneficiaries have access to this new benefit.

We also strongly encourage CMS to finally move forward with our NCD Request to cover standing systems in power wheelchairs by “opening” the NCD and seeking public comment.

### **B. Retiring the Upper-Limb Prosthetic Coding Guidance**

The ITEM Coalition applauds the Durable Medical Equipment Medicare Administrative Contractors (“DME MACs”) and the Pricing, Data Analysis and Coding contractor (“PDAC”) for retiring in March 2023 the coding clarification entitled, “Upper Limb Prostheses - Correct Coding” (hereinafter referred to as the “Guidance”). The restrictive language in this document around coding for upper limb prostheses was leading directly to the inability of individuals to receive care and devices that have a tremendous impact on the restoration of upper limb function following limb loss. We applaud CMS for making the decision to retire this problematic Guidance while stakeholders work to identify immediate, consensus-based recommendations on upper limb coding, identify outdated HCPCS codes, and build support for new HCPCS codes to fill in gaps created to the development of new upper limb prosthetic technologies.

### **C. Medicare Definition of “Brace” Included in the CY 2024 Home Health Rule**

The recently proposed CY 2024 Home Health payment rule also represents a positive step in the right direction towards greater access to orthotic care for Medicare beneficiaries with limb differences. While not perfect, the proposed rule would elevate the definition of an orthotic brace from the Medicare Benefit Policy Manual (“MBPM”) to the regulations at 42 C.F.R. § 410.2. This would strengthen the current definition of a brace under the Medicare benefit. Currently, the term “brace” is not defined in the Medicare statute or in its implementing regulations. Instead, the MBPM defines braces as “rigid and semi-rigid devices which are used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body.” Under the proposal, CMS would codify this definition in regulation.

While elevating the orthotic definition to regulation will help settle orthotic coverage, the non-binding language describing the regulatory change proposed uses outdated and fairly simplistic

concepts of orthotic treatment. This reflects how CMS views orthotics and signals a need to interpret the Medicare orthotic benefit through the lens of contemporary orthotic practice. The outdated language used by CMS in the proposed rule has not kept pace with current orthotic design and function. The potential impact of this language is to lock the orthotic benefit in the past without recognizing advancements in orthotic treatment. The ITEM Coalition supports the codification in regulation of the existing definition of orthotic braces, but urges CMS to interpret the orthotic benefit through contemporary orthotic clinical practice when making coding, coverage and payment decisions in the future.

CMS also confirmed in the Home Health proposed rule that devices with powered features designed to assist with traditional bracing functions are considered braces for Medicare coverage purposes. This is a major, positive decision that opens the door to coverage of a whole new family of powered orthotic treatments. For several years, CMS had been considering denying coverage for powered orthotic features but apparently reversed course through this proposed rule. In moving forward, CMS should work to ensure that candidates for powered orthoses are selected carefully to prevent waste and abuse, with appropriate training for the patient as well as orthotic clinicians.

Each of these examples demonstrate CMS's shift in the right direction to provide greater access for individuals with disabilities and chronic conditions. The ITEM Coalition is hopeful that CMS will continue to build on these accomplishments, and we welcome the opportunity to engage in further dialogue on these important and complex issues in the future.

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We appreciate your consideration of these comments. Should you have any further questions regarding this letter, please contact the ITEM Coalition Co-Coordinator at [Peter.Thomas@PowersLaw.com](mailto:Peter.Thomas@PowersLaw.com) and [Michael.Barnett@PowersLaw.com](mailto:Michael.Barnett@PowersLaw.com) or by calling 202-466-6550.

Sincerely,

**The Undersigned Members of the ITEM Coalition**

Access Ready  
ACCSES  
All Wheels Up  
***ALS Association\****  
American Association of People with Disabilities  
American Association on Health and Disability  
American Cochlear Implant Alliance  
American Congress of Rehabilitation Medicine  
American Medical Rehabilitation Providers Association  
American Music Therapy Association  
American Occupational Therapy Association  
American Therapeutic Recreation Association  
***Amputee Coalition\****

Association of Rehabilitation Nurses  
Autistic Women & Nonbinary Network  
Buoniconti Fund to Cure Paralysis  
***Christopher and Dana Reeve Foundation\****  
Clinician Task Force  
Council of State Administrators of Vocational Rehabilitation (CSAVR)  
Cure SMA  
Institute for Matching Person & Technology  
Lakeshore Foundation  
Miami Project to Cure Paralysis  
Muscular Dystrophy Association  
National Association for the Advancement of Orthotics and Prosthetics  
National Disability Rights Network  
National Registry of Rehabilitation Technology Suppliers  
***Paralyzed Veterans of America\****  
RESNA  
***Spina Bifida Association\****  
Support Sight Foundation  
The Simon Foundation for Continence  
Unite 2 Fight Paralysis  
United Cerebral Palsy  
***United Spinal Association\****  
Viscardi Center

***\* ITEM Coalition Steering Committee Member***