August 31, 2020

Seema Verma
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
200 Independence Ave., S.W., Mail Stop 314G
Washington, DC 20201

Dear Administrator Verma:

I write on behalf of the National Council on Disability (NCD) — an independent federal agency that advises the Administration, Congress, and federal agencies on disability policy — to respectfully request a meeting with you and your staff to discuss a matter of critical importance to millions of persons with mobility disabilities, many of whom are Medicare beneficiaries, and who rely upon the use of mobility devices in their daily lives. The purpose of the meeting is to discuss Medicare coverage for power seat elevation and power standing systems in Group 3 complex rehabilitative technology (CRT)\(^1\) power wheelchairs.\(^2\)

Over the years, NCD has heard from persons with mobility disabilities throughout the country, their loved ones, and their caregivers, as well as from rehabilitation technology professionals, CRT suppliers, and physicians for persons with mobility disabilities that require CRT, all conveying the need for Medicare coverage of power seat elevation and standing systems. Without these features and systems, wheelchair users have been and will continue to be harmed by potentially preventable medical complications such as pressure sores; musculoskeletal overuse injuries (e.g., neck, shoulder and wrist injuries); increased pain and decreased sitting tolerance; poorer respiratory support, pulmonary, toileting, and swallowing function; and compromised functional use of their arms. They may become confined to their bed and unable to perform mobility related activities of daily living (MRADLs) in their homes — the very criteria for Medicare coverage of mobility devices — nor access the community. Some may even need to be institutionalized due to their lack of access to appropriate CRT.

My brother, a disabled veteran, was a quadriplegic who relied on a power wheelchair for his freedom and independence. The wheelchair provided to him by the Veterans Affairs

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\(^1\) CRT is the category of durable medical equipment for people with complex, typically permanent disabilities who are unable to use standard durable medical equipment (see [https://www.ncart.us/uploads/userfiles/files/CRT%20Definition%206-1-14.pdf](https://www.ncart.us/uploads/userfiles/files/CRT%20Definition%206-1-14.pdf))

\(^2\) NCD is aware of an effort led by the Independence Through Enhancement of Medicare and Medicaid (ITEM) Coalition to submit a National Coverage Determination Request for Medicare coverage of seat elevation and standing systems in Group III CRT power wheelchairs and supports this request as it is consistent with NCD’s long-standing policy recommendations and statements.
(VA) did not include a standing system. The absence of the standing system required his wife and children to lift and hold him in a standing position to alleviate the pain and discomfort from prolonged sitting. As a direct result, his wife and children have lifelong back problems. Additionally, my brother’s premature death was caused by a combination of the medical issues associated with prolonged sitting and could have been mitigated by the usage of a standing system. I have personally witnessed the impact of a person with a disability not having access to the appropriate CRT and can affirmatively state that a standing and/or seat elevation system most assuredly provides a medical benefit and by CMS’s definition of Durable Medical Equipment (DME) these systems fall within that definition.

This is antithetical to the spirit of integration, inclusion, and support in the least restrictive environment, as laid out by the Olmstead Supreme Court decision and numerous federal consent decrees throughout the country. Indeed, the costs accrued due to the resultant harms from lack of appropriate CRT can in some cases far exceed the cost of the recommended and physician-prescribed mobility technology itself. Advancing broader coverage of mobility technology is not a novel matter for the National Council on Disability. NCD has released multiple reports regarding the struggles people with disabilities have incurred in their attempt to access durable medical equipment appropriate to suit their needs. In 2009, NCD authored a report titled, The Current State of Health Care for People with Disabilities, wherein NCD recommended:

“The Centers for Medicare & Medicaid Services (CMS) should update their current definitions of durable medical equipment and medical necessity, which are outdated and give little consideration to increasing an individual’s functional status. The current patchwork of both Federal and state health care and private insurance coverage contains barriers and gaps that leave many people with disabilities unable to obtain needed assistive technology.”

In 2016, NCD renewed these concerns and recommendations:

“A person with a severe disability may need wheelchair accessories such as standup features, the Centers for Medicare and Medicaid Services (CMS) does not provide clear definitions to distinguish complex rehabilitation technology (CRT) from durable medical equipment (DME). Action is needed to enable all people with disabilities to have access to the necessary technology that will give them the ability to achieve equal access to opportunity, inclusion, and self-determination.”

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In 2020, we renew our call for CMS to provide Medicare coverage for power seat elevation and power standing systems in Group 3 CRT power wheelchairs. We urge CMS to update existing durable medical equipment definitions and to clarify its coverage policy to improve the availability of much-needed durable medical equipment (e.g., power standing and seat elevation systems) for Medicare beneficiaries with disabilities.

**CMS Durable Medical Equipment Eligibility Determination History**

In 1996, CMS issued Ruling 96-1 that stated, “accessories to wheelchairs that are integral to their function are considered part of the durable medical equipment benefit.” The Ruling further stated:

“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 a 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 power standing and seat elevation systems embedded in certain CRT power wheelchairs support vertical movement in the beneficiary's home and support the motion of a body part. Both mechanisms are an integral part of the wheelchair seating system, allowing the individual to stand or elevate and achieve the full therapeutic benefit of the power wheelchair. As discussed below, power standing and seat elevation systems clearly provide a therapeutic medical benefit, simultaneously improving the ability of an individual to perform or participate in MRADLs in the home. Improving MRADL function is otherwise known as improving independence, a bedrock concept of disability policy. CMS Ruling 96-1 clearly establishes the agency's intent to define complex rehabilitative technology embedded within a wheelchair, such as power seat elevation and standing systems, as DME, and therefore as a Medicare-covered item, as long as the other prerequisites for classification are met.

In May 2005, CMS determined that evidence was adequate that mobility assistive equipment (MAE) is “reasonable and necessary for beneficiaries who have a personal mobility deficit sufficient to impair the participation in mobility related activities of daily living (MRADLs) in the home.” Both power standing and seat elevation systems

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6 CMS, National Coverage Determination (NCD) for Mobility Assistive Equipment (MAE), [https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=219&ncdver=2&MCId=19&McdName=Potential+NCD+Topics&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%257CCAL%257CCNCD%257CMEDC%257CCTA%257CMCD%257C%257C&ArticleType=Ed%257CKey%257CSAD%257CFAQ&PdicyType=Final&s=5%257C6%257C6%257C6%257C6%257C9%257C38%257C63%257C63%257C
provide a wheelchair user newfound independence to perform MRADLs (e.g., grooming, bathing, toileting) that would not be possible without the inclusion of the standing and/or seat elevation system embedded within the power wheelchair.

In 2004, after CMS's determination in Ruling 96-1 and before the May 2005 MAE determination, all four Durable Medical Equipment Medicare Administrative Contractors (DME MACs), providing no citations to medical literature supporting their conclusion, determined, via local coverage articles (LCAs), that seat elevation and standing systems in power wheelchairs are noncovered items because they were not “primarily medical in nature.” This determination was reaffirmed without citation to any evidence by the DME MACs via an LCA effective January of this year. This local coverage article was an addendum to a local coverage determination (LCD).

Since this determination was made via an LCA rather than a Local Coverage Determination (LCD), the DME MACs were not required to comply with the otherwise rigorous clinical evidence standards required for LCDs. In addition, there is no prescribed right of appeal for a benefit category determination. When the MACs (private companies who contract with CMS) issued this decision (originally in 2005 and again in 2020), they changed the landscape of CMS coverage. The method by which CMS chose to render this determination foreclosed the appeal process for Medicare beneficiaries. Most egregiously, the determination published by the DME MACs is inconsistent with current CMS policy and a substantial body of clinical literature.

**Wheelchair Standing Systems Provide a Medical Benefit and Assist in the Performance of or Participation in MRADLs in the Home**

The standing system, embedded within a power wheelchair, allows an individual to transition from a seated position to a standing position without the need of a wheelchair transfer. As discussed in a previous paragraph, for Medicare to classify an item as a DME, the item must meet the definition of durable medical equipment. This definition requires the item or device to be primarily medical in nature and not useful in the absence of an illness or injury. Once an item is determined to be part of the DME benefit, it will only be covered if it assists an individual with performance or participation in MRADLs.

NCD asserts that the power standing system is not only primarily medical in nature but assists an individual with MRADLs in the home. The power standing system assists those with limited reaching abilities to access objects within their home to assist in hygiene, dressing, grooming and meal preparation, all of which CMS considers

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41%257C64%257C65%257C44&KeyWord=wheelchairs&KeyWordLookUp=Doc&KeyWordSearchType=Exact&kq=true&bc=IAAAABAAAAAA, (accessed August 7, 2020)

7 CMS, Local Coverage Article: Wheelchair Options/Accessories-Policy Article (A52504), https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52504&ver=33&SearchType=Advanced&CoverageSelection=Local&ArticleType=BC|Reg&PolicyType=Both&s=All&KeyWord=Primarily+medical&KeyWordLookUp=Doc&KeyWordSearchType=Exact&kq=true&bc=EAAAAABAAAAA (Accessed August 8, 2020)
MRADLs. For those beneficiaries who require a power standing system in their power CRT wheelchair to perform MRADLs, the absence of this system as a Medicare-covered benefit limits their independence and ability to be self-sufficient in their own home and often requires additional personal assistance services through home health agencies or other programs which can add unnecessary costs.

As to the DME MACs’ determination that the power standing system is not “primarily medical in nature,” NCD posits the multitude of medical studies which have demonstrated that a power standing system does improve the overall health of a person with a disability. The use of a standing system can improve bone density, mobility, and lower limb function, and vital organ capacity including pulmonary, bowel, and bladder function. Standing systems can also offset the occurrence of pressure ulcers and reduce skeletal deformities. Prolonged sitting is associated with cardiovascular disease, diabetes and premature mortality. All of these medical conditions can be exacerbated by a wheelchair user’s inability to stand, and alleviated by the use of a standing system embedded in a power wheelchair.

The benefits associated with power standing systems as well as the aid with MRADLs that these systems provide make them primarily medical in nature. NCD respectfully requests that CMS direct the DME MACs to reverse and revoke their determination that a standing system on a power wheelchair is not eligible for Medicare coverage because it is not deemed to be used for primarily medical purposes.

**Power Wheelchair Seat Elevation Systems Provide a Medical Benefit and Assists in the Performance of or Participation in MRADLs in the home.**

The seat elevation system is a component to a CRT power wheelchair that is embedded in the mobility device itself. Like the power standing system, the seat elevation system was also determined by DME MACs to be “not primarily medical in nature”. A seat elevator raises or lowers the seat of the power wheelchair and is used to assist an individual when transferring from the wheelchair to another surface to perform MRADLs, such as a commode, bed, couch, chair, in order to perform or participate in MRADLs such as hygiene, grooming, dressing, and food preparation. The clinical literature indicates that seat elevation can reduce injuries due to falls during transfers and secondary injuries due to multiple transfers over the time of prolonged wheelchair use. Thus, a power seat elevation system fulfills CMS requirements for coverage under the NCD for MAE.

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9 Not to be overlooked, the seat elevation system is a critically important feature that will facilitate an individual's ability to either independently transfer or be transferred onto examination tables, examination chairs and medical diagnostic equipment, given the absence of height adjustable examination tables, examination chairs and medical diagnostic equipment. See, National Council on Disability, "The Current State of Health Care for People with Disabilities, footnote 3 above.
In 2014, a CMS Administrative Law Judge (ALJ) decision overturned the DME Macs’ determination of noncoverage of a power standing and seat elevation system determining that the seat elevation device “serves a medical purpose”.10 The position of the DME Macs' that a seat elevation system embedded in a power wheelchair does not primarily serve a medical need runs afoul of the clinical evidence in support of the medical benefits and assistance this feature offers beneficiaries in performing or participating in MRADL’s in the home.

A Medicare beneficiary who would otherwise be eligible for a power seat elevation system should not be required to adjudicate a claim in order to receive eligible benefits to which they are entitled. It is clear that a qualified wheelchair user does attain medical benefits from a power seat elevation system, as well as the ability to perform additional MRADLs in the home, which may be unattainable without power seat elevation. To ensure consistency with CMS policy and eliminate the burden of cases presented to ALJs, NCD recommends CMS require the DME MACs to revise their determination in the local policy articles to reflect that power seat elevation systems are primarily medical in nature and, thus, fall under the CMS definition of durable medical equipment and that medical necessity for these systems should be assessed on an individual basis.

**The MAC Determination That Power Wheelchair Standing and Seat Elevation Systems Are Not Primarily Medical in Nature Contradicts Long-Standing CMS Policy**

The DME MACs’ arbitrary determination that standing and seat elevation systems embedded in power wheelchairs are “not primarily medical” is contrary to the National Coverage Determination for MAE, ignores CMS national policy (i.e., CMS Ruling 96-1), is inconsistent with a substantial clinical evidence base, and deprives Medicare beneficiaries of their right to a coverage determination based on their individual medical circumstances. Medicare contractors are given some latitude to develop coverage policy, but they still must follow CMS national policies and may not take a position that is contrary to that policy.11 NCD asserts that the DME MACs’ determination that the power standing and power seat elevation systems are “not primarily medical” is a position contrary to CMS policy and must be overturned.

NCD therefore urges CMS to issue an affirmative benefit category determination establishing that standing and seat elevation systems embedded in power wheelchairs fall under the definition of durable medical equipment. CMS should amend the National Coverage Determination for MAE to clarify Medicare coverage of these systems. CMS should then proceed with development of a Local Coverage Determination to assess the medical necessity for such equipment on an individual basis in accordance with the National Coverage Determination for MAE. In order to affect this, CMS should require all DME MACs to rescind all DME coverage articles stating that the standing and seat

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10 ALJ Appeal No. 11097802958R1 (Midwestern Region, Cleveland Ohio, Joseph C. Pastrana, ALJ).
elevation systems embedded in power wheelchairs do not primarily serve a medical purpose. In addition, in order to prevent ambiguous future determinations, CMS should issue an affirmative benefit category determination establishing that the standing and seat elevation systems embedded in power wheelchairs do fall under the definition of durable medical equipment.

We welcome a meeting with you and your staff to discuss this matter. Please contact Lisa Grubb, Executive Director and CEO at lgrubb@ncd.gov and/or Joan Durocher, General Counsel and Director of Policy, at jdurocher@ncd.gov to schedule a meeting.

Respectfully,

Neil Romano
Chairman
Cc:   Paul Mango, Deputy Chief of Staff for Policy, Office of the HHS Secretary
      Demetrios Kouzoukas, Principal Deputy Administrator, CMS
      M.J. Chang, Director, Chronic Care Policy Group, CMS
      Tamara Syrek-Jenson, Director, Coverage and Analysis Group, Center for
      Clinical Standards and Quality, CMS