



VIA ELECTRONIC MAIL

March 8, 2024

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

Tamara Syrek-Jensen
Director, Coverage and Analysis Group
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Reaffirmation of Request for CMS to Open a National Coverage Analysis on Medicare Coverage of Standing Systems in Group 3 Power Wheelchairs

Dear Administrator Brooks-LaSure and Director Syrek-Jensen:

On behalf of the 60 undersigned members of the Independence Through Enhancement of Medicare and Medicaid (“ITEM”) Coalition and other supporting organizations that endorsed our original request in 2020 for the Centers for Medicare and Medicaid Services (“CMS”) to conduct a National Coverage Analysis (NCA) for Medicare coverage of seat elevation and standing systems in power wheelchairs, we write to reaffirm our request for CMS to expeditiously open an NCA for standing systems in Group 3 power wheelchairs, which are classified by Medicare as complex rehabilitative technology (CRT) wheelchairs.

This aspect of our pending National Coverage Determination (NCD) Reconsideration Request was bifurcated by CMS when it considered and granted Medicare coverage for seat elevation in powers wheelchairs between August 15, 2022 and May 15, 2023. Three and a half years have elapsed since the ITEM Coalition submitted its original NCD Reconsideration Request for Medicare coverage of standing systems and nine months have passed since the announcement of the final seat elevation NCD. During this time, Medicare beneficiaries with mobility disabilities in need of standing systems to perform Mobility Related Activities of Daily Living (MRADLs) and remain as healthy and functional as possible have gone without this vital benefit.

We strongly urge you and your colleagues at CMS to finally, formally open an NCA on Medicare coverage of standing systems in Group 3 CRT power wheelchairs at your earliest possible opportunity. With the change in personnel and familiarity with this issue that inevitably comes with the results of the impending national elections, however they turn out, time is of the essence.

Specifically, we seek reconsideration of the NCD for Mobility Assistance Equipment (MAE) to:

- (1) establish a benefit category determination (“BCD”) that power standing systems in power CRT wheelchairs are “primarily medical in nature” and, therefore, covered durable medical equipment (DME) under the Medicare program, and

(2) explicitly recognize coverage of these systems as reasonable and necessary for beneficiaries with a medical or functional need for standing systems in Group 3 power wheelchairs in order to perform or participate in MRADLs in the home.

The ITEM Coalition is a national consumer- and clinician-led coalition advocating for access to and coverage of assistive devices, technologies, and related services 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 providers who serve them, including such conditions as multiple sclerosis, spinal cord injuries, brain injuries, stroke, paralysis, limb loss, cerebral palsy, spina bifida, muscular dystrophy, neurological impairments, and other life-altering conditions.

As we noted in our original 2020 submission, the medical benefits of power standing systems in power CRT wheelchairs are beyond dispute. Spending one's life unable to stand or ambulate, restricted to a bed, chair, or wheelchair 24 hours a day, seven days a week, dramatically inhibits the ability to participate in and perform MRADLs and causes countless complications and secondary conditions that are almost entirely avoidable with access to power standing systems in Group 3 power wheelchairs.

Standing systems are critical to MRADL participation and performance, the standard for coverage under the Medicare mobility equipment benefit. Standing systems improve joint mobility and muscle tone, increase strength and bone density, assist bladder and bowel management, enhance cardiovascular and respiratory functions, and reduce pressure injuries of the skin. Standing systems provide medical and functional benefits while reducing costs to the Medicare program by decreasing falls, skin breakdowns, muscle contractures, and numerous other avoidable medical complications of long term or permanent wheelchair use. They will also allow beneficiaries with mobility impairments to be more functional and less reliant on other caregivers, whether these caregivers are family members or paid homecare providers or personal assistants.

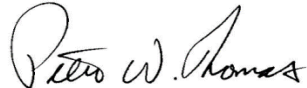
On September 26, 2023, the ITEM Coalition met with key members of the Center for Clinical Standards and Quality, Coverage and Analysis Group, to discuss the formal opening of the standing system NCA. In response to questions that arose during that call, we have attached a document that parses which Medicare beneficiaries with mobility impairments require seat elevation, which beneficiaries require standing systems, and which require both systems. (See Addendum No. 1.) Also attached to this letter, please find updated information and an updated set of clinical studies that demonstrate the evidence base and value of standing systems. (See Addendum No. 2.) Many of these new studies were published after submission of our formal 2020 NCD Reconsideration Request, also attached, which we incorporate into this reaffirmed Reconsideration Request by reference.

In preparing these updated materials on standing systems, the ITEM Coalition again relied on the Clinician Task Force, an ITEM Coalition member comprised of clinical experts in wheelchair seating and mobility, to re-examine the evidence base of power standing systems and compile the attached updated evidence-based coverage rationale. We believe that granting coverage of standing systems in Group 3 powers wheelchairs is crucial to help ensure that Medicare beneficiaries with mobility impairments are able to live as independently as possible, maintain and improve their health and function, and perform or participate in MRADLs in their homes.

Power standing systems have been available to individuals with mobility disabilities for decades and are covered by the Veterans Administration. Yet, Medicare beneficiaries have been deprived of access to this technology to date. Now is the time for Medicare—the largest health care payer in the country—to finally cover power standing systems in Group 3 power wheelchairs.

Thank you for your consideration of our request. Should you have any further questions regarding this issue, please contact me at Peter.Thomas@PowersLaw.com or call 202-607-5780.

Sincerely,



Peter W. Thomas, J.D.

ITEM Coalition Coordinator

On behalf of the signors to the original NCD Reconsideration Request Submitted to CMS in September 2020.

The Undersigned Members of the ITEM Coalition and Other Supporting Organizations

Academy of Spinal Cord Injury Professionals
ALS Association
American Academy of Physical Medicine and Rehabilitation
American Association for Homecare
American Association on Health and Disability
American Cochlear Implant Alliance
ACCSES
American Congress of Rehabilitation Medicine
American Medical Rehabilitation Providers Association
American Music Therapy Association
American Network of Community Options and Resources
American Occupational Therapy Association
American Physical Therapy Association
American Speech-Language-Hearing Association
American Therapeutic Recreation Association
Amputee Coalition
The Arc of the United States
Assistive Technology Industry Association
Association of Assistive Technology Act Programs
Association for Education and Rehabilitation of the Blind and Visually Impaired
Association of University Centers on Disabilities
Blinded Veterans Association
Brain Injury Association of America
The Buoniconti Fund
Caregiver Action Network
Center for Medicare Advocacy

Child Neurology Foundation
Christopher and Dana Reeve Foundation
Clinician Task Force
Council of State Administrators of Vocational Rehabilitation
Cure SMA
Disability Rights Education and Defense Fund
Easterseals DC MD VA
Lakeshore Foundation
Institute for Matching Person and Technology
Medicare Rights Center
The Miami Project to Cure Paralysis
National Association for the Advancement of Orthotics and Prosthetics
National Association for Home Care and Hospice
National Association for the Support of Long Term Care
National Association of Councils on Developmental Disabilities
National Association of Rehabilitation Research and Training Centers
National Coalition of Assistive and Rehab Technology
National Council on Independent Living
National Disability Rights Network
National Multiple Sclerosis Society
National Registry of Rehab Technology Suppliers
Paralyzed Veterans of America
Rehabilitation Engineering and Assistive Technology Society of North America
Spina Bifida Association
Team Gleason
Unite 2 Fight Paralysis
United Cerebral Palsy
United Spinal Association
The Viscardi Center

Additional Supporting Organizations

American Spinal Injury Association
Child Neurology Society
Falling Forward Foundation
National Association of State Head Injury Administrators
National Disability Institute

Addendum No. 1

Medicare Beneficiaries Who Require Standing Systems, Seat Elevation, or Both

With respect to the ITEM Coalition’s NCD Reconsideration Request involving Medicare coverage of standing systems in Group 3 power wheelchairs, and in response to Dr. Susan Miller’s request on September 26, 2023, to parse which beneficiaries require seat elevation, standing systems, or both, this document intends to describe the populations of Medicare beneficiaries for whom seat elevation and standing systems are medically necessary, considering areas of overlap and areas of separation. We explicitly incorporate by reference our original NCD Reconsideration Request on Medicare Coverage of Seat Elevation and Standing Systems in Group 3 Power Wheelchairs submitted to CMS in September 2020 as well as the supplemental summary of evidence of standing systems that accompanies this document.

Studies in direct support of the statements made in this Addendum will be sent electronically through a “Zip” file labeled “Population Differences” to the CMS Coverage and Analysis Group under separate coverage to avoid rejection of these materials due to the size of the files.

Power wheelchairs (PWCs) are covered by Medicare for people with mobility disabilities when they meet the stated coverage criteria.¹ In the same way, power options and systems such as elevating leg rests, tilt, recline, and power seat elevation systems that are used in PWCs are identified as reasonable and necessary for people who meet the coverage criteria.² Each power option and accessory has its own function and benefits that they provide the PWC user. When comparing and contrasting power seat elevation and power standing system users, the details must be considered. For example, both systems contribute to the function of the PWC user by facilitating reach and neutral line-of-sight – however, *how* each of these systems used in conjunction with a PWC facilitates these functions is different.^{3,4} The method each system employs to support the PWC user in these functional tasks results in unique influences to the person’s function and health.

Medical Nature of Power Standing Systems

Durable medical equipment classification relies on the medical nature of the product. Our original Reconsideration Request submitted in 2020 argues that power standing systems are primarily medical in nature with respect to joint mobility, muscle tone, strength, bone mineral density, bladder and bowel management, cardiovascular and respiratory systems, pressure management, and mobility related activities of daily living (MRADLs).⁵ Additionally, the literature update accompanying this letter (Addendum No. 2) identifies key studies that directly point to the medical nature of power standing systems in similar categories.

The differences between power seat elevation and power standing system may be attributed to the person’s position during use. While in a seated position, a large base of support stabilizes the body through the pelvis, upper thighs, and back. However, power standing systems move the person from a sitting to a supported standing position, transferring the person’s center of gravity from their thighs, buttocks, and back to over their lower extremities.⁶ The standing position

distributes the weight through the feet, a much smaller, more sensitive base of support, and also changes the orientation of many body systems with gravity.⁷ This difference provides the impetus for power standing systems to impact more health systems than power seat elevation systems.

The standing position stimulates more muscle activation and bone loading throughout the core and lower extremities than sitting, as well as promotes balance in other body systems, such as pelvic floor pressure.⁸⁻¹¹ Additionally, moving between sitting and standing (a skill can occur often using a power standing system on a power wheelchair) impacts health in many ways, maximizes independence and comfort, and even reduces mortality.^{8,12-14}

Based on the literature review, input from clinical experts in seating and wheeled mobility for clinical applicability and usefulness, also the defined coverage criteria for currently covered power options including tilt, recline, and power elevating legs, the clinical team compiled and proposed coverage criteria for power seat elevation and power standing systems (Appendix A). The coverage criteria were reviewed by additional members of the Clinician Task Force for confirmation prior to submission.

The language in the proposed coverage criteria demonstrated the differences in power seat elevation and power standing systems in clinical terms. Most notably, power standing systems are medically necessary for people at risk of acquiring comorbidities and medical complications from sitting for prolonged periods of time.¹² While power standing systems do aid with functional tasks such as reaching and completion of tasks from setup through cleanup, a person who presents without risk of compromised joint mobility, high tone, muscle spasms, bladder or bowel elimination concerns, circulation, or pulmonary function, can likely use a power seat elevation system for these functional tasks.

Diagnoses

The Clinician Task Force does not agree with the practice of diagnoses-driven coverage criteria; rather, we advocate for functional coverage criteria that derives from the evidence and guides health care providers in client-centered examination. However, to further demonstrate the similarities and differences in the population of people who may benefit from power seat elevation and power standing systems, this diagnostic comparison is made.

Both power seat elevation and power standing system users must first qualify for a PWC base, similar to power tilt, recline, and elevating legs. Such individuals must have a "...neurological condition, myopathy, or congenital skeletal deformity..."¹ (p.7) and are likely to use the PWC as their primary means of mobility. Similarly, qualifying secondary diagnoses of people who could use power seat elevation and power standing may overlap as well (Appendix B). Examining patterns in the Dobson and Davanzo report¹⁵ commissioned by the ITEM Coalition in 2020, people who may benefit from both systems have diagnoses associated with generalized, upper extremity, or spinal pain, presence of spinal deviations and/or postural deviations, and conditions associated with muscle tone changes such as quadriplegia or ataxia. For power standing systems, the diagnoses largely relate to the body systems impacted by power standing systems.

Function

Without additional power options, a PWC stabilizes the person in a sitting position, although being limited to sitting throughout the entire day and evening restricts the health and function of the individual in many ways.¹² Power seat elevation systems aid the individual by enabling function in a seated position, moving the person vertically in a sitting position, thereby facilitating efficiency and safety during transfers and ergonomic reaching for objects in order to perform mobility-related activities of daily living (MRADLs).⁴ Power seat elevation systems also raise the individual to see items in their environment with a neutral neck position, thereby reducing repetitive strain.¹⁶ Power standing systems enable similar function in reaching and line of sight, but by facilitating movement of the person from a seated into a supported standing position. During reaching, this not only raises the starting position of the upper extremity, but also brings them closer to the object (or the ‘load’ the person is reaching for), which decreases strain.¹⁷ In this position, PWC users can also look at items in the environment positioned at an ambulatory person’s level, placing their neck in a more neutral position.

While power seat elevation and power standing systems do present with similarities in supporting the PWC user’s functional status and ability to perform MRADLs, power standing systems contribute in a direct manner to the person’s health status. Because of these differences, the proposed coverage criteria for power standing systems does not address reaching or line of sight functions. If a beneficiary does not present with an underlying medical need for standing, a power seat elevation system should be sufficient to improve or enable the performance of MRADLs. However, the proposed coverage criteria for power standing systems focus on the contribution of the system to address the evidence-based medical needs directly, which will thereby support the person’s function in their home. Use of power standing systems by people with progressive and non-progressive neurological conditions, myopathies, and congenital skeletal deformities, where appropriate, will enhance their health and function and improve their overall quality of life.

Prepared by: Cara Masselink, PhD, OTRL, ATP
Executive Director, Clinician Task Force
Associate Professor, Western Michigan University

References

1. Center for Medicare and Medicaid Services. LCD – Power Mobility Devices (L33789). May 16, 2023. <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=33789&ver=31>
2. Center for Medicare and Medicaid Services. LCD – Wheelchair Options/Accessories (L33792). May 16, 2023. <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33792>
3. Masselink CE, LaBerge N, Detterbeck A. Policy Analysis on Power Standing Systems. *Prev Med Rep.* 2021;24, 101601.

4. Masselink CE, LaBerge NB, Piriano J, Detterbeck AC. Policy Analysis on Power Seat Elevation Systems. *Arch Phys Med Rehabil.* 2022;000;1-9.
5. Independence through Enhancement of Medicare and Medicaid (“ITEM”) Coalition. Formal request for reconsideration of the Medicare National Coverage Determination for Mobility Assistive Equipment (§ 280.3) to include seat elevation and standing systems for Group 3 complex rehabilitative power wheelchairs.
<https://itemcoalition.files.wordpress.com/2020/09/item.-request-for-reconsideration-of-ncd-for-mae.pdf>. Published September 15, 2020. Accessed October 1, 2023.
6. Sprigle S, Maurer C, Sorenblum SE. Load redistribution in variable position wheelchairs in people with spinal cord injury. *J Spinal Cord Med.* 2010;33(1):58-64.
doi:10.1080/10790268.2010.11689674
7. Tessem S, Hagstrøm N, Fallang B. Weight distribution in standing and sitting positions, and weight transfers during reaching tasks, in seated stroke subjects and healthy subjects. *Physiother Res Int.* 2007;12(2):82-94.
8. Cudlip AC, Callaghan JP, Dickerson CR. Effects of sitting and standing on upper extremity physical exposures in materials handling tasks. *Ergonomics.* 2015;58(10):1637-1646, DOI: 10.1080/00140139.2015.1035763
9. Fehér-Kiss A, Nagy E, Domján A, Jakab K, Kránicz J, Horváth G. Trunk alignment in different standing positions in healthy subjects and stroke patients – a comparative study with a simple method for the everyday practice: Trunk alignment in healthy and stroke subjects. *Top Stroke Rehabil.* 2018;25(8):561-568.
10. Kusoffsky A, Apel I, Hirschfeld H. Reaching- lifting-placing task during standing after stroke: coordination among ground forces, ankle muscle activity, and hand movement. *Arch Phys Med Rehabil.* 2001;82:650-60.
11. Saeterbakken AH, Fimland MS. Muscle activity of the core during bilateral, unilateral, seated and standing resistance exercise. *Eur J Appl Physiol.* 2012;112:1671-1678.
12. LaBerge NB, Detterbeck A, Nooijen CFJ. Comorbidities and medical complexities of mobility device users: a retrospective study. *Disabil & Rehabil: Assist Tech.* 2021. DOI: 10.1080/17483107.2021.1969453
13. van der Ploeg HP, Chey T, Ding D, Chau JY, Stamatakis E, Bauman AE. Standing time and all-cause mortality in a large cohort of Australian adults. *Prev Med.* 2014;69:187-191.
14. Gohlke JH & Kenyon LK. Exploring powered wheelchair standing device use in children and adults: a longitudinal case series. *Disabil Rehabil Assist Technol.* 2022. doi: 10.1080/17483107.2022.2120101
15. Health S, McMahon P, Hu J, Dobson A, DaVanzo J. Financial Impact of Medicare Coverage of Complex Rehabilitative Power Wheelchair Seat Elevation and Standing Systems. September 3, 2020.
16. Sabari J, Shea M, Chen L, Laurenceau A, Leung E. Impact of wheelchair seat height on neck and shoulder range of motion during functional task performance. *Assist Tech,* 2016;28(3), 184-189. DOI: 10.1080/10400435.2016.1140692
17. National Institute for Occupational Safety and Health [NIOSH] (1997). A primer based on workplace evaluations of musculoskeletal disorders. Retrieved from: <https://www.cdc.gov/niosh/docs/97-117/>

Addendum No. 2

Summary of Updated Evidence for National Coverage Analysis on Standing Systems as an Accessory to Group 3 Power Wheelchairs for Medicare Beneficiaries

The Clinician Task Force (CTF) has been involved in the NCD Reconsideration Request for Power Seat Elevation Systems and Power Standing Systems since the original submission to the Centers for Medicare and Medicaid Services (CMS) in September 2020, compiling and assessing the evidence base of these power systems with expert healthcare provider consensus, combined with perspectives and experiences gained while working with CRT users. The CTF supports and appreciates CMS coverage for power seat elevation systems and joins the ITEM Coalition in seeking an immediate formal opening of an NCA for standing systems in Group 3 Power Wheelchairs, consistent with the ITEM Coalition's September 2020 Reconsideration Request.

The CTF is a 501(c)(4) non-profit organization comprised of a group of healthcare providers that practice, serve, and provide education on best practices in seating and wheeled mobility clinical services, and advocate for individuals who require complex rehab technology (CRT) equipment. The CTF membership consists of occupational and physical therapists across the United States with expertise in seating and wheeled mobility, maintaining a majority of at least 80% of the membership actively evaluating CRT equipment in a wide variety of settings including inpatient and outpatient rehabilitation, private practice, educational settings, community-based programs, and more. Membership guidelines mandate that no more than 20% of the membership are employed full-time for CRT manufacturer/suppliers to ensure an ethical balance is maintained.

The CTF is equipped to update the evidence on power standing systems for power wheelchairs. The CTF was instrumental in the evidence compilation and review for power seat elevation systems on power wheelchairs (PWCs) and encourages CMS to move forward with opening the power standing system reconsideration request.

Evidence Selection Strategy

The following evidence review was completed using the criteria laid out in the national coverage analysis for power seat elevation systems and applied to power standing system evidence. In summary, the following criteria from the *National Coverage Analysis on Power Seat Elevation Systems*¹ were considered:

- Evidence should focus on power standing on PWCs¹ (p. 15) and demonstrate how power standing would be necessary for effective use of a power wheelchair¹ (p. 14).
- Preferred literature would be clinical studies demonstrating the biomechanical, electromyographic and/or functional abilities of wheelchair users.
- Study population includes wheelchair users; however, the search may be expanded to other populations (e.g. ambulatory older adults, manual wheelchair users) when appropriate. Seat elevation study participants were people with mobility limitations and/or physical impairments, including the frail elderly and various living situations. Furthermore, studies that would apply to a functional activity for power standing, but not use a PWC or standing system, may be included¹ (p. 53).

- Therefore, studies in supported standing devices should be considered, when the study focuses on outcomes that would also apply to a power standing system user such as the impact of supported standing on range of motion, muscle tone and spasms, digestive health, and more.²
- Therefore, studies with an adolescent population would also apply to a power standing system user, when the study examines outcomes that are not developmental in nature and would also apply to an adult power standing system user such as mobility-related activities of daily living (MRADL) performance.²
- No single case studies. When evaluating studies, CMS will consider 1) quality of individual studies, 2) generalizability of findings to the Medicare population, and 3) the extent that overarching conclusions can be drawn from the body of evidence on the direction and magnitude of the intervention’s potential risks and benefits.
- Included studies would 1) answer the assessment question conclusively, and 2) improve health outcomes for patients.

Power Standing Evidence Update

Following the NCA on Power Seat Elevation,¹ the 18 studies below appear to be model studies that fit criteria of what CMS would consider in the coverage of power standing systems. Of the 18 studies, 8 were not initially presented to CMS in the original reconsideration request; however, do appear to fit within the description of key evidence utilized in the NCA.¹ **Copies of these studies will be sent electronically through a “Zip” file labeled “Power Standing” to the CMS Coverage and Analysis Group under separate coverage to avoid rejection of these materials due to the size of the files.**

The studies below are categorized by health categories and participation, for assessing the quantity and quality of evidence related to each outcome. Each row specifies the abbreviated study citation and the specific body function the study examines (column 1), the study type (column 2), the participants and standing device (column 3), and key notes about the study and a summarized study outcome (column 4).

1. Range of Motion, Muscle Strength, and Motor Function

| Studies in Reconsideration Request | | | |
|--|--|---|--|
| Baker et al. (2007) ³ [ROM] | Single blind randomized crossover design | 6 subjects with Multiple Sclerosis <i>Standing frame</i> | Hip extension/ankle dorsiflexion range of motion improved significantly. |
| Netz et al. (2007) ⁴ [Muscle strength] | Experiment with control period | 13 residents in nursing home unable to transfer and stand independently <i>Supported standing device</i> | More improvements than deterioration noted in hip/knee extensors, abductors, and ankle muscle strength. No significant differences in hip/knee flexors and UE. |
| Riek et al. (2008) ⁵ [ROM] | Case series | 5 subjects with Spinal Cord Injury <i>Standing in a frame</i> | Lab study. Upper extremity (UE) posture in supported standing improves shoulder position. |

| New Studies (not submitted in previous Reconsideration Request) | | | |
|--|---|--|--|
| Bayley et al. (2020) ⁶ <i>[ROM, motor function]</i> | Stepped wedge design over 12 months | 14 adolescents with parents with DMD <i>Power standing system</i> | Through video analysis, joint angles were maintained over 12 months, power standing system on PWC use was associated with improved mental health, and functional independence improved. |
| Freeman et al. (2019) ⁷ <i>[ROM, motor function]</i> | Randomized controlled superiority trial | 140 subjects with Multiple Sclerosis (71 usual care, 69 standing) <i>Standing frame</i> | The standing frame group had a mean 0.018 (95% CI -0.014 to 0.051) additional quality-adjusted life-years (QALYs) compared with those of the usual care group, and the estimated incremental cost-per-QALY was approximately £14 700. AMCA scores [motor function scale] was 4.7 points higher in standing group at week 36. |
| Hendrie et al. (2015) ⁸ <i>[motor function]</i> | Mixed methods with quantitative single-case experiments over 48 weeks | 9 participants with Multiple Sclerosis <i>Standing frame</i> | Regular standing showed visual improvements and statistically significant improvement across time period on AMCA. |

2. Bone mineral density (BMD)

| Studies in Reconsideration Request | | | |
|--------------------------------------|--|---|---|
| Alekna et al. (2008) ⁹ | Prospective study during first 2 years post-injury | 54 participants with SCI <i>Standing frame</i> | Supported standing group had higher BMD in lower extremities than the non-standing group. |
| de Bruin et al. (1999) ¹⁰ | Single case experimental multiple-baseline design over 1.5 years | 19 participants with acute SCI <i>Standing frame</i> | CT scans measured trabecular, cortical, and area moment of inertia. In patients with loading (standing), the type of exercise didn't cause an obvious difference, and only a moderate loss or even moderate increase in BMD was observed. |

3. Digestive, metabolic, and endocrine systems

| Studies in Reconsideration Request | | | |
|---|---|---|---|
| Kaplan et al. (1981) ¹¹ [endocrine] | Experimental | 10 participants with SCI <i>Tilt table</i> | Compared early and late spinal cord injury (SCI) and standing vs strengthening's impact on hypercalcuria. Participants who consistently stood earlier post-SCI had reduced calcium output over those who stood later. |
| New Studies (not submitted in previous Reconsideration Request) | | | |
| Collins et al. (2010) ¹² [metabolic] | Descriptive lab study | 170 adults with SCI <i>Supported standing, likely frame</i> | People with incomplete SCI found that static supported standing expended 1.17 metabolic equivalents (MET), as measured after standing for at least 5 minutes, and static standing expended more energy than the person did while lying down at rest. |
| Gohlke & Kenyon (2022) ¹³ [digestion] | Longitudinal case series over 12 months in home setting | 8 participants (5 adults, 3 children) users of <i>Power standing system</i> | 3 of 4 participants who reported issues with constipation at the onset of the series achieved clinically significant improvements in their total PAC-QOL scores between the baseline and final PAC-QOL administrations. The 4th participant's total PAC-QOL score approached clinical significance. |
| LaBerge et al (2023) ¹⁴ [endocrine] | Retrospective chart review | 13 subjects who used a <i>Power standing system</i> | 6% people without a power standing system on their PWC had UTIs the year prior, and 3% after; 23% people who received a power standing system on their PWC had UTIs the year prior, reduced to 8% after. |
| Verschuren et al. (2014) ¹⁵ [metabolic] | Exploratory cohort study | 19 subjects with Cerebral Palsy ages 4-10yrs (mean 10-14yrs) <i>Standing frame</i> | Energy expenditure was >1.5 METs during standing for all GMFCS-E&R levels and, therefore, may be considered as a viable, introductory intervention to reduce sedentary behavior among |

| | | | |
|--|--|--|-------------------------------|
| | | | children with cerebral palsy. |
|--|--|--|-------------------------------|

4. Cardiovascular and Respiratory

| Studies in Reconsideration Request | | | |
|---|--------------------------------------|--|---|
| Antonio et al. (2019) ¹⁶ | Experimental lab study | 10 subjects with dorso-lumbar SCI <i>Non-commercial Power standing system</i> | Lab study, one session. Pulse and oxygen saturation and blood pressure (BP) closer to normal in standing, with systolic BP being the most sensitive. “From a physiological point of view, a therapy with standing devices is necessary, especially for heart functioning, as it presents more variations that are closer to normal values.” P. 822 |
| Edward & Layne (2007) ¹⁷ | Experimental lab study over 12 weeks | 4 subjects with SCI <i>Non-commercial standing frame</i> | With standing, heart rate changed for all subjects and BP changes occurred – with increases in systolic BP for 2 subjects and decreases for 2 subjects. |
| New Studies (not submitted in previous Reconsideration Request) | | | |
| Kyriakides et al. (2019) ¹⁸ | Cross sectional lab study | 10 people w/ cervical SCI & 14 with low thoracic SCI <i>Standing frame</i> | ECG readings examined heart rate variability (HRV) in response to postural changes in sedentary and physically active groups. Measurements showed lower HRV in patients with SCI than in controls. The change in high and low frequency and the ratio of HRV following sitting was greater in controls than SCI and greater in people with paraplegia than tetraplegia. Supported standing was related to better HRV profile. |

5. Skin integrity

| Studies in Reconsideration Request | | | |
|------------------------------------|-----------------------------|--|--|
| Cotie et al. (2011) ¹⁹ | Randomized crossover design | 7 subjects with SCI 10 <i>Tilt table, treadmill</i> | Supported standing resulted in altered skin temp at all sites. One session of tilt-table use decreased temp at 2 of 6 sites. |

| | | | |
|-------------------------------------|------------------------|--|---|
| | | | No changes in resting blood flow observed. |
| Sprigle et al. (2010) ²⁰ | Experimental lab study | 11 subjects with SCI, 6 able-bodied subjects <i>Power standing system</i> | Full standing (seat angle 75deg) provided greater unloading than full tilt (seat angle 55deg). Only the standing position (compared to tilt and recline) decreased loads at seat and backrest simultaneously. |

6. MRADLs

Bayley et al. (2020) and Gohlke and Kenyon (2022) examine MRADL participation, but also appeared in motor function and digestion categories, respectively.

| New Studies (not submitted in previous Reconsideration Request) | | | |
|---|---|--|--|
| Bayley et al. (2020) ⁶ | Stepped wedge design over 12 months | 14 adolescents with parents with DMD <i>Power standing system</i> | Power standing system on PWC use was associated with improved anxiety/depression and peer relations, and lower dependency scores on PARS III. |
| Gohlke & Kenyon (2022) ¹³ | Longitudinal case series over 12 months in home setting | 8 participants (5 adults, 3 children) users of <i>Power standing system</i> | COPM results increased in occupational performance issues mainly in area of reaching and upper extremity function, and kitchen tasks (stirring pot, cooking, turning water on in sink) and cleaning the house with use of power standing system. |
| Schofield et al. (2020) ²¹ | Delphi method | <i>Power standing system</i> on PWC users, clinicians, and parents | Power standing system users, parents, and clinicians achieved consensus that the power standing system on PWC should enable functional activities in the standing position for prescription of the system. |
| Vorster et al. (2019) ²² | *Qualitative grounded theory (CMS may not consider due to study design, but does reveal important outcomes) | adolescents with DMD, 11 parents & teachers <i>Power standing system</i> | Participants described power standing system on PWC as supporting grooming in bathroom, standing to go toilet, reaching higher places at home, leisure activity participation. |

7. Clinical Practice Guidelines and Position Papers

Paralyzed Veterans of America (2021). Management of Neurogenic Bowel Dysfunction in Adults after Spinal Cord Injury. Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8152174/pdf/i1082-0744-27-2-75.pdf> “7.2 For some individuals, a standing program may be beneficial for bowel function but should be weighed against other means of physical activity, as well as against precautions to undertake the activity safely. (Level - III; Strength - C; Agreement - strong)”²³ p. 84

Multidisciplinary Association of Spinal Cord Injury Professionals (MASCIP). Clinical guideline for standing adults following spinal cord injury. <https://www.mascip.co.uk/wp-content/uploads/2015/05/Clinical-Guidelines-for-Standing-Adults-Following-Spinal-Cord-Injury.pdf>. Published April 2013. Accessed June 15, 2023.²⁴

Masselink CE, Detterbeck A, LaBerge NA, Paleg G. Clinician Task Force and RESNA Position on the Application of Supported Standing Devices: Current state of the literature. https://www.resna.org/Portals/0/Position%20and%20Scoping%20Review%20on%20Supported%20Standing%201_23.pdf Published February, 2023. Accessed February, 2023.²

The above evidence demonstrates the impact that supported standing has on the health outcomes and quality of life of PWC users. The CTF commits to continuing evidence review and information gathering for power standing systems on PWC users throughout the NCA process.

Prepared by: Cara Masselink, PhD, OTRL, ATP
Executive Director, Clinician Task Force
Associate Professor, Western Michigan University

References

1. Centers for Medicare and Medicaid Services. Seat Elevation Systems as an Accessory to Power Wheelchairs (Group 3) [National Coverage Analysis]. May 16, 2023. <https://www.cms.gov/medicare-coverage-database/view/ncacal-tracking-sheet.aspx?ncaid=309>
2. Masselink CE, Detterbeck A, LaBerge NB, Paleg G. RESNA and CTF Position on the Application of Supported Standing Devices: Current state of the literature [Position Paper]. January, 2023. https://www.resna.org/Portals/0/Position%20and%20Scoping%20Review%20on%20Supported%20Standing%201_23.pdf
3. Baker K, Cassidy E, Rone-Adams S. Therapeutic standing for people with multiple sclerosis: Efficacy and feasibility. *Int J Ther Rehabil*. 2007;14(3):104-109. doi:10.12968/ijtr.2007.14.3.23523
4. Netz Y, Argov E, Burstin A, Brown R, Heyman SN, Dunsky A, Alexander NB. Use of a device to support standing during a physical activity program to improve function of

- individuals with disabilities who reside in a nursing home. *Disabil Rehabil: Assist Tech*. 2007;2:1:43-49. doi: 10.1080/17483100601143371
5. Riek LM, Ludewig PM, Nawoczinski DA. Comparative shoulder kinematics during free standing, standing depression lifts and daily functional activities in persons with paraplegia: considerations for shoulder health. *Spinal Cord*. 2008;46(5):335-343. doi:10.1038/sj.sc.3102140
 6. Bayley K, Parkinson S, Jacoby P, et al. Benefits of powered standing wheelchair devices for adolescents with Duchenne muscular dystrophy in the first year of use. *J Paediatr Child Health*. 2020;56(9):1419-1425. doi:10.1111/jpc.14963
 7. Freeman J, Hendrie W, Jarrett L, et al. Assessment of a home-based standing frame programme in people with progressive multiple sclerosis (SUMS): a pragmatic, multi-centre, randomised, controlled trial and cost-effectiveness analysis. *Lancet Neurol*. 2019;18(8):736-747. doi:10.1016/S1474-4422(19)30190-5
 8. Hendrie WA, Watson MJ, McArthur MA. A pilot mixed methods investigation of the use of Oswestry standing frames in the homes of nine people with severe multiple sclerosis. *Disabil Rehabil*. 2015;37(13):1178-1185. doi: 10.3109/09638288.2014.957790
 9. Alekna V, Tamulaitiene M, Sinevicius T, Juocevicius A. Effect of weight-bearing activities on the bone mineral density in spinal cord injured patients during the period of the first two years. *Spinal Cord*. 2008; 46:727-732. doi:10.1038/sc.2008.36
 10. de Bruin ED, Frey-Rindova P, Herzog RE, Dietz V, Dambacher MA, Stüssi E. Changes of tibia bone properties after spinal cord injury: effects of early intervention. *Arch Phys Med Rehabil*. 1999;80:214-20.
 11. Kaplan PE, Roden W, Gilbert E, Richards L, Goldschmidt JW. Reduction of hypercalcaemia in tetraplegia after weight-bearing and strengthening exercises. *Paraplegia*. 1981;19:289-293.
 12. Collins EG, Gater D, Kiratli J, Butler J, Hanson K, Langbein WE. Energy cost of physical activities in persons with spinal cord injury. *Med Sci Sports Exerc*. 2010;42(4):691-700. doi:10.1249/MSS.0b013e3181bb902f
 13. Gohlke JH & Kenyon LK. Exploring powered wheelchair standing device use in children and adults: a longitudinal case series. *Disabil Rehabil Assist Technol*. 2022. doi: 10.1080/17483107.2022.2120101
 14. LaBerge NB, Detterbeck A, Nooijen CFJ. Comorbidities and medical complexities of mobility device users: a retrospective study. *Disabil Rehabil Assist Technol*. 2023;18(7):1-8.
 15. Verschuren O, Peterson MD, Leferink S, Darrah J. Muscle activation and energy-requirements for varying postures in children and adolescents with cerebral palsy. *J Pediatr*. 2014;165:1011-6.
 16. Antonio TS, Urrutia F, Larrea A, Espín V, Latta MA. Variations in vital signs associated with postural changes when using a stand-up wheelchair in patients with spinal cord injury. *Adv. Intell. Syst*. 2019;794:818-823. https://doi.org/10.1007/978-3-319-94947-5_80
 17. Edward LC, Layne CS. Effect of dynamic weight bearing on neuromuscular activation after spinal cord injury. *Am J Phys Med Rehabil*. 2007;86:499-506.
 18. Kyriakides A, Poulidakos D, Galata A, Konstantinou D, Panagiotopoulos E, Chroni E. The effect of level of injury and physical activity on heart rate variability following spinal

- cord injury. *J Spinal Cord Med.* 2019;42(2):212-219.
doi:10.1080/10790268.2017.1383709
19. Cotie LM, Geurts CLM, Adams MME, MacDonald MJ. Leg skin temperature with body-weight-supported treatment and tilt-table standing training after spinal cord injury. *Spinal Cord.* 2011;49:149-153.
 20. Sprigle S, Maurer C, Sorenblum SE. Load redistribution in variable position wheelchairs in people with spinal cord injury. *J Spinal Cord Med.* 2010;33(1):58-64.
doi:10.1080/10790268.2010.11689674
 21. Schofield C, Evans K, Young H, et al. The development of a consensus statement for the prescription of powered wheelchair standing devices in duchenne muscular dystrophy. *Disabil Rehabil.* 2022;44(10):1889-1897. doi:10.1080/09638288.2020.1810786
 22. Vorster N, Evans K, Murphy N et al. Powered standing wheelchairs promote independence, health and community involvement in adolescents with Duchenne muscular dystrophy. *Neuromuscl Disord.* 2019;29:221-230.
 23. Johns J, Krogh K, Rodriguez GM, et al. Management of Neurogenic Bowel Dysfunction in Adults after Spinal Cord Injury [Clinical Practice Guidelines: Spinal Cord Medicine]. Paralyzed Veterans of America. 2021.
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8152174/pdf/i1082-0744-27-2-75.pdf>
 24. Multidisciplinary Association of Spinal Cord Injury Professionals (MASCIP). Clinical guideline for standing adults following spinal cord injury. Published April 2013. Accessed June 15, 2023. <https://www.mascip.co.uk/wp-content/uploads/2015/05/Clinical-Guidelines-for-Standing-Adults-Following-Spinal-Cord-Injury.pdf>.

Appendix A: Proposed coverage criteria for Power Standing Systems

POWER STANDING (E2301):

A power standing system used in conjunction with a Group 3 CRT PWC will be covered if criteria 1, 2, 3, and 4 are met and if criteria 5 or 6 and 7 or 8, are met:¹

1. The beneficiary meets all the coverage criteria for a Group 3 PWC described in the PMD LCD; and
2. A specialty evaluation that was performed by a licensed/certified medical professional, such as a PT, OT, or physician who has specific training and experience in rehabilitation wheelchair evaluations of the beneficiary's seating and positioning needs. The PT, OT, or physician may have no financial relationship with the supplier; and
3. The wheelchair is provided by a supplier that employs a RESNA-certified ATP who specializes in wheelchairs and who has direct, in-person involvement in the wheelchair selection for the beneficiary; and
4. The beneficiary can achieve a supported standing position in the power standing system.
5. The beneficiary is at high risk for the development of a pressure injury and is unable to perform a functional weight shift; or
6. The power standing system is needed to manage increased tone, spasticity or muscles spasms.
7. The beneficiary is at high risk for:
 - contractures; or
 - loss of joint mobility; or
 - loss of bone density; or
8. The beneficiary must utilize a power standing system to manage one or more of the following:
 - bladder emptying and associated genitourinary conditions
 - bowel motility, elimination, or constipation
 - circulation
 - pulmonary function

¹ The musculoskeletal system (7) and bowel and/or bladder (8) needs emerged in the evidence as primary benefits of standing in a power standing system. The needs of people who only need pressure management (5) may be met with power tilt; the presence of circulatory or pulmonary issues in conjunction with pressure relief needs would benefit from the standing position. Tone, spasticity, or muscle spasms (6) has shown to benefit from longer periods of standing. Muscle tone, spasticity, and/or muscle spasms that impact joint mobility and/or bowel and/or bladder would likely benefit from a power standing system.

Appendix B: ICD-10 codes selected for power seat elevation, power standing, and both, as analyzed by Dobson and Davanzo (2020, p. 24-26)

Secondary Diagnoses that May Be Expected to Include Clinical Conditions that Indicate Need for a Power Seat Elevation System

| ICD-10 Code | Description |
|--------------------|---|
| M170 | Bilateral primary osteoarthritis of knee |
| M1711 | Unilateral primary osteoarthritis, right knee |
| M1712 | Unilateral primary osteoarthritis, left knee |
| M1990 | Unspecified osteoarthritis, unspecified site |
| M2450 | Contracture, unspecified joint |
| M623 | Immobility syndrome (paraplegic) |

Secondary Diagnoses that May Indicate Need for a Power Standing System

| ICD-10 Code | Description |
|--------------------|--|
| I951 | Orthostatic hypotension |
| I959 | Hypotension, unspecified |
| J449 | Chronic obstructive pulmonary disease, unspecified |
| J811 | Chronic pulmonary edema |
| J9610 | Chronic respiratory failure, unspecified whether with hypoxia or hypercapnia |
| J9611 | Chronic respiratory failure with hypoxia |
| J9612 | Chronic respiratory failure with hypercapnia |
| K210 | Gastro-esophageal reflux disease with esophagitis |
| K219 | Gastro-esophageal reflux disease without esophagitis |
| K2970 | Gastritis, unspecified, without bleeding |
| K5900 | Constipation, unspecified |
| K5901 | Slow transit constipation |
| K5909 | Other constipation |
| K592 | Neurogenic bowel, not elsewhere classified |
| L89150 | Pressure ulcer of sacral region, unstageable |
| L89152 | Pressure ulcer of sacral region, stage 2 |

| | |
|--------|---|
| L89153 | Pressure ulcer of sacral region, stage 3 |
| L89154 | Pressure ulcer of sacral region, stage 4 |
| L89214 | Pressure ulcer of right hip, stage 4 |
| L89223 | Pressure ulcer of left hip, stage 3 |
| L89224 | Pressure ulcer of left hip, stage 4 |
| L89309 | Pressure ulcer of unspecified buttock, unspecified stage |
| L89312 | Pressure ulcer of right buttock, stage 2 |
| L89313 | Pressure ulcer of right buttock, stage 3 |
| L89314 | Pressure ulcer of right buttock, stage 4 |
| L89322 | Pressure ulcer of left buttock, stage 2 |
| L89323 | Pressure ulcer of left buttock, stage 3 |
| L89324 | Pressure ulcer of left buttock, stage 4 |
| L89892 | Pressure ulcer of other site, stage 2 |
| L89893 | Pressure ulcer of other site, stage 3 |
| L89894 | Pressure ulcer of other site, stage 4 |
| L89899 | Pressure ulcer of other site, unspecified stage |
| M62838 | Other muscle spasm |
| N200 | Calculus of kidney |
| N201 | Calculus of ureter |
| N289 | Disorder of kidney and ureter, unspecified |
| N312 | Flaccid neuropathic bladder, not elsewhere classified |
| N319 | Neuromuscular dysfunction of bladder, unspecified |
| N390 | Urinary tract infection, site not specified |
| N400 | Benign prostatic hyperplasia without lower urinary tract symptoms |
| N401 | Benign prostatic hyperplasia with lower urinary tract symptoms |
| R140 | Abdominal distension (gaseous) |
| R338 | Other retention of urine |
| R339 | Retention of urine, unspecified |

| | |
|--------|--|
| Z87440 | Personal history of urinary (tract) infections |
| Z87442 | Personal history of urinary calculi |

Secondary Diagnoses that May Indicate Need for a Power Seat Elevation OR Power Standing System

| ICD-10 Code | Description |
|--------------------|---|
| G8929 | Other chronic pain |
| G894 | Chronic pain syndrome |
| M069 | Rheumatoid arthritis, unspecified |
| M150 | Primary generalized (osteo)arthritis |
| M159 | Polyosteoarthritis, unspecified |
| M19011 | Primary osteoarthritis, right shoulder |
| M25511 | Pain in right shoulder |
| M25512 | Pain in left shoulder |
| M25551 | Pain in shoulder |
| M419 | Scoliosis, unspecified |
| M4628 | Osteomyelitis of vertebra, sacral and sacrococcygeal region |
| M47812 | Spondylosis without myelopathy or radiculopathy, cervical region |
| M47816 | Spondylosis without myelopathy or radiculopathy, lumbar region |
| M47817 | Spondylosis without myelopathy or radiculopathy, lumbosacral region |
| M4800 | Spinal stenosis, site unspecified |
| M4802 | Spinal stenosis, cervical region |
| M48061 | Spinal stenosis, lumbar region without neurogenic claudication |
| M5416 | Radiculopathy, lumbar region |
| M542 | Cervicalgia |
| M545 | Low back pain |
| M546 | Pain in thoracic spine |

| | |
|--------|--|
| M6250 | Muscle wasting and atrophy, not elsewhere classified, unspecified site |
| M62830 | Muscle spasm of back |
| R270 | Ataxia, unspecified |
| R293 | Abnormal posture |
| R532 | Functional quadriplegia |
| Z741 | Need for assistance with personal care |
| Z89511 | Acquired absence of right leg below knee |
| Z89512 | Acquired absence of left leg below knee |
| Z89611 | Acquired absence of right leg above knee |
| Z89612 | Acquired absence of left leg above knee |