March 17th, 2022

SUBMITTED ELECTRONICALLY VIA Medicare Coverage Database Portal

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

Re: CAG-00461N: Seat Elevation Systems as an Accessory to Power Wheelchairs

Dear Administrator Brooks-LaSure:

In service of the neuromuscular disease (NMD) patient community, the Muscular Dystrophy Association (MDA) thanks the Centers for Medicare and Medicaid Services (CMS) for the opportunity to comment on CMS' national coverage redetermination (NCR). We are grateful for CMS' proposal to cover seat elevation systems for Group 3 wheelchairs, as these features are vital for our constituents' health, safety, and independence. Additionally, however, we urge CMS to consider extending coverage for the purposes of reach and line of sight needs in addition to weight-bearing transfers and specialty evaluations, and to extend coverage to group 2 wheelchairs.

MDA is the nation's leading nonprofit organization dedicated to empowering the lives of individuals living with neuromuscular diseases through innovations in science and innovations in care. MDA fulfills its mission by funding biomedical research, providing access to expert clinical care and support through its national MDA Care Center Network, and championing public policies and programs that benefit those we serve. Since its inception, MDA has invested more than $1 billion in research grants to accelerate treatments and cures for neuromuscular disorders, making MDA the largest source of neuromuscular disease research funding in the U.S. outside of the federal government.

Background:

Neuromuscular diseases affect individuals' muscles, limbs, and mobility and often lead to reliance on a wheelchair or other assistive mobility device. To completely address the loss of function that results from mobility-related disabilities, we encourage CMS to acknowledge the full range of functional loss. People who qualify for complex rehab power wheelchairs classified as Group 3, as well as those that use Group 2 chairs, require the use of their wheelchair for all activities throughout the day.

The reduced mobility brought on by wheelchair use has many effects on those with neuromuscular diseases. Most notably, there are a large number of health effects that stem from

using a wheelchair.[1] Additionally, using a wheelchair results in reduced mobility and presents obstacles to self-sufficiency as well as safety concerns.[2] Due to these limitations and the consequences therein, it is essential that CMS provide coverage for these features.

The benefit of Seat Elevation Technologies:

The medical issues posed by standard wheelchairs outlined above are all significantly ameliorated by seat elevation systems.[3] CMS has received many peer-reviewed articles from other organizations that will provide considerably more data on the many additional benefits of seat elevation systems, including the benefits for improved circulation, mobility, gastrointestinal health, range of motion, promotion of vital organ capacity, improved bone density, and reduced occurrence of skin ulcers and skeletal deterioration.[4] Given the data provided to CMS, it is clear that coverage of these devices is medically necessary.

In addition to the medical necessity of these devices, we would like to draw CMS' attention to the fact that seat elevation systems vastly improve users' ability to perform daily living activities such as bathing, cooking, and cleaning more safely and with less physical strain which only furthers the health of users.[5] Finally, seat elevation systems make transfers in and out of seats vastly safer and less physically costly.[6] Not only does this ease of transfer help with the quality of life of users generally, but also, safe transfer makes travel considerably more accessible. This accessibility for travel is particularly important for members of the NMD community as traveling to see medical specialists across the country is common.

In light of these benefits, we believe CMS should expand its coverage determination to include those that would benefit from increased reach and line of sight. CMS limited its evidence review to only clinical studies regarding transfers.[7] However, as can be seen in the data provided in this comment, and in the many others submitted by healthcare providers and other patient advocacy organizations, there is extensive data to show that there are both medical benefits and benefits to mobility-related activities of daily living (MRADLs) associated with increased ability to reach and adjust neck positioning.[8] Based on this evidence, it is abundantly clear that the medical value provided by seat elevation systems for reach and line of sight meets the reasonable and necessary standard required.

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[1] *See generally,* Caulton, et. al. *A randomized controlled trial of standing programme on bone mineral density in non-ambulant children with cerebral palsy,* ARCHIVES OF DISEASE IN CHILDHOOD, *89(2), 131-35.*
[2] *See generally,* Arva et. al. *RESNA Position on the Application Seat-Elevating Devices for Wheelchair Users,* https://www.rstce.pitt.edu/RSTCE_Resources/Resna_position_on_seat%20elevation.pdf
[3] Newman et. al. *The effect of supported standing in adults with upper motor neurone disorders: a systematic review,* Rev 26(12):1059–1077. *See also generally,* Arva et. al. Supra, note 2.
[4] *Id.*
[5] Herberts et. al. *Shoulder pain and heavy manual labor,* Clinical Orthopaedics & Related Research, 166-78. *See also,* Palmerud et al. *Intramuscular pressure of the infra- and supraspinatus muscles in relation to hand load and arm posture,* European Journal of Applied Physiology Rev. 83, 223-30
[6] *Id.*
[7] National Coverage Analysis Proposed Decision Memo, Centers for Medicare and Medicaid Services, Seat Elevation Systems as an Accessory to Power Wheelchairs (Group 3) (Feb. 15, 2023). https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=Y&NCAId=309 [hereinafter National Coverage Analysis]
[8] *See generally,* Palmerud et. al. Supra, note 5.

The Benefit of Seat Elevation Technologies in Group 2 Wheelchairs:

In addition to covering seat elevations for the purposes of reach and line of sight, MDA is grateful for CMS' consideration of expanding coverage for seat elevation systems to Group 2 wheelchairs and would encourage CMS to do so. Many in the NMD community, those living with inclusion body myositis and myasthenia gravis, for example, are candidates for Group 2 wheelchairs, and would benefit greatly from standing just as those who use Group 3 wheelchairs, such as those living with amyotrophic lateral sclerosis (ALS) and muscular dystrophy would. The benefits of seat elevation systems for those that use Group 2 wheelchairs are similar to the benefits for those that use Group 3 wheelchairs.

Seat elevation systems would provide all of the medical benefits listed above, as well as assist with MARDLs and reduce strain during "sit to stand transfers".[9] Many in the NMD community are deemed a high fall risk and experience falls when standing, or attempting to stand, while performing MARDLs.[10] As above, given the medical benefit of seat elevation and the risk of harm while performing transfers and/or MARDLs, it is clear that the benefit to those that use Group 2 wheelchairs rises to the reasonable and necessary standard required.

Request for clarification:

MDA seeks clarification in the following areas with regard to the text of the NCR to ensure that future Local Coverage Determinations (LCDs) do not come into conflict with the intent of CMS' NCR.

Clarification on the meaning of "weight-bearing transfers"

The proposed decision memo states that power seat elevation can be found to be reasonable and necessary for beneficiaries who perform "weight-bearing transfers" to and from their power wheelchair within the home. The coverage criteria states that this can include the use of upper extremities for non-level sitting transfers and/or the use of lower extremities during a sit-to-stand transfer and can be supported with or without caregiver assistance. However, the decision memo is then silent as to its intended definition, and limitations therein, of the term "weight-bearing transfer."[11]

This definition may exclude those that perform dependent transfers as they cannot assist with their own transfers by bearing their own weight. Given that all transfers to and from a wheelchair require weight to be borne *somewhere*, all transfers *are* weight bearing transfers. Additionally, those that perform dependent transfers will still medically benefit from a seat elevation system's assistance with performing MRALDs, meeting the standard laid out by the NCR.

[9] *Id. See also generally,* Arva et. al. Supra, note 2.
[10] *See,* Berends et. al. High incidence of falls in patients with myotonic dystrophy type 1 and 2: A prospective study, Neuromuscular Disorders, Vol. 29, Issue 10, 758,758-65, Oct. 2019.
[11] National Coverage Analysis, supra, note 7.

Therefore, we request that CMS clarify this term to ensure that all individuals who would benefit from transfers are included in coverage, and particularly those that perform dependent transfers, are not precluded from accessing seat elevation systems.

Clarification on treatment of beneficiaries who use patient transfer devices

Similarly, CMS states in its proposed decision memo that "[t]ransfers may be accomplished with or without caregiver assistance and/or the use of assistive equipment (e.g. sliding board, cane, crutch, walker)."[12] While this list is not exhaustive, we did take note of CMS' lack of language to open the list, and the lack of more advanced assistive technologies, such as patient transfer devices that may be mounted to the floor or ceiling to assist with patient transfers. As with those that rely on a caregiver for a dependent transfer, patients that use devices such as mounted mechanical lifts would still benefit from seat elevation systems to perform MRALDs and when transferring to a surface in their home that is not accessed by their mounted mechanical lift.

We encourage CMS to clarify that patient transfer devices such as mounted lifts are included in the intended definition of "assistive technology" used in the proposed decision memo and that the use of such devices should not preclude a beneficiary from otherwise qualifying for coverage.

Conclusion:

MDA is committed to ensuring that individuals with neuromuscular diseases have access to devices to promote safe and healthy lives. We encourage CMS to provide coverage for seat elevation systems.

We appreciate this opportunity to provide comment on CMS's national coverage redetermination. For questions regarding MDA or the above comments, please contact me at 336-409-4000 or jcartner@mdausa.org.

Sincerely,

Joel Cartner

Joel Cartner, Esq.
Director, Access Policy
Muscular Dystrophy Association

[12] *Id.*