



July 14, 2025

The Honorable Robert F. Kennedy, Jr.
Secretary
United States Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

Re: ITEM Coalition' Comments in Response to the Request for Information on Ensuring Lawful Regulation and Unleashing Innovation to Make America Healthy Again (AHRQ-2025-0001)

Dear Secretary Kennedy:

The undersigned members of the Independence Through Enhancement of Medicare and Medicaid ("ITEM") Coalition appreciate the opportunity to submit comments in response to the Department of Health and Human Services' ("HHS") Request for Information ("RFI") entitled, "Ensuring Lawful Regulation and Unleashing Innovation to Make American Healthy Again." The ITEM Coalition is comprised of 100 national, nonprofit organizations that seek to improve access to and coverage of assistive devices and technologies that enhance the function of people with disabilities and chronic conditions of all ages. Many of the individuals our member organizations represent use wheelchairs and other mobility devices to ambulate and perform Mobility-Related Activities of Daily Living ("MRADLs") in their homes. Our members represent individuals with a wide range of disabling conditions, as well as the providers who serve them, including such conditions as spinal cord injuries, brain injuries, multiple sclerosis, stroke, paralysis, limb loss, cerebral palsy, spina bifida, muscular dystrophy, neurological impairments, and other life-altering conditions.

The ITEM Coalition appreciates HHS's interest in improving care for individuals with chronic conditions by repealing regulations and guidance that may pose unnecessary barriers to care. As HHS initiates its review of existing regulations and guidance for potential repeal or revision, the ITEM Coalition respectfully urges the Centers for Medicare and Medicaid Services ("CMS") to eliminate Medicare guidance that prohibits Medicare coverage of standing systems in power wheelchairs. Specifically,

- CMS should direct the Durable Medical Equipment Medicare Administrative Contractors ("DME MACs") to remove language in Local Coverage Article ("LCA") A52504 indicating that Medicare does not cover power standing features.
- In addition, with the new Administration in place and CMS now under your leadership, the ITEM Coalition respectfully urges the agency to move forward with opening the

long-pending National Coverage Analysis (“NCA”) for power standing systems as soon as possible.

Supported Standing Systems in Power Wheelchairs

The ITEM Coalition has consistently advocated for Medicare coverage of standing systems in power wheelchairs. Standing systems are integrated with power wheelchairs to allow individuals who rely on their power wheelchairs for mobility to move into a supported standing position safely, without the need to transfer into another device.¹ For individuals who spend large parts of their day in a seated position, the value of being able to easily assume a supported standing position, bear weight on the lower limbs, allow gravity to aid in metabolic functions, and enable the performance of MRADLs is well established in the clinical literature. Medicare coverage of standing systems in power wheelchairs would significantly improve the health, function, and quality of life of beneficiaries with significant mobility disabilities such as spinal cord injury, paralysis, multiple sclerosis, amyotrophic lateral sclerosis, muscular dystrophy, limb amputation, and other mobility-related conditions.

The “sitting down disease” that Administrator Oz warned about in a 2014 Pioneer Press article is not exclusive to individuals living without disabilities. In fact, for individuals with significant mobility disabilities who are physically unable to stand on their own, the health risks are even greater. The ability to achieve a supported standing position on a frequent basis throughout the day may counter the negative effects of prolonged sitting and provide therapeutic benefits for beneficiaries who are experiencing problems, including, but not limited to, contractures, tight muscles, decreased range of motion, kidney stones, recurring urinary tract infection (“UTIs”) due to the inability to completely empty their bladder, constipation and decreased circulation and pulmonary function. Moreover, standing is known to reduce pressure and the resulting skin injuries that are extremely debilitating, expensive to treat, and can lead to infections to sepsis and even to death.

Power standing systems allow the beneficiary to perform or participate in MRADLs—continuing to be able to move/operate the power wheelchair while in a standing position in the home. They enable beneficiaries with mobility impairments to be more functional and less reliant on other caregivers, whether these caregivers are family members, paid homecare providers or personal assistants. In addition, standing systems in power wheelchairs reduce the costs to the Medicare program of treating the consequences of falls, skin breakdowns, muscle contractures, and numerous other avoidable medical complications which are prevalent in the mobility-impaired population.

I. Medicare Guidance Barring Coverage of Standing Systems in Power Wheelchairs

Power standing systems have been available to individuals with mobility disabilities since the late 1970’s and are covered by the Veterans Administration, several Medicaid programs, workers compensations programs, and some private payers. Yet, Medicare beneficiaries with mobility impairments have been deprived of access to this technology to date. Medicare currently does

¹ Power standing system is described by HCPCS Code E2301.

not cover power standing systems. Since 2015, the four DME MACs have issued an identical LCA claiming that power standing systems do not fall under the Medicare DME benefit because they do not primarily serve a medical purpose.² Specifically, the LCA states, in relevant part:³

POWER STANDING SYSTEM:

A power standing feature (E2301) is non-covered because it is not primarily medical in nature. If a wheelchair has an electrical connection device described by code E2310 or E2311 and if the sole function of the connection is for a power standing feature, it will be denied as non-covered.

The DME MACs provided no rationale for their conclusion and no citation to medical literature. In fact, the DME MACs' policy article incorrectly assesses the evidence because power standing systems assist certain mobility-impaired beneficiaries in performing or participating in Activities of Daily Living ("ADLs") and, specifically, MRADLs in the home by enabling movement through the vertical plane. Additionally, as mentioned above, power standing systems ameliorate numerous adverse physiological effects of excessive and prolonged sitting. The absence of Medicare coverage for standing systems leaves many beneficiaries who use power wheelchairs without access to critical technology that can significantly improve their health outcomes, functional abilities, and quality of life.

Therefore, CMS should direct the DME MACs to eliminate the aforementioned language in the LCA to remove barriers for claim by claim consideration of Medicare coverage of power standing systems for Medicare beneficiaries for whom these systems are medically necessary.

II. Request for Reconsideration of the Medicare National Coverage Determination for Mobility Assistive Equipment (§ 280.3)

On September 15, 2020, the ITEM Coalition submitted a formal Request for Reconsideration of the National Coverage Determination for Mobility Assistive Equipment ("NCD for MAE") to include coverage of power seat elevation and power standing systems in power wheelchairs for certain beneficiaries. Specifically, we sought reconsideration of the NCD for MAE to:

- (1) establish a benefit category determination ("BCD") that both power seat elevation and power standing systems in power wheelchairs are "primarily medical in nature" and, therefore, covered DME under the Medicare program, and
- (2) explicitly recognize coverage of these systems for beneficiaries with a medical or functional need for vertical movement in a power wheelchair in order to perform or assist in participating in MRADLs in the home.

² Noridian Healthcare Solutions, LLC & CGS Administrators, LLC, *Local Coverage Article: Wheelchair Options/Accessories – Policy Article (A52504)*.

³ *Id.*

In response, CMS chose to bifurcate the ITEM Coalition's request by first opening an NCA for seat elevation in power wheelchairs and promising to open a separate NCD for standing systems in power wheelchairs at an unspecified date in the future. In March 2023, CMS published a favorable NCD for seat elevation systems in power wheelchairs, which was warmly embraced by the disability and rehabilitation communities.

The ITEM Coalition continues to eagerly await the opening of an NCD for standing systems in power wheelchairs. We remain deeply concerned that our related request for standing systems remains unresolved, with CMS having yet to initiate the NCA process or provide a timeline for action. Despite the submission in 2024 of updated clinical evidence and patient population data, CMS has not offered an opportunity for public comment or transparency on the path forward to date. After five years of waiting, it is time for this process to finally advance.

With a new Administration now in place and CMS under your leadership, the ITEM Coalition implores the agency to finally open the pending NCA for power standing systems at your earliest possible opportunity. As the 35th Anniversary of the Americans with Disabilities Act ("ADA") approaches on July 26th, we believe there is no better way to celebrate the successes of this landmark law for people with disabilities over the past three and a half decades than for CMS to open this critically important NCA to address the mobility needs of individuals with disabilities. Doing so would reaffirm CMS's commitment to the disability community and align with the values embodied by the ADA. We believe that granting coverage of standing systems in power wheelchairs is crucial to help ensure that Medicare beneficiaries with mobility impairments are able to live as independently as possible, maintain and improve their health and function, and perform or participate in MRADLs in their homes.

We appreciate your consideration of these requests and stand ready to assist CMS as it considers Medicare coverage of standing systems in power wheelchairs as soon as possible. Should you have any additional questions, please do not hesitate to reach out to ITEM Coalition co-coordinators Peter.Thomas@PowersLaw.com, Michael.Barnett@PowersLaw.com, or Leela.Baggett@PowersLaw.com by calling 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 Congress of Rehabilitation Medicine
American Music Therapy Association
American Occupational Therapy Association
American Physical Therapy Association
Amputee Coalition*
Autistic Women & Nonbinary Network
Blinded Veterans Association
Center on Aging and DIS-Ability Policy
Christopher & Dana Reeve Foundation*
Clinician Task Force
CureLGMD2i
3DA
Epilepsy Foundation of America
Institute for Matching Person and Technology
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
NCART
RESNA
Spina Bifida Association*
Team Gleason*
The Viscardi Center
United Spinal Association*

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