



September 14, 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: Medicare Coverage of Seat Elevation and Standing Systems in Power Wheelchairs

Dear Administrator Brooks-LaSure:

The Independence Through Enhancement of Medicare and Medicaid (ITEM) Coalition submits these comments to assist the Centers for Medicare and Medicaid Services (CMS) in assessing the pending National Coverage Determination (NCD) Request for Reconsideration of the NCD for Mobility Assistive Equipment (MAE), originally submitted in September 2020 and formally accepted by CMS as “complete” in November 2020. The Reconsideration Request seeks Medicare coverage of seat elevation and standing systems in power wheelchairs for Medicare beneficiaries with mobility impairments. The ITEM Coalition prepared and submitted the original NCD Reconsideration Request, which was detailed and well-documented, totaling 62 pages in length with 129 evidentiary sources and 314 footnotes and citations. Over 60 national clinical, disability, and research organizations offered written support in favor of the NCD Reconsideration Request.

The ITEM Coalition is comprised of nearly 100 national 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. As the original submitter of the NCD Reconsideration Request on Medicare Coverage of Seat Elevation and Standing Systems in Powers Wheelchairs, we believe it is unnecessary to submit comments that restate and support our original request. However, the ITEM Coalition submits these comments to help CMS identify additional specific evidence and support for our request since the filing of our original NCD Reconsideration Request more than two years ago. This additional evidence lends further support to a favorable coverage determination of seat elevation AND standing systems in power wheelchairs. While the current National Coverage Analysis (NCA) only considers seat elevation systems, we reiterate our contention that the two systems are linked and were included together in the original NCD Reconsideration Request, and thus we continue to urge CMS to quickly open an advance an NCA for coverage of standing systems as well.

ITEM Coalition Request:

The ITEM Coalition's Reconsideration Request asks CMS to revise the NCD for MAE to make two determinations for BOTH seat elevation and standing systems in power wheelchairs:

- 1) A benefit category determination establishing that power seat elevation and power standing systems are primarily medical in nature, and therefore, satisfy the Medicare definition of durable medical equipment (DME); and,
- 2) A coverage determination establishing that power seat elevation and power standing systems are covered DME benefits for Medicare beneficiaries with mobility impairments who can demonstrate need for these systems.

The NCD Request seeks these two determinations, minor amendments to the NCD for MAE to permit coverage of these systems, a new Local Coverage Determination (LCD) to identify which beneficiaries can benefit most from coverage of these systems, and additional coding and payment changes to ensure appropriate access to care.

However, CMS chose to bifurcate the ITEM Coalition 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 later date. The ITEM Coalition submitted a joint request and, from the perspective of Medicare beneficiaries with mobility impairments, believes the coverage of these two systems is interrelated. While disappointed that CMS chose to bifurcate its coverage request, the ITEM Coalition submits comments on seat elevation coverage at this time and strongly encourages CMS to press forward with opening a separate NCD Reconsideration Request for standing systems in power wheelchairs at the earliest possible opportunity.

Reconsideration Request Blazes No New Trails:

The ITEM Coalition's Reconsideration Request is not based on a novel theory, nor does it ask CMS to ignore or stretch the bounds of its existing benefit category or coverage rules. Both seat elevation and standing systems squarely meet the five-prong regulatory definition of DME. These systems are durable and can withstand repeated use. Despite the contention of CMS' Medicare Administrative Contractors to the contrary, they are primarily medical in nature, are generally not useful in the absence of an illness or injury, and they are medically necessary for use in the beneficiary's home. Much like power tilt and recline systems that Medicare routinely covers as DME, seat elevation and standing systems clearly qualify as DME.

In addition, the request for coverage of both seat elevation and standing systems is completely consistent with the NCD for Mobility Assistive Equipment, which establishes medical necessity based on beneficiary participation in or performance of mobility related activities of daily living (MRADLs) in the home. Evidentiary studies in support of coverage of both seat elevation and standing systems are highlighted in the ITEM Coalition's original NCD Reconsideration Request.

In short, there is no statutory or regulatory bar to Medicare coverage of these systems. The benefit category and coverage determinations that CMS renders on seat elevation and standing systems in power wheelchairs will turn on a reasonable interpretation of existing statutory, regulatory, and guidance provisions and the strength of the clinical evidence base.

The Current LCA on Seat Elevation and Standing Systems May be Invalid:

Not only is there no existing statutory or regulatory bar to Medicare coverage of seat elevation and standing systems in power wheelchairs, the Local Coverage Article (LCA) on which current non-coverage relies may be invalid. In 2004, the DME Medicare Administrative Contractors (DME MACs) published a Local Coverage Article (A52504), which states that power seat elevation and power standing systems are “not primarily medical in nature” and, therefore, are non-covered. (Noridian Healthcare Solutions, LLC & CGS Administrators, LLC, Local Coverage Article: Wheelchair Options/Accessories – Policy Article (A52504)).

This LCA was issued without any rationale or evidentiary support, and it was issued without being exposed to public notice and comment. The LCA inappropriately restricts access to these two medically necessary benefits to which certain Medicare beneficiaries with mobility impairments and other medical needs are entitled. A recent decision by the U.S. Supreme Court calls into question the continued validity of LCA A52504 because it establishes a substantive legal standard for payment of power seat elevation and power standing systems that was not issued through notice-and-comment rulemaking. (See, *Azar v. Allina Health Servs.*, 139 S. Ct. 1804 (2019)). CMS must reconcile the *Allina* holding with the LCA on seat elevation and standing systems in power wheelchairs and should revisit this decision in this NCD Reconsideration Request.

Robust Support for Coverage:

The opening of the NCA for Seat Elevation has generated extensive and unwavering support for CMS to cover these systems as DME and to develop a reasonable coverage policy to meet beneficiary needs. At the time of this writing, CMS has received over 3,200 separate and unique comments from Medicare beneficiaries with mobility impairments, rehabilitation therapists who address the mobility device needs of beneficiaries, physicians who treat this patient population, rehabilitation hospitals, seating clinics, researchers, manufacturers and suppliers, and the general public. Numerous national organizations have submitted robust comments in support of seat elevation, including the Clinician Task Force, a group of dedicated experts in wheelchair seating and positioning, as well as the American Medical Association, whose House of Delegates passed a resolution in recent years supporting Medicare coverage of seat elevation and standing systems in power wheelchairs.

The ITEM Coalition also hosted a public petition through the organization www.Change.org that garnered nearly 3,500 signatures to date since being launched on August 14, 2022, the date of the opening of the seat elevation NCA. The petition states as follows:

“The Medicare program currently denies coverage for seat elevation and standing systems in power wheelchairs. This means that Medicare beneficiaries with mobility

impairments are forced to go without medically necessary wheelchair technology if they are not able to afford the costs out of pocket. The Medicare program is currently reviewing a request to provide coverage for these critical systems, known as a "National Coverage Determination" or "NCD Request."

If successful, Medicare will recognize for the first time that these systems are "primarily medical in nature," and, therefore, covered durable medical equipment benefits - not convenience or luxury items for wheelchair users. These systems help wheelchair users carry out important daily activities more independently, such as cooking, eating, and toileting. They also provide numerous health benefits, such as decreased risk of falls or injuries when moving in and out of wheelchairs, improved heart and lung functions, increased bone strength, and improved joint mobility, bladder function, and muscle strength.

Medicare has denied access to these technologies for far too long. Sign your name below to request that Medicare provide coverage for seat elevation and standing systems and allow Medicare beneficiaries with mobility disabilities access to the care they need!"

A key reason for the robust support for coverage of these systems lies in the value they bring to non-ambulatory individuals. In fact, given the fact that both of these systems have been available to persons with mobility disabilities for over twenty years, the ITEM Coalition believes that Medicare coverage is long overdue. Both seat elevation and standing systems assist or enable beneficiaries with mobility impairments to perform MRADLs in the home. Seat elevation is a feature that allows non-ambulatory individuals to participate in or perform MRADLs such as grooming, preparing meals, toileting, and other MRADLs in the home, the existing standard for mobility device coverage under the NCD for MAE. Seat elevation assists individuals with transfers from one surface to another, decreases the risk of falls during transfers, and helps relieve neck and back pain when interacting with others from a seated position.

Standing systems elevate the seated power wheelchair user into a standing position which helps the individual participate in or perform MRADLs and has been demonstrated to improve a wide range of bodily systems for individuals who are otherwise largely sedentary. The evidence base is replete with studies of how standing (and gravity) can help with bone density, muscle tone, motility, respiration, circulation, skin integrity, and other bodily systems.

National Council on Disability Roundtable:

The National Council on Disability, a quasi-federal agency that addresses policies impacting persons with disabilities, has been focused on coverage of seat elevation for many years, most recently hosting a Roundtable discussion on Medicare coverage of these two systems held on August 3, 2022. The written report on the Roundtable, which features perspectives from all stakeholders in seat elevation and standing system policy, will be sent to CMS in the near future. The Roundtable emphasized the evidentiary foundation for Medicare coverage of these important benefits for persons with mobility impairments with every speaker strongly supporting Medicare coverage of both seat elevation and standing systems.

New Evidence on Seat Elevation Since Submission of the NCD Reconsideration Request:

In the 23 months between submission of the NCD Reconsideration Request and the opening of the NCD for public comment, several evidence-based articles were published on the efficacy of seat elevation and standing systems that were not able to be included in the original 62-page NCD Reconsideration Request. A summary of that evidence pertaining to seat elevation is well summarized by the Clinician Task Force, an ITEM Coalition member that submitted comments to CMS during the open public comment period. The Clinician Task Force is a non-profit organization comprised of professionals who practice, serve, provide education to, and advocate for individuals who require seating and wheeled mobility technologies. The CTF mission is to provide clinically based expertise to inform and promote public policy, best practices, and positive outcomes regarding people with disabilities who require Complex Rehab Technology (CRT) products and related services.

The original NCD Reconsideration Request detailed the medical and functional advantages of power seat elevation in relationship to MRADLs, specifically for power wheelchair users' performance of transfers, and in activities requiring reach and line of sight. CMS specifically requested additional information on the measurable characteristics related to the performance of transfers. The CTF summarized new research on transfers and we refer CMS to these comments for more detailed information.

Also summarized in the CTF submission is recent evidence that continues to support the use of power seat elevation systems during transfers. Most notably, a large-scale retrospective study of 1,733 power wheelchair users compared those with a seat elevator (256 users) to those who did not use seat elevators (1,468 users). When responding about functional status on the Functional Mobility Assessment, people with power seat elevation systems reported significantly higher scores of overall function and transfer status than those without power seat elevation systems (Mesoros et al., 2022). These results were for all power wheelchair users; however, a secondary analysis revealed maintained significance in these areas for people using only Group 3 power wheelchairs (Mesoros et al., 2022). Furthermore, this study supports the assertion in the original request that the use of power seat elevation systems would reduce falls – in this research study, people using power seat elevation systems in power wheelchairs were 21% less likely to report falls, remaining consistent for Group 3 power wheelchair users (Mesoros et al., 2022). (This article has been approved for publication and should be available online with an assigned DOI within a few days of the end of the public comment period; more detail on this analysis can also be found in the public comment submitted by Mark Schmeler, PhD, one of the authors on the study).

To bolster the published research on the impact of seat elevation on transfers, the CTF took the lead during the 30-day comment period to develop a survey that elicited expert clinical opinion on this issue, one of the pillars of evidence-based practice. The survey was distributed to expert health care providers involved in seating and mobility equipment and was open for respondents between August 22, 2022 and September 7, 2022. Respondents consisted of 29 (43%) physical therapists, 26 (38%) occupational therapists, 11 (16%) physiatrists, and 2 (3%) physician and physician assistants. The results of the survey are summarized in the CTF's public comments,

and we refer you to them. The results represent strong consensus on the value of seat elevation for people using Group 3 power wheelchairs.

ITEM Coalition Request Summary:

After nearly two years waiting for CMS to open the NCD Reconsideration Request for Medicare Coverage of Seat Elevation and Standing Systems in Powers Wheelchairs, we urge CMS to expeditiously review and consider the public comments to the seat elevation NCD and publish a preliminary decision for public comment as expeditiously as possible. We also strongly urge the agency to open the standing system NCD at its earliest opportunity and continue to weigh the evidence for coverage of both of these important wheelchair accessories for Medicare beneficiaries with mobility disabilities.

Sincerely,

Peter Thomas, JD and Joe Nahra
ITEM Coalition Co-Coordiators