August 7, 2018

VIA ELECTRONIC MAIL

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Meeting Request and Two Attachments Regarding Medicare Coverage of Standing Feature and Seat Elevation in Power Wheelchairs

Dear Secretary Azar:

The undersigned members of the Steering Committee of the Independence through Enhancement of Medicare and Medicaid (ITEM) Coalition write to request a meeting with you to discuss Medicare coverage of the "standing feature" and "seat elevation" feature in power wheelchairs.

The ITEM Coalition is a national consumer and clinician-led coalition advocating for access to and coverage of assistive devices and technologies 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 clinicians and providers who serve them, including such conditions as multiple sclerosis, paralysis, hearing and speech impairments, cerebral palsy, visual impairments, spinal cord injuries, brain injury, stroke, spina bifida, myositis, limb loss, Osteogenesis Imperfecta (OI), and other life-altering conditions.

Attached please find two separate requests for the Centers for Medicare and Medicaid Services (CMS) to reconsider the current coverage policy for standing feature and seat elevation in power wheelchairs. Our coalition members believe CMS should issue benefit category determinations that standing feature and seat elevation meet the definition of durable medical equipment for purposes of Medicare coverage.

We respectfully request this meeting to further discuss these important matters. We note that many members of the disability community, including member organizations of the ITEM Coalition, have not yet had the pleasure of meeting you. We hope that you will meet with us in person to discuss these important priorities for Medicare beneficiaries with mobility impairments.

To contact the ITEM Coalition to follow up and arrange a meeting with us, please contact Peter Thomas and Leif Brierley at 202-466-6550 or Peter.Thomas@PowersLaw.com and Leif.Brierley@PowersLaw.com. We look forward to hearing from you soon.

Sincerely,

The ITEM Coalition Steering Committee

Alexandra Bennewith, United Spinal Association ABennewith@unitedspinal.org
Laura Weidner, National Multiple Sclerosis Society Laura.Weidner@nmss.org
Dan Ignaszewski, Amputee Coalition dan@amputee-coalition.org
Kim Beer, Christopher and Dana Reeve Foundation KBeer@christopherreeve.org
Mark Richert, American Foundation for the Blind MRichert@afb.net
Lee Page, Paralyzed Veterans of America LeeP@pva.org

CC:

Seema Verma, Administrator, Centers for Medicare and Medicaid Services (CMS)
Demetrios Kouzoukas, Principal Deputy Administrator and Director, Center for Medicare, CMS
Elizabeth Richter; Deputy Center Director, Center for Medicare, CMS
Kate Goodrich, M.D., Director and CMS Chief Medical Officer, Center for Clinical Standards and Quality, CMS
Laurence Wilson, Director, Chronic Care Policy Group, CMS
Joel Kaiser, Director of DME Policy, CMS

August 7, 2018

VIA ELECTRONIC MAIL

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Coverage of Seat Elevation in Power Wheelchairs

Dear Secretary Azar:

The undersigned members of the Independence Through Enhancement of Medicare and Medicaid (ITEM) Coalition write to follow-up on our previous request of the Centers for Medicare and Medicaid Services (CMS) that it reconsider and revise its policy related to Medicare coverage of seat elevation for power wheelchair users. We hereby formally request that CMS reconsider this policy and make an affirmative benefit category determination ("BCD") that the seat elevation function qualifies as durable medical equipment and is a covered benefit for qualified Medicare beneficiaries with mobility impairments.

We previously met with former CMS Administrator, Marilyn Tavenner, in 2013 requesting that CMS clarify Medicare coverage policy on seat elevation for power wheelchair users. We subsequently met with CMS' Director of the Center on Medicare's Chronic Care Policy Group, Laurence Wilson, in that same year to discuss the coverage policy and articles issued by its Durable Medical Equipment Medicare Administrative Contractors ("DME MACs") stating that seat elevation does not primarily serve a medical purpose.

The ITEM Coalition takes strong issue with this view. We believe it is inconsistent with national Medicare coverage policy for Mobility Assistance Equipment ("MAE") and fails to take into account the medical and therapeutic benefits of seat elevation for individuals with mobility impairment. At the time, we were not able to reach a conclusion on our discussions with CMS. We now request that CMS reconsider its current Medicare coverage policy on seat elevation for beneficiaries in need of this feature in power wheelchairs.

Background

The seat elevation feature is an accessory to power wheelchairs that is embedded in the mobility device itself. Seat elevation assists an individual with mobility impairment to raise

and lower him- or herself in the seated position through the use of an electromechanical lift system. The seat elevation feature is described by HCPCS Code E-2300 and coverage is indicated in the HCPCS Level II Code Book to be at "carrier discretion."[1]

Seat elevation assists individuals in transferring from a wheelchair to a commode, bed, or other surface by elevating or lowering the seat height of the wheelchair allowing for independence in hygiene, grooming, dressing and other mobility-related activities of daily living ("MRADLs"), performance of which is the standard for coverage under the National Coverage Determination ("NCD") for MAE.[2] Without the seat elevation feature, Medicare beneficiaries have limited options to achieve performance of MRADLs. Transfer from surfaces at differing heights is difficult if not impossible and may cause harm if the beneficiary is unable to transfer themselves properly. The assistance of another person may be required, limiting independent function in the home. For individuals with limited reaching abilities, the seat elevation feature allows for access to objects within the home and assists an individual with hygiene, dressing, grooming and meal preparation, all of which the NCD for MAE considers MRADLs. In short, seat elevation is essential in allowing an individual with a mobility impairment to accomplish MRADLs without assistance.

Position of Medicare DME Contractors

With no rationale for their conclusion and no citation to medical literature, the DME MACs take the position, as set forth in local coverage articles, that the seat elevation feature described by HCPCS Code E-2300 along with related accessories "are noncovered because they are not primarily medical in nature."[3] The local coverage article is an addendum to a local coverage determination ("LCD") on "wheelchair options/accessories."[4]

Because this is a Benefit Category Determination ("BCD") rather than an LCD, the DME MACs have not had to comply with the rigorous clinical evidence standards required for LCDs.[5] In addition, the legal processes available to beneficiaries to challenge LCDs are not available to challenge BCD determinations. This means that private companies contracting with CMS (i.e., the DME MACs) wield extensive influence over access to benefits to which Medicare beneficiaries are entitled with no meaningful due process to challenge these decisions.

CMS Policy on Mobility Assistance Equipment

The NCD for MAE grants coverage for mobility assistance equipment when:

> "Evidence is adequate to determine that MAE is reasonable and necessary for beneficiaries who have a personal mobility deficit to impair their participation in

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[1] HCPCS Level II Expert; Optum, p. 35 (2017).
[2] CMS Pub. 100-03, Ch. 1, § 280.3.
[3] See, e.g., Local Coverage Article for Wheelchair Options/Accessories - Policy Article Al9846 published by Noridian.
[4] Local Coverage Determination: Wheelchair Options/Accessories (L33792), published by CGS Administrators and Noridian Healthcare Solutions (revised Jan. 1, 2018).
[5] Medicare guidance requires that LCDs, which address medical necessity under Section 1862(a), be supported by "the strongest evidence available." CMS Pub. 100-8, Ch. 13 § 13.7.1.

> mobility-related activities of daily living (MRADLs) such as toileting, feeding, dressing, grooming, and bathing in customary locations within the home."[6]

The NCD sets forth a complex nine-step algorithm or "decision tree" for determining the clinical circumstances by which a specific type of MAE is appropriate for an individual covered under the Medicare program. Essential in applying this decision tree is the extent to which MAE will assist the individual to participate in MRADLs. For example, the criteria include whether the individual has a mobility limitation that "significantly impairs his/her ability to participate in one or more MRADLs at home." It also asks whether the individual has a comorbidity that would prevent effective use of MAE. The criteria include analysis of a number of other factors related to the home environment, access to caregivers and family support, and safety issues. Although the NCD refers to canes, crutches, walkers, manual wheelchairs, power wheelchairs, and scooters, it specifically states that "this list, however, is not exhaustive."

HCFA Ruling 96-1

In HCFA Ruling 96-1, CMS provided clarification on the statutory DME and orthotics benefit categories. The case that prompted the issuance of HCFA Ruling 96-1 involved certain orthoses that were attached to a wheeled frame which was considered DME. In ruling that these orthoses could not be billed to Medicare Part B separately from the underlying wheeled DME frame, the agency stated, unequivocally, that accessories to wheelchairs and other items of DME are part of the DME benefit:

> "To the extent that a wheelchair seating system or other equipment may or may not function properly or not achieve its full 'therapeutic benefit' without attached components supporting or restricting motion in a body part, the attachments are appropriately viewed as a necessary accessory that is an integral part of the durable medical equipment and is, accordingly, payable as durable medical equipment, provided that the other prerequisites for classification as durable medical equipment are met."

Seat elevation clearly meets this standard for a subset of Medicare beneficiaries with mobility impairment. Seat elevation is an accessory to a power wheelchair that is integral to its function for a person who needs to be able to adjust vertical seat position in order to achieve the full therapeutic benefit of a power wheelchair (i.e., DME). Seat elevation supports motion in a body part (i.e., the entire body) that enables and facilitates the individual's ability to independently transfer and reach in order to perform MRADLs. For this reason, HCFA Ruling 96-1 is directly on point as it relates to the benefit category determination of seat elevation.

National Coverage Determination for Seat Lifts

CMS has issued an NCD that allows coverage for seat lifts, recognizing that seat lifts can provide a therapeutic benefit for patients with neuromuscular diseases or severe arthritis of the hip or knee. The same rationale applies to coverage of seat elevation.

[6] CMS Pub. 100-03, Ch. 1, § 280.3.

NCD 280.4 states in relevant part:

> "Reimbursement may be made for the rental or purchase of a medically necessary seat lift when prescribed by a physician for a patient with severe arthritis of the hip or knee and patients with muscular dystrophy or other neuromuscular diseases when it has been determined the patient can benefit therapeutically from use of the device. In establishing medical necessity for the seat lift, the evidence must show that the item is included in the physician's course of treatment, that it is likely to effect improvement, or arrest or retard deterioration in the patient's condition, and that the severity of the condition is such that the alternative would be chair or bed confinement."

There is no meaningful distinction between coverage of a seat lift and coverage of seat elevation. Like a seat lift, the seat elevation feature in a power wheelchair enables individuals with mobility impairments to achieve a higher/lower physical position in order to perform MRADLs and has therapeutic benefits because it improves performance of these same activities of daily living. Indeed, the medical nature of seat elevation is even more apparent than the medical nature of seat lifts because the seat elevation feature is an accessory to a power wheelchair, which is well-established as primarily medical in nature. It is inconsistent for CMS to cover seat lifts as DME while refusing to acknowledge similar treatment of seat elevation in power wheelchairs.

National Coverage Determination for iBOT 4000 Mobility System

In 2006, CMS issued an NCD for the iBOT 4000 Mobility System that covered the "Standard Function" of the device but not its other functions, including a "Balance Function" that raised the position of the seated user.[7] The Standard Function of the iBOT is similar to a traditional power-operated wheelchair. The Balance Function enables a user to move from a seated position to an elevated seated position where the four wheels rotate to a vertical position balancing on two wheels. The user remained seated at all times. In denying coverage for the Balance Function, CMS reasoned that "[s]eat elevation serves the same purpose as other equipment that assist all persons in reaching items out of reach or having an 'eye-level' conversation with a standing person."[8] The agency therefore determined that the Balance Function was not presumptively medical in nature.

The NCD for the iBOT Mobility System has limited applicability to the unique features of the iBOT, a device that is no longer on the market. CMS' reasoning for denying coverage for the iBOT's Balance Function should not be extended to seat elevation in power wheelchairs, which has different functional benefits from the Balance Function of the iBOT. Seat elevation goes beyond simply assisting individuals with "reaching items out of reach or having an eye-level conversation with a standing person." It enables non-ambulatory individuals to perform essential MRADLs that form the coverage standard for MAE under CMS' NCD, including grooming, dressing, hygiene, and toileting. Seat elevation is not primarily a convenience item but has direct

[7] NCD 280.15 (effective July 27, 2006).
[8] CMS Decision Memorandum for the INDEPENDENCE 4000 iBOT Mobility System (July 27, 2006), https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=5&fromdb=true.

therapeutic benefits for individuals with mobility impairment by assisting with the performance of essential MRADLs. As a result, CMS' coverage determination with respect to the iBOT Balance Function is extremely narrow in applicability and should not be extended to seat elevation in power wheelchairs.

Administrative Decisions Related to Seat Elevation Devices

Although none of the decisions discussed below constitute precedent that is binding on the agency, we believe they provide useful background. In a 2014 Administrative Law Judge ("ALJ") decision,[9] an ALJ ordered one of the four DME MACs ("CGS") and the Qualified Independent Contractor ("QIC") to pay a beneficiary's claim for seat elevation, reasoning that the seat elevation device serves a medical purpose.[10] The beneficiary was originally denied coverage for both seat elevation (E2300) and standing feature (E2301), and on appeal the ALJ issued a favorable decision for the beneficiary with respect to both items. However, CMS requested review of the case by the Medicare Appeals Council which reviewed the decision with respect to seat elevation only[11] and remanded the case to the ALJ based in part on the ALJ's failure to accord substantial deference to the local coverage article, which states that seat elevation is not primarily medical in nature.

On remand, the ALJ accorded deference to the local coverage article but nonetheless departed from it. The ALJ concluded that "the exclusion of coverage for the power seat elevation system is arbitrary" given that CMS has issued an NCD for seat lifts. The ALJ did not find any major distinction between a seat lift and a power seat elevation system, and in fact found that the case for the medical nature of seat elevation was even more compelling because it is an accessory to a power wheelchair, which is primarily medical in nature. The ALJ also relied on the medical opinion of an occupational therapist in finding that seat elevation serves a medical purpose "because it is therapeutic for patients to be able to transfer out of a wheelchair to use the bathroom, to bathe, or to perform other activities necessary to their health."

Similarly, in a 2007 decision appealing the DME MAC (Noridian) and the QIC's denial of a seat elevation device, an ALJ overturned the contractor's decision and determined that the device should be covered for an individual with quadriplegia. The ALJ, relying on the CMS NCD for MAEs, found that "the ability to transfer independently is essential to the Beneficiary's participation in MRADLS" and, as such, the device served "a medical need."[12]

The Medicare Appeals Council has issued a contrary decision, however. The Appeals Council decided, on its own motion, to review an ALJ decision holding that a seat elevation device was covered for an individual with myositis who had severe weakness in his forearms and thighs.[13] The Appeals Council reversed the ALJ's decision based on the Noridian Article A19846 without offering any clinical support for its conclusion that seat elevation

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[9] While ALJ decisions and most Medicare Appeals Council decisions do not constitute precedent that is binding on the agency, they are instructive and serve as useful background.
[10] ALJ Appeal No. 1-1097802958R1 (Midwestern Region, Cleveland, Ohio, Joseph C. Pastrana, ALJ).
[11] CMS referred the matter to the Appeals Council with respect to seat elevation only, so the Appeals Council did not review the ALJ's favorable decision with respect to standing feature.
[12] ALJ Appeal No. 1-291831845 (Western Region, Irvine, California, William J. Cown, ALJ.)
[13] Medicare Appeal Council Docket No. M-11-2045, September 20, 2011.

devices are presumptively non-medical, stating:

> "Because it does not meet the definition of DME, it is not covered regardless of whether it is medically reasonable and necessary"

Moreover, the Appeals Council incorrectly concluded that the DME MAC Article was developed in accordance with the requirements of CMS Pub. 100-8 §13.1.3 and thus subject to the rigorous clinical evidence standard required for development of LCDs. That guidance applies only to LCDs which, by definition, are limited to determinations of medical necessity under section 1862 of the Act and not to benefit category determinations. Thus, the Appeals Council was mistaken in assuming that the policy in question was supported by clinical evidence and developed in consultation with local medical societies and other stakeholders. For this reason, the Appeals Council's deference to the DME MAC Article is misplaced.

Importantly, Appeals Council decisions are not binding on CMS, and this decision, therefore, has no precedential value. We examine it here to illustrate how the DME MAC Article is adversely affecting Medicare beneficiaries. As explained below, the DME MAC policy relied upon by the Council is inconsistent with Ruling 96-1 and the NCD on MAE. CMS should clarify that seat elevation in a power wheelchair is primarily medical in nature and is, therefore, covered under the DME benefit category. When medically necessary and appropriate, seat elevation in a power wheelchair should be a covered benefit for Medicare beneficiaries.

<u>Position of DME Contractors is Inconsistent with CMS Policy</u>

The position taken by the DME MACs that seat elevation does not primarily serve a medical purpose is not consistent with CMS policy as articulated in Ruling 96-1 and the NCD on MAE. Although contractors have some latitude to develop policy, they must follow NCDs and other national policies and may not take a position contrary to national policy.[14]

- **Seat Elevation Is DME**

A seat elevation accessory or component of a power wheelchair meets the definition of durable medical equipment and CMS should explicitly issue a BCD to that effect. As already stated, the position of the MACs is contrary to HCFA Ruling 96-1.[15] In that Ruling, the agency specifically considered the role of wheelchair accessories including "seating systems, rests and supporting and positional attachments" that are intended to be used with a seating system to which they are attached. The agency, citing the legislative history of the amendments to section 1834(a)(4) of the Act found that:

> "Ample evidence establishes that the Congress intended sophisticated wheelchairs, including chairs with functional attachments, to be classified in their totality as

[14] CMS Pub. 100-08 § 13.1.1.
[15] HCFA rulings are "binding on all [CMS] components, intermediaries and carriers . . ." and "promote consistency in interpretation of policy and adjudication of disputes."

durable medical equipment."[16]

Thus, CMS and Congress both take the position that the DME benefit includes attachments and accessories to power wheelchairs. This includes the seat elevation accessory.

- **Seat Elevation Devices Are Covered by Medicare When Clinically Appropriate**

CMS has presumptively determined that MAE that assists an individual in performing MRADLs must primarily serve a medical purpose and thus falls squarely within the DME benefit category. Since seat elevation can assist in the performance of MRADLs (e.g., toileting, grooming), it logically follows that seat elevation also primarily serves a medical purpose to the same extent as power wheelchairs or other MAE.

In the NCD for MAE, CMS developed a complex algorithm for determining whether a particular item of MAE is medically necessary for a particular beneficiary. Part of that individual determination evaluates whether—and the extent to which—the MAE will help an individual participate in MRADLs. If the MAE does not assist an individual in performing MRADLs in the home, then, under the algorithm set forth in the NCD, the MAE may not be covered. The DME MACs' position to the contrary ignores CMS national policy, as articulated in the NCD and results in categorical denial regardless of individual need. It also deprives Medicare beneficiaries of their right to a determination based on their individual medical circumstances.

The position of the DME MACs that a seat elevation feature embedded in a power wheelchair does not primarily serve a medical need runs counter to the overwhelming weight of the clinical evidence and common sense. The seat elevation feature clearly serves several medical needs including, most importantly, transferring from one surface to another in order to assist in performing MRADLs. The importance of seat elevation in assisting in MRADLs is described in a position paper published by the Rehabilitation Engineering & Assistive Technology Society of North American ("RESNA") and in the clinical literature cited therein.[17]

The seat elevation feature allows for a transfer in a downhill direction that is gravity-assisted and places less strain on upper extremities. This permits an individual to transfer independently to a toilet or bed or other surface without the assistance of a caregiver. This increases independence and is essential for participation in MRADLs such as toileting and bathing. For individuals with mobility impairment or limited reaching abilities, the seat elevation feature can provide access to objects and surfaces necessary to complete MRADLs such as feeding or meal preparation as well as grooming and dressing. Further, reaching from an elevated position has been shown to reduce shoulder muscle load and the development of shoulder pain.

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[16] HCFA Ruling 96-1, September 1996.

[17] Arva J, et al. *RESNA Position on the Application of Seat-Elevating Devices for Wheelchair Users*, Assistive Technology, 21:69-72, 2009.

The following case study from the RESNA article is illustrative. It describes a 67-year old woman with Osteogenesis Imperfecta, a right below-knee amputation, limited active shoulder flexion to 100 degrees, and short stature (5 feet tall) who uses a power wheelchair. She lives alone in an accessible apartment and is independent with all MRADLs using a power wheelchair with the seat elevation feature. She requires seat elevation to perform sliding board transfers in a downhill direction as she does not have adequate upper extremity strength to slide herself across a level surface or uphill. She also requires seat elevation to reach and carry out tasks at different surface heights such as stovetop cooking. Without the seat elevation feature of her power wheelchair, she would not be able to transfer or perform necessary MRADLs and would not be able to live independently. Clearly the seat elevation feature, as used by this individual and those with similar mobility impairments, is primarily used to serve a medical purpose.

Conclusion

It is critical for CMS to clarify Medicare coverage policy on seat elevation in power wheelchairs. Seat elevation is vital for people with mobility impairment to perform MRADLS in the home. DME MAC Articles to the contrary are inconsistent with existing CMS policy, as expressed in Ruling 96-1 and the National Coverage Decision on Mobility Assistance Equipment.

We therefore urge CMS to require the DME MACs to determine coverage of seat elevation on an individual basis according to the NCD for MAE. In order to affect this, CMS must reconsider coverage of seat elevation in power wheelchairs and work with the DME MACs to rescind all DME Articles stating that seat elevation does not primarily serve a medical purpose. CMS must also render a benefit category determination that establishes seat elevation as qualifying under the definition of durable medical equipment when embedded in a power wheelchair. Medicare beneficiaries are entitled to an individual determination of coverage of all MAE, including seat elevation, based on their unique medical and functional circumstances.

Thank you for your consideration of this issue and we look forward to discussing this request with you further. If you have any questions, please contact Peter Thomas, ITEM Coalition Coordinator, at peter.thomas@powerslaw.com or at 202-466-6550 at your convenience.

Sincerely,

The Undersigned Members and Friends of the ITEM Coalition
Academy of Spinal Cord Injury Professionals
ACCSES
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 Foundation for the Blind

American Medical Rehabilitation Providers Association
American Occupational Therapy Association
American Physical Therapy Association
American Therapeutic Recreation Association
Amputee Coalition
Association for Education and Rehabilitation of the Blind and Visually Impaired (AER)
Association of Assistive Technology Act Programs
Association of University Centers on Disabilities
Autism Self Advocacy Network
Brain Injury Association of America
Center for Assistive Technology, Buffalo, NY
Center for Medicare Advocacy
Christopher and Dana Reeve Foundation
Clinician Task Force
Institute for Matching Person & Technology, Inc.
Lakeshore Foundation
National Association for the Advancement of Orthotics and Prosthetics
National Coalition for Assistive & Rehab Technology
National Council on Independent Living
National Disability Rights Network
National Multiple Sclerosis Society
National Registry of Rehabilitation Technology Suppliers
Paralyzed Veterans of America
Rehabilitation Engineering and Assistive Technology Society of North America
Spina Bifida Association
The Arc of the United States
The Buoniconti Fund to Cure Paralysis
The Miami Project to Cure Paralysis
The Myositis Association
The Simon Foundation for Continence
Unite 2 Fight Paralysis
United Spinal Association
University of Pittsburgh, Department of Rehabilitation Science & Technology

cc:

Seema Verma, Administrator, Centers for Medicare and Medicaid Services (CMS)
Demetrios Kouzoukas, Principal Deputy Administrator and Director, Center for Medicare, CMS
Elizabeth Richter; Deputy Center Director, Center for Medicare, CMS
Kate Goodrich, M.D., Director and CMS Chief Medical Officer, Center for Clinical Standards and Quality, CMS
Laurence Wilson, Director, Chronic Care Policy Group, CMS
Joel Kaiser, Director of DME Policy, CMS

August 7, 2018

VIA ELECTRONIC MAIL

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Coverage of Standing Feature in Power Wheelchairs

Dear Secretary Azar:

The undersigned organizations write to request that the Centers for Medicare and Medicaid Services (CMS) review, reconsider, and revise its policy related to Medicare coverage of the "standing feature" in power wheelchairs.

Under current policy, Medicare, through determinations made solely by its Durable Medical Equipment Medicare Administrative Contractors ("DME MACs"), does not cover the standing feature in powered wheelchairs based on the assertion that standing feature does not fit within the DME benefit category because it does not serve a medical purpose. This coverage policy is inconsistent with national Medicare policy and is contradicted by overwhelming clinical evidence. As a result, Medicare beneficiaries with mobility impairments do not have access to this critical technology.

Functional and Medical Benefits of Standing Feature

The standing feature of a power wheelchair allows an individual to transition from a seated position to a standing position without the need to transfer from the wheelchair. It is typically operated through the wheelchair's controller which manipulates an electric-powered assist that moves the wheelchair from a sitting position to a full vertical position. The legrests and backrest achieve a vertical position, which allows the individual to stand within the wheelchair. In many cases, the standing feature also allows an individual to obtain a slanted position that is in between sitting and full vertical standing.

The standing feature is described by HCPCS Code E-2301, which was added to the Healthcare Common Procedure Coding System in 2004. The standing feature assists individuals with limited reaching abilities to access objects within the home and assists an individual with hygiene, dressing, grooming and meal preparation, all of which the Medicare program considers

mobility-related activities of daily living ("MRADLs"). Performance of MRADLs is the standard for coverage under the National Coverage Determination for Mobility Assistance Equipment (NCD for MAE).[1] Two position papers published by the Rehabilitation Engineering & Assistive Technology Society of North America ("RESNA")[2] and clinical literature cited therein establish the importance of standing feature in assisting in MRADLs. The RESNA studies explain that "[s]tanding adds a significant amount of vertical access," which enables people to access kitchen cabinetry, light switches, microwaves, mirrors, sinks, hangers, thermostats, medicine cabinets, and other surfaces to enable performance of MRADLs.

The standing feature has both functional and medical benefits. The RESNA articles detail the following medical benefits of standing feature, in addition to the improved functional reach and enhanced ability to perform MRADLs such as:

- Improved mobility and lower limb function in those with preserved muscle strength in lower limbs;
- Improved range of motion and reduced risk of contractures;
- Promotion of vital organ capacity including pulmonary, bowel and bladder function;
- Promotion of bone health;
- Improved circulation;
- Reduced abnormal muscle tone and spasticity;
- Reduced occurrence of pressure ulcers; and
- Reduced occurrence of skeletal deformities.

Numerous clinical studies describe the negative impact of sitting for long periods of time and the health benefits of periodic standing for all individuals. Repeated exposure to sitting for long periods of time is associated with bone mineral density destruction/damage in women independent of whether they engage in physical activity.[3] Prolonged sitting is also negatively associated with cardiovascular disease, diabetes, and premature mortality.[4] Breaking up long periods of sitting with standing has been shown to improve lipid metabolism and have a positive impact on cardio-metabolic health.[5] Periodic standing is also beneficially associated with reducing the risk of type 2 diabetes and other chronic diseases.[6] The documented health benefits of periodic standing have led to changes in workplace environments that are primarily desk-based. Public health professionals highly recommend alternating between sitting and standing throughout the day regardless of whether an individual uses a power wheelchair.[7] The physical

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[1] CMS Pub. 100-03, Ch. 1, § 280.3.
[2] Arva J, et al., *RESNA Position on the Application of Wheelchair Standing Devices*, 21:161-168 (2009); Dicianno B, et al., *RESNA Position of Wheelchair Standing Devices: 2013 Current State of the Literature* (2013).
[3] Chastin S, et al., *Associations between objectively-measured sedentary behavior and physical activity with bone mineral density in adults and older adults, the NHANES study*, Elsevier (2014).
[4] Healy G, et al., *Replacing sitting time with standing or stepping: associations with cardio-metabolic risk biomarkers*, European Heart Journal (2015).
[5] *Id*.
[6] Thorp A, et al., *Alternating Bouts of Sitting and Standing Attenuate Postprandial Glucose Responses*, American College of Sports Medicine (2014).
[7] *See, e.g.*, Buckley J et al, *The sedentary office: a growing case for change towards better health and productivity. Expert statement commissioned by Public Health England and the Active Working Community Interest Company*, British Journal of Sports Medicine (2015).

benefits of standing are even more obvious for individuals using a power wheelchair who are forced to assume a permanent seated position during the day.[8]

Position of Medicare DME MACs

With no rationale for their conclusion and no citation to medical literature, the DME MACs take the position, as set forth in local coverage articles, that the standing feature described by HCPCS Code E-2301 along with related accessories "are non-covered because they are not primarily medical in nature."[9] The local coverage article is attached to an LCD on "wheelchair options/accessories."[10]

Because this is a Benefit Category Determination ("BCD") rather than a local coverage determination (LCD), the DME MACs have not had to comply with the rigorous clinical evidence standards required for LCDs.[11] In addition, the legal processes available to beneficiaries to challenge LCDs are not available to challenge BCD determinations. This means that private companies contracting with CMS (i.e., the DME MACs) wield extensive influence over access to benefits to which Medicare beneficiaries are entitled with no meaningful due process to challenge these decisions.

CMS Policy on Mobility Assistive Equipment

The NCD for MAE grants coverage for mobility assistance equipment when:

> "evidence is adequate to determine that MAE is reasonable and necessary for beneficiaries who have a personal mobility deficit to impair their participation in mobility-related activities of daily living (MRADLs) such as toileting, feeding, dressing, grooming, and bathing in customary locations within the home."[12]

The NCD sets forth a complex nine-step algorithm or "decision tree" for determining the clinical circumstances by which a specific type of MAE is appropriate for an individual covered under the Medicare program. Essential in applying this decision tree is the extent to which MAE will assist the individual to participate in MRADLs. For example, the criteria include whether the individual has a mobility limitation that "significantly impairs his/her ability to participate in one or more MRADLs at home." It also asks whether the individual has a comorbidity that would prevent effective use of MAE. The criteria include analysis of a number of other factors related to the home environment, access to caregivers and family support, and safety issues. Although the NCD refers to canes, crutches, walkers, manual wheelchairs, power wheelchairs, and scooters, it specifically states that "this list, however, is not exhaustive."

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[8] Arva J, et al., *RESNA Position on the Application of Wheelchair Standing Devices*, 21:161-168 (2009); Dicianno B, et al., *RESNA Position of Wheelchair Standing Devices: 2013 Current State of the Literature* (2013).
[9] Local Coverage Article for Wheelchair Options/Accessories – Policy Article A52504, published by CGS Administrators and Noridian Healthcare Solutions (revised Jan. 1, 2018).
[10] Local Coverage Determination: Wheelchair Options/Accessories (L33792), published by CGS Administrators and Noridian Healthcare Solutions (revised Jan. 1, 2018).
[11] Medicare guidance requires that LCDs, which address medical necessity under Section 1862(a0, be supported by "the strongest evidence available." CMS Pub. 100-08, Ch. 13 §13.7.1.
[12] CMS Pub. 100-03, Ch. 1, § 280.3.

HCFA Ruling 96-1

In HCFA Ruling 96-1, CMS provided clarification on the statutory DME and orthotics benefit categories. The case that prompted the issuance of HCFA Ruling 96-1 involved certain orthoses that were attached to a wheeled frame which was considered DME. In ruling that these orthoses could not be billed in a nursing home setting to Medicare Part B separately from the underlying wheeled DME frame, the agency stated, unequivocally, that accessories to wheelchairs and other items of DME are part of the DME benefit:

> "To the extent that a wheelchair seating system or other equipment may or may not function properly or not achieve its full "therapeutic benefit" without attached components supporting or restricting motion in a body part, the attachments are appropriately viewed as a necessary accessory that is an integral part of the durable medical equipment and is, accordingly, payable as durable medical equipment, provided that the other prerequisites for classification as durable medical equipment are met."

The standing feature is an accessory to a power wheelchair that is integral to its function for a person who needs to be able to adjust to a vertical standing position in order to achieve the full therapeutic benefit of a power wheelchair (i.e., DME). The standing feature supports motion in a body part (i.e., the entire body) that enables and facilitates the individual's ability to reach and access objects in order to perform MRADLs. For this reason, HCFA Ruling 96-1 is directly on point as it relates to the benefit category determination of standing feature.

National Coverage Determination for Seat Lifts

CMS has issued an NCD that allows coverage for seat lifts, recognizing that seat lifts can provide a therapeutic benefit for patients with neuromuscular diseases or severe arthritis of the hip or knee. The same rationale applies to coverage of the standing feature.

NCD 280.4 states in relevant part:

> "Reimbursement may be made for the rental or purchase of a medically necessary seat lift when prescribed by a physician for a patient with severe arthritis of the hip or knee and patients with muscular dystrophy or other neuromuscular diseases when it has been determined the patient can benefit therapeutically from use of the device. In establishing medical necessity for the seat lift, the evidence must show that the item is included in the physician's course of treatment, that it is likely to effect improvement, or arrest or retard deterioration in the patient's condition, and that the severity of the condition is such that the alternative would be chair or bed confinement."

The standing feature has even greater therapeutic benefit than a seat lift because, in addition to allowing an individual to perform MRADLs, it helps to improve cardio-metabolic health, bone density, and other physical conditions, as described above. It also serves to lessen the risk of secondary conditions such as decubitus ulcers in non-ambulatory individuals. Moreover, the standing feature is attached as an accessory to a power wheelchair, which is considered primarily

medical in nature, in contrast to a seat lift which is attached to a non-medical stationary chair. There is no reason why CMS should distinguish between coverage of a seat lift and coverage of the standing feature, especially since the standing feature presents an even stronger case on the issue of whether the device is sufficiently medical in nature.

National Coverage Determination for iBOT 4000 Mobility System

In 2006, CMS issued an NCD for the iBOT 4000 Mobility System that covers the "Standard Function" of the system but not its other functions, including a "Balance Function" that involves seat elevation.[13] The Standard Function is similar to a traditional power operated wheelchair. The Balance Function enables a user to move from a seated position to an elevated seated position where the four wheels rotate to a vertical position balancing on two wheels while the user remains in a seated function. In denying coverage for the Balance Function, CMS reasoned that "[s]eat elevation serves the same purpose as other equipment that assist all persons in reaching items out of reach or having an 'eye-level' conversation with a standing person."[14] The agency therefore determined that the Balance Function is not primarily medical in nature.

The NCD for the iBOT Mobility System has limited applicability to the unique features of the iBOT, a device that is no longer on the market. CMS' reasoning for denying coverage for the iBOT's Balance Function should not be extended to a power standing system, which has different functional and clinical benefits from the Balance Function. The standing feature goes beyond simply assisting individuals with "reaching items out of reach or having an eye-level conversation with a standing person." Power standing enables non-ambulatory individuals to perform essential MRADLs, including grooming, dressing, hygiene, and meal preparation.

Moreover, the physical benefits of attaining a vertical standing position through the standing feature have a direct therapeutic impact on individuals with mobility related diseases. Studies have found that the standing feature results in improved mobility and lower limb function in individuals with preserved muscle strength in the lower limbs, improves range of motion, reduces the risk of contractures, promotes bone density, and has a positive impact on cardio-metabolic health.[15] The power standing system is not primarily a convenience item but has direct therapeutic benefits for individuals with mobility related conditions. As a result, CMS' coverage determination with respect to the iBOT Balance Function is extremely narrow in applicability and should not be extended to the power standing system.

Relevant Administrative Decisions

In a 2014 Administrative Law Judge (ALJ) decision,[16] an ALJ ordered one of the four DME MACs (CGS) and the Qualified Independent Contractor (QIC) to pay a beneficiary's claim for

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[13] NCD 280.15 (effective July 27, 2006).

[14] CMS Decision Memorandum for the INDEPENDENCE 4000 iBOT Mobility System (July 27, 2006), https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=5&fromdb=true.

[15] Arva J, et al., *RESNA Position on the Application of Wheelchair Standing Devices*, 21:161-168 (2009); Dicianno B, et al., *RESNA Position of Wheelchair Standing Devices: 2013 Current State of the Literature* (2013).

[16] While ALJ decisions and most Medicare Appeals Council decisions do not constitute precedent that is binding on the agency, they are instructive and serve as useful background.

seat elevation, reasoning that the seat elevation device serves a medical purpose.[17] The beneficiary was originally denied coverage for both seat elevation (E2300) and standing feature (E2301), and on appeal the ALJ issued a favorable decision for the beneficiary with respect to both items. However, CMS requested review of the case by the Medicare Appeals Council which reviewed the decision with respect to seat elevation only[18] and remanded the case to the ALJ based in part on the ALJ's failure to accord substantial deference to the local coverage article, which states that seat elevation is not primarily medical in nature.

On remand, the ALJ accorded deference to the local coverage article but nonetheless departed from it. Although seat elevation was at issue, the reasoning applied by the ALJ could be similarly applied to coverage of the standing feature. The ALJ concluded that "the exclusion of coverage for the power seat elevation system is arbitrary" given that CMS has issued an NCD for seat lifts. The ALJ did not find any major distinction between a seat lift and a power seat elevation system, and in fact found that the case for the medical nature of seat elevation was even more compelling because it is an accessory to a power wheelchair, which is primarily medical in nature. The ALJ also relied on the medical opinion of an occupational therapist in finding that seat elevation serves a medical purpose "because it is therapeutic for patients to be able to transfer out of a wheelchair to use the bathroom, to bathe, or to perform other activities necessary to their health."

Again, although the standing feature was not the focus of the ALJ's decision on remand, a similar case can be made for coverage of standing feature given that it is an accessory to a power wheelchair that improves performance of MRADLs such as independence in hygiene, grooming, bathing, etc. Standing also has therapeutic benefits to the non-ambulatory beneficiary such as improved circulation, increased bone density, reduction of secondary injury such a decubitus ulcers (i.e., skin breakdown) and other health benefits as discussed more fully above.

In another case, however, the Appeals Council issued a contrary decision in 2011 with respect to standing feature.[19] The Appeals Council deferred to the local coverage article and found that the standing feature was "primarily for convenience." The beneficiary argued that the local coverage article was not entitled to deference because the contractor did not produce scientific evidence in support of the article. However, the Appeals Council reviewed scientific articles produced by the beneficiary and found that they did not express a consensus that the use of the standing feature was an effective medical treatment to prevent medical complications resulting from being bedfast or chairfast. More recent evidence clearly establishes the medical benefits of standing, especially for non-ambulatory individuals, as detailed above. Appeals Council decisions are not binding on CMS, and this decision, therefore, has no precedential value. We include it here to illustrate how the DME MAC local coverage article is adversely affecting Medicare beneficiaries.

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[17] ALJ Appeal No. 1-1097802958R1 (Midwestern Region, Cleveland, Ohio, Joseph C. Pastrana, ALJ).

[18] CMS referred the matter to the Appeals Council with respect to seat elevation only, so the Appeals Council did not review the ALJ's favorable decision with respect to standing feature.

[19] Medicare Appeals Council Docket No. M-10-1590, Jan. 20, 2011.

Position of DME Contractors is Inconsistent with CMS Policy

The position taken by the DME MACs that standing feature does not primarily serve a medical purpose is not consistent with CMS policy as articulated in Ruling 96-1 and the NCD on MAE. Moreover, it arbitrarily denies coverage even though standing feature has the same or even greater therapeutic benefits than a seat lift, which is covered by Medicare. Although Medicare contractors may have some latitude to develop policy, they must follow NCDs and other national policies and may not take a position contrary to national policy.[20]

- **The Standing Feature is DME**

A standing feature accessory or component of a power wheelchair meets the definition of durable medical equipment and CMS should explicitly issue a benefit category determination (BCD) to that effect. The position of the MACs is contrary to HCFA Ruling 96-1.[21] In that Ruling, the agency specifically considered the role of wheelchair accessories including "seating systems, rests and supporting and positional attachments" that are intended to be used with a seating system to which they are attached. The agency, citing the legislative history of the amendments to section 1834(a)(4) of the Act found that:

> "Ample evidence establishes that Congress intended sophisticated wheelchairs, including chairs with functional attachments, to be classified in their totality as durable medical equipment."[22]

Thus, CMS and Congress both take the position that the DME benefit includes attachments and accessories to power wheelchairs. This would include the standing feature accessory.

- **The Standing Feature Should Be Covered by Medicare When Medically Necessary and Clinically Appropriate**

CMS has presumptively determined that MAE that assists an individual in performing MRADLs must primarily serve a medical purpose and thus falls squarely within the DME benefit category. The standing feature can assist individuals to attain a standing position while in their wheelchairs, improving functional reach and enabling grooming, dressing, hygiene, and meal preparation, all of which CMS considers MRADLs. Since the standing feature can assist in the performance of these MRADLs, it follows that standing feature also primarily serves a medical purpose to the same extent as power wheelchairs and other MAE.

In the NCD for MAE, CMS has developed a complex algorithm for determining whether a particular item of MAE is medically necessary for a particular beneficiary. It is an *individual* determination that evaluates whether—and the extent to which—the MAE will help an individual participate in MRADLs. If the MAE does not assist an individual in performing MRADLs in the home, then, under the algorithm set forth in the NCD, the MAE may not be

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[20] CMS Pub. 100-08 §13.1.1.
[21] HCFA rulings are "binding on all [CMS] components, intermediaries and carriers . . ." and "promote consistency in interpretation of policy and adjudication of disputes."
[22] HCFA Ruling 96-1, September 1996.

covered. The DME MACs' position on coverage of standing feature is contrary to the NCD for MAE, ignores CMS national policy, and results in categorical denial regardless of individual need. It also deprives Medicare beneficiaries their right to a coverage determination based on their individual medical circumstances.

The overwhelming weight of the clinical evidence and common sense run counter to the position of the DME MACs that the standing feature embedded in a power wheelchair does not primarily serve a medical purpose. In fact, the standing feature helps improve the non-ambulatory individual's range of motion, increases circulation, promotes vital organ capacity, increases bone density, improves gastrointestinal track function, decreases the risk of secondary injury such as decubitus ulcers, and provides other documented health benefits, as detailed in the RESNA articles and numerous other studies that describe the positive health benefits of standing.

Moreover, the RESNA studies note that, in addition to physical/medical benefits, the standing feature provides numerous psychosocial and quality of life benefits for individuals using a power wheelchair. Recent federal mental health parity laws that place equal emphasis on the coverage of treatment for mental as well as physical conditions provide strong policy and public health support for the position that improvements in psychosocial status are just as relevant as improvements in physical status for purposes of determining whether the standing feature is sufficiently medical in nature to meet the definition of DME.

The following case study from the 2013 RESNA article is illustrative of the medical benefits of a standing wheelchair. It describes a 14-year-old boy with Duchenne Muscular Dystrophy who has difficulty with ambulation and is highly susceptible to falling. He requires bilateral upper extremity support for balance, which limits his independence with MRADLs in the standing position. He uses a power standing wheelchair to achieve therapeutic standing and allow for greater functional independence so he can perform his MRADLs. The standing feature also decreases the overall rate of progression of contractures, scoliosis, and the secondary complications that arise from such deformities (e.g., respiratory compromise, pain, etc.). Clearly the standing feature of a power wheelchair, as used by this individual with Duchenne Muscular Dystrophy, is primarily used to serve a medical purpose.

Conclusion

It is critical for CMS to clarify Medicare coverage policy on the standing feature in power wheelchairs. The standing feature is vital for people with mobility disabilities to perform MRADLs in the home and offers non-ambulatory beneficiaries numerous medical and psychosocial benefits. DME MAC Articles to the contrary are inconsistent with existing CMS policy, as expressed in Ruling 96-1 and the National Coverage Decision on Mobility Assistive Equipment.

We therefore urge CMS to require the DME MACs to determine coverage of the standing feature on an individual basis according to the NCD for MAE. In order to affect this, CMS must reconsider coverage of the standing feature in power wheelchairs and work with the DME MACs to rescind all DME Articles stating that standing feature does not primarily serve a medical purpose. CMS must also render a benefit category determination that establishes the standing

feature as qualifying under the definition of durable medical equipment when embedded in a power wheelchair. Medicare beneficiaries are entitled to an individual determination of coverage of all MAE, including the standing feature, based on their unique medical and functional circumstances.

Thank you for your consideration of this issue and we look forward to discussing this request with your further. If you have any questions, please contact Peter Thomas, ITEM Coalition Coordinator, at peter.thomas@powerslaw.com or 202-466-6550 at your convenience.

Sincerely,

The Undersigned Members and Friends of the ITEM Coalition
Academy of Spinal Cord Injury Professionals
ACCSES
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 Foundation for the Blind
American Medical Rehabilitation Providers Association
American Occupational Therapy Association
American Physical Therapy Association
American Therapeutic Recreation Association
Amputee Coalition
Association for Education and Rehabilitation of the Blind and Visually Impaired (AER)
Association of Assistive Technology Act Programs
Association of University Centers on Disabilities
Autism Self Advocacy Network
Brain Injury Association of America
Center for Assistive Technology, Buffalo, NY
Center for Medicare Advocacy
Christopher and Dana Reeve Foundation
Clinician Task Force
Institute for Matching Person & Technology, Inc.
Lakeshore Foundation
National Association for the Advancement of Orthotics and Prosthetics
National Coalition for Assistive & Rehab Technology
National Council on Independent Living
National Disability Rights Network
National Multiple Sclerosis Society
National Registry of Rehabilitation Technology Suppliers
Paralyzed Veterans of America
Rehabilitation Engineering and Assistive Technology Society of North America
Spina Bifida Association

The Arc of the United States
The Buoniconti Fund to Cure Paralysis
The Miami Project to Cure Paralysis
The Myositis Association
The Simon Foundation for Continence
Unite 2 Fight Paralysis
United Spinal Association
University of Pittsburgh, Department of Rehabilitation Science & Technology

cc:

Seema Verma, Administrator, Centers for Medicare and Medicaid Services (CMS)
Demetrios Kouzoukas, Principal Deputy Administrator and Director, Center for Medicare, CMS
Elizabeth Richter; Deputy Center Director, Center for Medicare, CMS
Kate Goodrich, M.D., Director and CMS Chief Medical Officer, Center for Clinical Standards and Quality, CMS
Laurence Wilson, Director, Chronic Care Policy Group, CMS
Joel Kaiser, Director of DME Policy, CMS