



**FORMAL REQUEST FOR RECONSIDERATION OF THE MEDICARE
NATIONAL COVERAGE DETERMINATION**

for

MOBILITY ASSISTIVE EQUIPMENT (§ 280.3)

to include

**SEAT ELEVATION SYSTEMS AND STANDING SYSTEMS FOR GROUP 3 COMPLEX
REHABILITATIVE POWER WHEELCHAIRS**

Submitted by

**THE INDEPENDENCE THROUGH ENHANCEMENT OF MEDICARE AND
MEDICAID (“ITEM”) COALITION**

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OBJECTIVE: To secure coverage of power seat elevation and power standing systems in Group 3 power wheelchairs, which are classified by Medicare as complex rehabilitative wheelchairs, for certain Medicare beneficiaries with mobility impairments in order to perform or participate in mobility-related activities of daily living in the home. We seek a clinical review by medical professionals with experience in medical rehabilitation and wheelchair and seating assessment and prescription to reconsider the National Coverage Determination for Mobility Assistive Equipment in order to (1) establish a benefit category determination that both power seat elevation and power standing systems in Group 3 power wheelchairs are “primarily medical in nature” and, therefore, included within the durable medical equipment benefit category under the Medicare program, and (2) explicitly recognize coverage of these systems for beneficiaries with a medical or functional need for vertical movement in a Group 3 power wheelchair in order to perform or obtain assistance to participate in mobility-related activities of daily living in the home.

I. Executive Summary

Power seat elevation systems and power standing systems used in conjunction with a Group 3 power wheelchair (“PWC”)¹ are two systems that can be critical to the health, function, independent living, and wellbeing of Medicare beneficiaries with mobility impairments as a result of a permanent disability and other clinical needs, as described herein.² People who are eligible for Medicare based on Social Security Disability Insurance (“SSDI”) eligibility comprise the largest portion of Medicare beneficiaries who have a medical need for Group 3 PWCs and related accessories, including the two systems that are the focus of this NCD request. Currently, these and other Medicare beneficiaries are denied coverage of these systems because the four Durable Medical Equipment (“DME”) Medicare Administrative Contractors (“MACs”) have issued an identical “policy article” claiming that power seat elevation and power standing systems do not fall under the Medicare DME benefit because they do not primarily serve medical purposes.³

This policy article is inconsistent with a wide body of clinical evidence, inconsistent with the existing National Coverage Determination (“NCD”) for Mobility Assistive Equipment (“MAE”), and inconsistent with other binding Medicare determinations, including a decades-old

¹ All Group 3 PWCs are considered complex rehabilitative wheelchairs.

² Based on the Power Mobility Devices Local Coverage Determination, Group 3 PWCs are only covered when the beneficiary’s mobility limitation is due to a neurological condition, myopathy, or congenital skeletal deformity. Noridian Healthcare Solutions, LLC & CGS Administrators, LLC, *Local Coverage Determination: Power Mobility Devices (L33789)*, <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33789&ver=31&Date=06%2f21%2f2020&DocID=L33789&bc=hAAAAAgAAAA&> (Last revised Jan. 1, 2020).

³ Noridian Healthcare Solutions, LLC & CGS Administrators, LLC, *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%7cSAD%7cRTC%7cReg&PolicyType=Both&s=All&Keyword=Wheelchair&KeywordLookUp=Title&KeywordSearchType=Exact&kq=true&bc=EAAAABAAAA&> (Last modified Jan. 1, 2020).

NCD that governs coverage of a similar, less-complex seat lift mechanism. In addition, the policy article establishes a substantive legal standard for payment that was issued without notice-and-comment rulemaking. For all of these reasons, the Centers for Medicare and Medicaid Services (“CMS”) should direct the DME MACs to rescind the policy article and amend the NCD for MAE to establish a benefit category determination for power seat elevation and standing systems and to clarify that these systems are covered DME benefits. CMS should then determine when these systems are reasonable and necessary for certain Medicare beneficiaries with mobility impairments.

The DME MACs’ policy article incorrectly assesses the evidence because both systems assist certain mobility-impaired beneficiaries in performing or participating in activities of daily living (“ADLs”) and specifically those considered mobility-related ADLs (“MRADLs”) in the home by enabling movement through the vertical plane. Additionally, the power seat elevation system addresses primary and secondary injuries caused by prolonged wheelchair use while power standing systems ameliorate numerous adverse physiological effects of excessive and prolonged sitting, as described herein.

Therefore, both systems satisfy the coverage requirements specified by CMS in the NCD for MAE. The position of the DME MACs necessitates that CMS clarify that these systems are covered DME benefits and direct the DME MACs to rescind the policy article and those portions of the Local Coverage Determinations (“LCDs”) that do not comport with the revised NCD. We believe this can be accomplished by amending the NCD for MAE to clarify that power seat elevation and power standing systems are covered DME benefits as features/accessories that are integrated into a Group 3 PWC.

Group 3 PWCs are covered and reimbursed under the Medicare program as DME when the beneficiary meets defined coverage criteria. Due to the DME MACs’ policy article, power seat elevation and power standing systems are *not* currently covered under Medicare although they meet the five-prong test to qualify under the DME benefit category. In contrast, the power tilt and/or recline system does, in fact, satisfy the DME benefit definition.⁴ A CMS regulation defines DME as items that 1) can withstand repeated use; 2) have an expected life of at least three years; 3) are primarily and customarily used to serve a medical purpose; 4) are generally not useful in the absence of an illness or injury; and 5) are appropriate for use in the home.⁵

The power seat elevation system is referred to as an “accessory” to PWCs in Medicare parlance, but it is best described as a critical component integral to the full function of a Group 3 PWC for certain beneficiaries, assisting a beneficiary to raise and lower himself or herself in the

⁴ Tilt and recline power options are currently covered through criteria for Group 2 and Group 3 Single or Multiple Power Option PWCs. Noridian Healthcare Solutions, LLC & CGS Administrators, LLC, *Local Coverage Determination: Power Mobility Devices (L33789)*, <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33789&ver=31&Date=06%2f21%2f2020&DocID=L33789&bc=hAAAAAgAAAA&> (Last modified Jan. 1, 2020).

⁵ 42 C.F.R. § 414.202.

seated position through the use of an electromechanical system. Determining the most appropriate seat-to-floor height for a PWC is critical and varies significantly based on a beneficiary's activities. Many factors are impacted by this decision, such as ground clearance and head clearance during movement from one location in the home to another. Seat height dramatically impacts the beneficiary's ability to transfer to various surfaces in the home and other routinely encountered environments.

Power seat elevation alleviates the problem created by a single seat height by allowing the beneficiary to adjust the seat height independent of the wheelchair base to the necessary height to perform or participate in activities related to hygiene, grooming, and dressing, and transfers from a wheelchair to a commode, bed, or other surface that are necessary to perform as part of a daily routine. The power seat elevation system also reduces the risk of falls and other injuries related to uneven or unsafe transfers. Accessing surfaces to perform or participate in routine MRADLs in the home may be dangerous or impossible without the ability of the beneficiary to move within the vertical plane.

The power standing system is also referred to by the Medicare program as an accessory to a Group 3 PWC, but it too is a critical component integral to the full function of a Group 3 PWC for beneficiaries who need this functionality. Standing systems are only available in PWCs classified as Group 3 and above. The standing system moves the beneficiary from a seated position to a standing position within the vertical plane. Power standing systems allow the beneficiary to perform or participate in routine MRADLs while continuing to be able to move/operate the PWC. The power standing system utilizes gravity and weight bearing to provide therapeutic benefits to beneficiaries who experience prolonged sitting due to illness, injury or disability that impacts body structure and body function.

Other power seating systems covered by Medicare (i.e., tilt and/or recline systems) which are used to address and reduce the risk of skin injuries move the beneficiary into a tilted and/or reclined position in order to relieve pressure on susceptible areas of the body. This is a critical benefit for certain Medicare beneficiaries, but there are some drawbacks with tilt and/or recline systems as compared to seat elevation and standing systems, which have different purposes. The degree of tilt and/or recline required to relieve pressure moves the beneficiary into a position that reduces the visual field, prevents the user from performing or participating in many MRADLs, and prevents the wheelchair from moving.

Participation in MRADLs in customary locations within the home is the basis for coverage under the NCD for MAE.⁶ Among other things, the policy considers whether the mobility limitation significantly impairs the beneficiary's ability to participate in one or more MRADLs in the home. In the sequential questions set forth in the NCD, question three (3) specifically asks whether the limitation can "be ameliorated or compensated sufficiently such

⁶ The NCD for MAE sets forth a complex nine-step algorithm or "decision tree" for determining the clinical circumstances by which a specific type of MAE is appropriate for a beneficiary covered under the Medicare program.

that the additional provision of MAE will be reasonably expected to significantly improve the beneficiary's ability to perform or obtain assistance to participate in MRADLs in the home?" Without the addition of a power seat elevation or power standing system, certain Medicare beneficiaries are limited in their ability to perform or participate in important MRADLs in the home.

However, in 2004, the DME MACs published an identical Local Coverage Article ("LCA") A52504, which states that the power seat elevation and power standing systems are "not primarily medical in nature" and, therefore, are non-covered.⁷ 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. For the reasons set forth in this NCD Reconsideration Request, CMS should instruct the DME MACs to rescind LCA A52504.

The DME MACs have taken the position that these features are "not primarily medical in nature," with no rationale for their conclusion and no citation to medical literature.⁸ Prior to the enactment of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 ("BIPA"), the Durable Medical Equipment Regional Carriers ("DMERCs") (now DME MACs) issued Local Medical Review Policies ("LMRPs") that contained reasonable and necessary language, conditions for coverage, as well as coding, benefit language, and statutory requirements. In implementing section 522 of BIPA,⁹ the information formerly in the single LMRP was divided into two documents: an LCD, which contains "reasonable and necessary" language, and an LCA, which provides other necessary coding information, statutory requirements, and benefit language. In addition, BIPA distinguished the right to challenge NCDs and LCDs from the appeal rights that Medicare beneficiaries have for the adjudication of Medicare claims. The LCA documents are not subject to the same rigorous clinical evidence standards required for LCDs, and there is no meaningful process to challenge LCAs.¹⁰

A recent Supreme Court decision calls into question the continued validity of LCA A52504 because it establishes a substantive legal standard for payment for the power standing and power seat elevation systems and was not issued through notice-and-comment rulemaking.¹¹ The uncertain status of the LCA is an additional reason for CMS to order its rescission and to

⁷ Noridian Healthcare Solutions, LLC & CGS Administrators, LLC, *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%7cSAD%7cRTC%7cReg&PolicyType=Both&s=All&Keyword=Wheelchair&KeywordLookUp=Title&KeywordSearchType=Exact&kq=true&bc=EAAAABAAAA&> (Last modified Jan. 1, 2020).

⁸ *Id.*

⁹ Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. No. 106-554, § 522, 114 Stat. 2763A-463, 2763A-543-2763A-547.

¹⁰ *See, e.g., In Re CMS LCD Complaint: Wheelchair Options/Accessories (L11451)*, DAB No. 2370 (H.H.S. Mar. 29, 2011) ("We reverse the ALJ Decision because the ALJ exceeded the permissible scope of his authority by reviewing a policy determination that is not an LCD as defined in the Act and regulations subject to review, and that is expressly excluded from his review by the governing regulations."); 42 U.S.C. § 1395ff(f)(2).

¹¹ *See Azar v. Allina Health Servs.*, 139 S. Ct. 1804 (2019).

clarify in the NCD for MAE that power standing and seat elevation systems are covered by Medicare.

Furthermore, the agency has clarified in Health Care Financing Administration (“HCFA”) Ruling 96-1 that accessories to wheelchairs and other items of DME that are integral to the function of a wheelchair are part of the DME benefit.¹² Both the power seat elevation and power standing systems are critical components of a Group 3 PWC for certain beneficiaries and, like the tilt and/or recline system, are embedded in the design of the Group 3 PWC. Thus, these systems clearly meet the HCFA 96-1 standard for purposes of the benefit category determination (“BCD”). Neither of these accessories function independently without being integrated into a Group 3 PWC base. Moreover, these accessories are, in fact, primarily medical in nature and reasonable and necessary for a subset of Medicare beneficiaries with certain mobility limitations and other impairments, and who qualify for a Group 3 PWC, as described herein.

CMS has also issued an NCD¹³ allowing coverage for seat lifts for stationary chairs in the home, recognizing that seat lifts can facilitate sitting to standing for patients with neuromuscular diseases or severe arthritis of the hip and knee who are otherwise ambulatory. The seat lift mechanism of a stationary chair is designed to allow beneficiaries to achieve a standing position so they can self-ambulate. While similar in concept, a seat lift mechanism of a stationary chair is very different and considerably less complex than power seat elevation and power standing systems, which are significantly more sophisticated in materials and construction. The electromechanical components and wheelchair interfaces are specifically designed to function in a Group 3 PWC to address MRADL performance/participation and medical needs.

Although seat lifts in stationary chairs and power seat elevation systems integral to PWCs serve unique populations and are designed and function very differently, it stands to reason that if a stationary seat lift intended to assist a beneficiary with movement from sitting to standing is considered DME, power seat elevation integral to a Group 3 PWC that assists in transferring and enables performance of or participation in MRADLs should also be considered DME.

The current lack of coverage for power seat elevation and power standing systems is inconsistent with Medicare directives, denies Medicare beneficiaries access to critical PWC features to which they are entitled, and places beneficiaries at risk for increases in medical complications, interventions, and health care costs. The position taken by the DME MACs that power seat elevation and power standing systems do not primarily serve a medical purpose is inconsistent with a wide body of clinical literature and CMS policy, as detailed in the NCD for

¹² HCFA Ruling 96-1 reads, in part, “To the extent that a wheelchair seating system or other equipment may or may not function properly or not achieve its full ‘therapeutic benefit’ without attached components supporting or restricting motion in a body part, the attachments are appropriately viewed as a necessary accessory that is an integral part of the durable medical equipment and is, accordingly, payable as durable medical equipment, provided that the other prerequisites for classification as durable medical equipment are met.” HCFA, *HCFA Ruling No. 96-1* (Sept. 1996), <https://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/Downloads/HCFAR961.pdf>.

¹³ CMS, Medicare NCD Manual, Pub. 100-03, § 280.4.

MAE, HCFA Ruling 96-1, and the NCD on seat lifts. This conflict denies access to critical technologies, which are necessary for certain beneficiaries to perform or participate in MRADLs in the home that require access to the vertical plane. Additionally, as the clinical evidence detailed in this request clearly demonstrates, this denied access places beneficiaries at increased risk of incurring additional, detrimental medical conditions that could be avoided with the use of these systems (i.e., urinary tract infections (“UTIs”), falls, skin pressure injuries, respiratory conditions, etc.).

Accordingly, the ITEM Coalition requests that CMS revise the NCD for MAE to make two determinations for these systems:

- 1) A benefit category determination establishing that power seat elevation and power standing systems are primarily medical in nature, and therefore, satisfy the Medicare DME definition; and,
- 2) A coverage determination establishing that power seat elevation and power standing systems are covered DME benefits.

We understand that CMS must make a benefit category determination before a coverage policy will be fully considered and, accordingly, we highlight that the 129 published articles we cite in support of our request are equally relevant to both the benefit category determination and the coverage decision. *We therefore expect CMS to rely heavily on its medical officers and advisors in rendering the benefit category determination as well as the coverage decision.* Whether power seat elevation and power standing systems are primarily medical in nature is a medical decision. Clinicians with experience in wheelchair seating and treatment of beneficiaries with mobility impairments will be critical to this determination. This is not a question of whether these systems satisfy other requirements of the DME regulatory definition such as durability or usefulness in the home. The benefit category determination turns on medical and clinical factors and, therefore, medical professionals with experience in this area must be involved in the determination.

Once CMS favorably determines that these systems constitute covered durable medical equipment, CMS officials will have to work with the DME MACs to take additional steps necessitated by the NCD change (i.e., revise LCA A52504 and related LCDs accordingly, activate and/or modify existing Healthcare Common Procedure Coding System (“HCPCS”) billing codes, and determine fee schedule amounts for both codes). The ITEM Coalition stands ready to work with CMS and the DME MACs in implementing sound, evidence-based coverage policies governing the appropriate use of power seat elevation and power standing systems.

The ITEM Coalition makes this request on behalf of Medicare beneficiaries with disabilities and other medical conditions who are being harmed by the lack of access to important Group 3 PWC accessories resulting from inappropriate Medicare policy. The ITEM Coalition is a national consumer and clinician-led coalition advocating for access to and coverage of assistive devices and technologies for persons with injuries, illnesses, disabilities,

and chronic conditions of all ages. Our members represent individuals with a wide range of disabling conditions, as well as the providers who serve them, including such conditions as multiple sclerosis, paralysis, spinal cord injury, brain injury, stroke, spina bifida, myositis, limb loss, cerebral palsy, hearing and speech impairments, visual impairments, Osteogenesis Imperfecta, amyotrophic lateral sclerosis, muscular dystrophy, movement disorders and other life-altering conditions.

In addition to the numerous ITEM Coalition organizations supporting this request, it is the policy of the American Medical Association (“AMA”) that CMS should “render a benefit category determination that establishes that the seat elevation and standing features of power wheelchairs are primarily medical in nature and qualify under the definition of durable medical equipment when used in a power wheelchair.”¹⁴

II. Description of the Systems

A. Power Seat Elevation

A PWC replaces a beneficiary’s loss of mobility due to impaired lower extremity and upper extremity function by enabling the beneficiary to move between two points in the horizontal plane in a safe and timely manner throughout the day. However, beneficiaries live in three-dimensional homes. To address the beneficiary’s functional impairments, it is necessary to also enable movement in the vertical plane. The power seat elevation system is classified by the Food and Drug Administration (“FDA”) as a 510(k)-exempt wheelchair accessory under product code “KNO.”¹⁵ The power seat elevation system is an accessory used with a PWC to provide the wheelchair user with access to the vertical plane through seat height controls.

A power seat elevation system raises and lowers the wheelchair seat height, independent of the wheelchair base height, using an electrically powered mechanical system. A power seat elevation system does not change the seat to back angle or the angle of the seat to the ground. Instead, it allows changes in the seat’s height relative to the ground, as needed. The ability of the PWC user to alter the seat-to-floor height to the necessary height improves the beneficiary’s biomechanics during transfers from one surface to another. The power seat elevation system is described by HCPCS Code E2300,¹⁶ which went into effect in 2004, and is described in LCA A52504 as follows:¹⁷

¹⁴ AMA, *Protecting Patient Access to Seat Elevation and Standing Features in Power Wheelchairs D-330.899*, <https://policysearch.ama-assn.org/policyfinder/detail/seat%20elevation?uri=%2FAMADoc%2Fdirectives.xml-D-330.899.xml> (Last modified 2019).

¹⁵ FDA, *Product Classification: Accessories, Wheelchair*, <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=KNO> (Last modified June 15, 2020).

¹⁶ HCPCS Code E2300 is described as “[w]heelchair accessory, power seat elevation system, any type.”

¹⁷ Noridian Healthcare Solutions, LLC & CGS Administrators, LLC, *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%7cS>

A power seat elevation system (E2300) includes: a motor and related electronics with or without variable speed programmability; a switch control which is independent of the PWC drive control interface; any hardware that is needed to attach the seating system to the wheelchair base. It must provide a seat elevation of at least 6 inches.

Basic technology requirements are needed for power seat elevation systems. Power seat elevation systems are available on Group 2 (limited offerings) and Group 3 and above PWC bases. The systems available on Group 2 PWCs offer less seat height variation and cannot be combined with other power seating systems. Coverage criteria for Group 2 PWCs is targeted toward orthopedic and cardiorespiratory diagnoses, such as Osteoarthritis and Chronic Obstructive Pulmonary Disease.¹⁸

Coverage for Group 3 PWCs requires a diagnosis of a neurological condition, myopathy, or congenital skeletal deformity.¹⁹ Beneficiaries eligible for Group 3 PWCs present with greater mobility limitations and reliance on their PWC, and are at greater risk for comorbid and secondary health conditions.²⁰ Power seat elevation systems available on Group 3 PWCs provide for a greater range of seat adjustment and are capable of being combined with other power systems such as tilt/recline and standing systems. The technological features are important to meet the needs of beneficiaries who qualify for Group 3 PWCs. The severity of need is greater for beneficiaries eligible for Group 3 PWCs. Accordingly, this request focuses on Group 3 PWCs only. CMS certainly has the authority to determine whether broader coverage of these technologies is warranted.

B. Power Standing

The power standing system used with a Group 3 PWC is necessary for the beneficiary who has a mobility limitation and additional clinical indicators that require a standing protocol to reduce the negative impact of sitting on body structures and body functions. In addition, the power standing system allows the beneficiary to accomplish MRADLs in the home, without limiting mobility from point A to point B within the home. The power standing system is typically operated through the wheelchair's controller, using expanded electronics to activate

[AD%7cRTC%7cReg&PolicyType=Both&s=All&Keyword=Wheelchair&KeywordLookup=Title&KeywordSearchType=Exact&kq=true&bc=EAAAABAAAA&](#) (Last modified Jan. 1, 2020).

¹⁸ See Noridian Healthcare Solutions, LLC & CGS Administrators, LLC, *Local Coverage Determination: Power Mobility Devices (L33789)*, <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33789&ver=31&Date=06%2f21%2f2020&DocID=L33789&bc=hAAAAAgAAAA&> (Last modified Jan. 1, 2020).

¹⁹ *Id.*; Sprigle S, Taylor SJ. Data-mining analysis of the provision of mobility devices in the United States with emphasis on complex rehab technology. *Assist Tech*. 2019;31(3):141-146. DOI: 10.1080/10400435.2017.1402391.

²⁰ Krause JS, Saunders LL. Health, Secondary Conditions, and Life Expectancy After Spinal Cord Injury, *Arch Phys Med Rehabil* 2011; 92:1770-5, doi:10.1016/j.apmr.2011.05.024.

multiple electrically powered mechanical movements that safely and ergonomically move the Group 3 PWC user from the seated position to a standing position.

This moves the PWC user incrementally from a seated position (a seat angle of 0° and seat-to-lower-leg support angle of 90°) to less hip and knee flexion (i.e., greater hip and knee extension) as the wheelchair user comes into an upright standing position. At maximum range, a fully open seat angle (90°) supports the wheelchair user in a position of full hip and knee extension. The full standing position is not necessary to achieve the benefits of standing. The negative effects of sitting are commonly accepted as a significant health risk for everyone, but these effects are of particular concern for people who use a wheelchair and are restricted to a seated position for the majority or entirety of their day.

The ability to achieve a standing position on a frequent basis throughout the day may counter the negative effects of prolonged sitting and provide therapeutic benefits for beneficiaries who are experiencing problems, including, but not limited to, contractures, tight muscles, decreased range of motion, kidney stones, recurring UTIs due to the inability to completely empty their bladder, and decreased circulation and pulmonary function. Moreover, standing is known to reduce pressure and the resulting skin injuries that cannot be resolved through the use of other technologies. Additionally, power standing systems allow the beneficiary to perform or participate in routine MRADLs—continuing to be able to move/operate the PWC while following a standing protocol. Other power systems used to address skin injuries (i.e., tilt and/or recline systems) place the beneficiary in a position that prevents performance or participation in many MRADLs, including mobility, and reduces the visual field while in the necessary position.

The power standing system is described by HCPCS Code E2301,²¹ which also went into effect in 2004. The power standing system also provides movement in the vertical plane, and assists beneficiaries with limited reaching abilities within the home and assists a beneficiary in performing or participating in MRADLs in the home, such as toileting, hygiene, dressing, grooming, and meal preparation, all of which the Medicare program considers MRADLs. A power standing system is described in LCA A52504.²²

A power standing system (E2301) includes: a solid seat platform and a solid back; detachable or flip-up fixed height armrests; hinged legrests; anterior knee supports; fixed or flip-up footplates; a motor and related electronics with or without variable speed programmability; a basic switch control which is independent of the PWC drive control interface; any hardware that is needed to

²¹ HCPCS Code E2301 is described as “[w]heelchair accessory, power standing system, any type.”

²² Noridian Healthcare Solutions, LLC & CGS Administrators, LLC, *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%7cSAD%7cRTC%7cReg&PolicyType=Both&s=All&Keyword=Wheelchair&KeywordLookup=Title&KeywordSearchType=Exact&kq=true&bc=EAAAABAAAA&> (Last modified Jan. 1, 2020).

attach the seating system to the wheelchair base. It does not include a headrest. It must have the following features: ability to move the beneficiary to a standing position; ability to support beneficiary weight of at least 250 pounds.

The FDA refers to the power standing system as a “standup wheelchair.”²³ The power standing system is classified by the FDA as a class II device under product code “IPL.”²⁴ The power standing system is subject to 510(k) premarket notification.²⁵

The ability to accommodate power standing systems requires performance characteristics not available on all PWCs. Power standing systems are only available on Group 3 and higher PWC bases. More complex technology is required for power standing systems than power seat elevation systems due to the complex combination of movements the PWC must coordinate to move the user from a seated to standing position. Products vary in how they achieve this movement. Select PWCs may be ordered with power standing alone; more often, power standing systems require the coordination of power tilt, power seat elevation, power elevating legrests, and power standing systems to achieve this movement. Additionally, these systems offer the wheelchair user the ability to operate each of the components independent of each other, as well as in combination.

III. Legal Background

A. The Medicare DME Benefit

DME is a statutory benefit category.²⁶ The Medicare statute does not specifically define the term “durable medical equipment” but simply refers to it by example to include “iron lungs, oxygen tents, hospital beds, and wheelchairs . . . used in the patient’s home . . . whether furnished on a rental basis or purchased”²⁷ A CMS regulation interprets the DME benefit through a five-part definition:

Durable medical equipment means equipment, furnished by a supplier or a home health agency that meets the following conditions:

- 1) Can withstand repeated use.
- 2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
- 3) Is primarily and customarily used to serve a medical purpose.
- 4) Generally is not useful to an individual in the absence of an illness or injury.

²³ FDA, *Product Classification: Wheelchair, Standup*, <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpdc/classification.cfm?id=5227> (Last updated June 22, 2020).

²⁴ *Id.*

²⁵ *Id.*

²⁶ 42 U.S.C. §. 1395x(n).

²⁷ *Id.*

5) Is appropriate for use in the home.²⁸

The Medicare Benefits Policy Manual (“MBPM”), ch. 15, § 110.1 elaborates further on the regulatory definitions of withstanding repeated use (durability) and medical equipment:

- Durability. “An item is considered durable if it can withstand repeated use, i.e., the type of item that could normally be rented.”²⁹
- Medical Equipment. “Medical equipment is equipment primarily and customarily used for medical purposes and is not generally useful in the absence of illness or injury.”³⁰ This same section of the MBPM considers a “wheelchair” to be equipment that is considered “presumptively medical.”³¹

While the term “appropriate for use in the home” is not defined in the Medicare statute or regulations, the MBPM states that “a beneficiary’s home may be his/her own dwelling, an apartment, a relative’s home, a home for the aged, or some other type of institution.”³²

B. NCD for MAE

On May 5, 2005, CMS issued Transmittal 37, an NCD for what CMS termed “Mobility Assistive Equipment” or “MAE.” The NCD for MAE is currently located in the National Coverage Determinations Manual, CMS Pub. 100-03, § 280.3. In the NCD, CMS found that the evidence is adequate to determine that MAE is reasonable and necessary as follows:³³

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

The NCD sets forth a comprehensive nine-step algorithm or “decision tree” for determining the clinical circumstances by which a specific type of MAE is appropriate for a beneficiary covered under the Medicare program:³⁴

1. Does the beneficiary have a mobility limitation that significantly impairs his/her ability to participate in one or more MRADLs in the home?

²⁸ 42 C.F.R. § 414.202.

²⁹ CMS, MBPM, Pub. 100-02, ch. 15, § 110.1.

³⁰ *Id.*

³¹ *Id.*

³² *Id.*

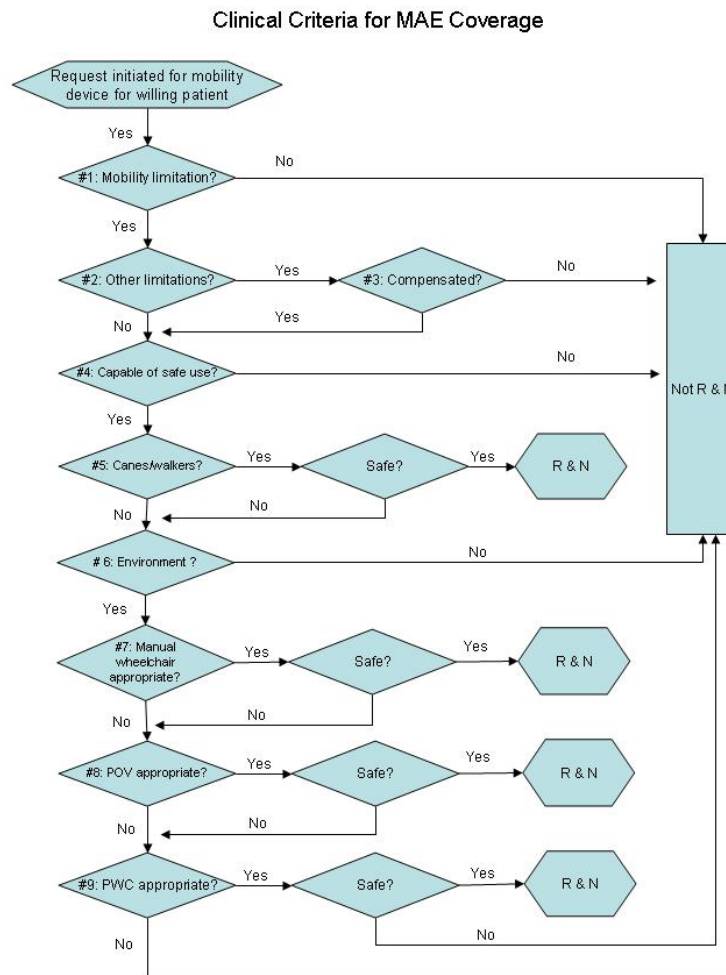
³³ CMS, Medicare NCD Manual, Pub. 100-03, § 280.3.

³⁴ *Id.*

2. Are there other conditions that limit the beneficiary's ability to participate in MRADLs at home?
3. If these other limitations exist, can they be ameliorated or compensated sufficiently such that the additional provision of MAE will be reasonably expected to significantly improve the beneficiary's ability to perform or obtain assistance to participate in MRADLs in the home?
4. Does the beneficiary or caregiver demonstrate the capability and the willingness to consistently operate the MAE safely?
5. Can the functional mobility deficit be sufficiently resolved by the prescription of a cane or walker?
6. Does the beneficiary's typical environment support the use of wheelchairs including scooters/power-operated vehicles (POVs)?
7. Does the beneficiary have sufficient upper extremity function to propel a manual wheelchair in the home to participate in MRADLs during a typical day?
8. Does the beneficiary have sufficient strength and postural stability to operate a POV/scooter?
9. Are the additional features provided by a PWC needed to allow the beneficiary to participate in one or more MRADLs?

The NCD includes additional information for each of the nine questions. The NCD provides the following flow chart to illustrate the application of the nine factors:³⁵

³⁵ *Id.*



Essential in applying this decision tree is the extent to which MAE will assist the beneficiary in performing or participating in MRADLs. Although the NCD for MAE refers to canes, crutches, walkers, manual wheelchairs, PWCs, and scooters, it specifically states that “this list ... is not exhaustive.”³⁶ The NCD for MAE suggests that PWC features and accessories facilitate the performance of or participation in MRADLs; however, more explicit language is necessary to acknowledge the limitations experienced by wheelchair users in their home environments during routine MRADLs. This will, in turn, direct subsequent policies to cover PWC features—such as power seat elevation and power standing systems—that are medically necessary and directly impact MRADL performance/participation.

³⁶ *Id.*

C. LCA on Power Seat Elevation and Standing Systems

All four regional DME MACs have issued LCA A52504, “Wheelchair Options/Accessories,” which governs the benefit category determination and, hence, coverage status of power seat elevation and power standing systems.³⁷ According to this LCA, “[a] power seat elevation feature (E2300) and power standing feature (E2301) are non-covered because they are not primarily medical in nature.”³⁸ The DME MACs provide no rationale for their conclusion and no citation to medical literature. The LCA is related to the LCD on “wheelchair options/accessories.”³⁹

Because this policy is set forth in an LCA, as opposed to an LCD, the DME MACs have not had to comply with the rigorous clinical evidence standards required for LCDs. In addition, the legal processes available to beneficiaries to challenge LCDs are not available to challenge BCD determinations in the form of an LCA.⁴⁰ This means that private companies contracting with CMS (i.e., the DME MACs) wield extensive influence over access to benefits to which Medicare beneficiaries are entitled, with no meaningful due process to challenge these decisions.

A recent Supreme Court decision calls into question the continued validity of LCA A52504. In *Azar v. Allina Health Services*, the Court held that the Medicare statute requires the Medicare program to use notice-and-comment rulemaking before issuing guidance that establishes or changes a substantive legal standard governing Medicare payment for services.⁴¹ The LCA establishes a substantive legal standard for payment for seat elevation and standing systems in PWCs, but the LCA was not issued pursuant to notice-and-comment procedures. Therefore, LCA A52504 is invalid. This is yet another reason why CMS should amend the NCD for MAE to clarify that power seat elevation and standing systems of Group 3 PWCs are indeed covered by Medicare.⁴²

³⁷ Noridian Healthcare Solutions, LLC & CGS Administrators, LLC, *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%7cSAD%7cRTC%7cReg&PolicyType=Both&s=All&Keyword=Wheelchair&KeywordLookUp=Title&KeywordSearchType=Exact&kq=true&bc=EAAAABAAAA&> (Last modified Jan. 1, 2020).

³⁸ *Id.*

³⁹ Noridian Healthcare Solutions, LLC & CGS Administrators, LLC, *Local Coverage Determination: Wheelchair Options/Accessories (L33792)*, <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33792&ver=28&Date=06%2f21%2f2020&DocID=L33792&bc=hAAAAAgAAAA&> (Last modified Jan. 1, 2020).

⁴⁰ See, e.g., *In Re CMS LCD Complaint: Wheelchair Options/Accessories (L11451)*, DAB No. 2370 (H.H.S. Mar. 29, 2011); 42 U.S.C. § 1395ff(f)(2).

⁴¹ *Azar v. Allina Health Servs.*, 139 S. Ct. 1804 (2019).

⁴² The Medicare statute expressly exempts NCDs from notice-and-comment requirements, so NCDs are not subject to the *Allina* holding. 42 U.S.C. § 1395hh(a)(2).

D. Related CMS Guidance

1. HCFA Ruling 96-1

In HCFA Ruling 96-1, CMS clarified the statutory DME and orthotics benefit categories.⁴³ HCFA (now CMS) issued Ruling 96-1 in response to an orthotics and prosthetics manufacturer/supplier that attached a series of orthoses to a wheeled frame to assist beneficiaries with significant muscle contractures and other catastrophic impairments. HCFA ruled that these devices could not be billed as orthoses in a nursing home setting to Medicare Part B separately from the underlying wheeled frame, which CMS considered DME.⁴⁴ The agency stated, unequivocally, that accessories to wheelchairs and other items of DME are part of the DME benefit:

To the extent that a wheelchair seating system or other equipment may or may not function properly or not achieve its full “therapeutic benefit” without attached components supporting or restricting motion in a body part, the attachments are appropriately viewed as a necessary accessory that is an integral part of the durable medical equipment and is, accordingly, payable as durable medical equipment, provided that the other prerequisites for classification as durable medical equipment are met.⁴⁵

2. NCD for Seat Lifts

CMS has issued NCD § 280.4 that allows coverage for seat lifts used in conjunction with stationary chairs to assist a beneficiary in achieving a standing position so that they can self-ambulate.⁴⁶ This recognizes that seat lifts can provide a therapeutic benefit for patients with muscular dystrophy, other neuromuscular diseases, or severe arthritis of the hip or knee.⁴⁷ NCD § 280.4 states in relevant part:

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

⁴³ HCFA, *HCFA Ruling No. 96-1* (Sept. 1996), <https://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/Downloads/HCFAR961.pdf>.

⁴⁴ *See id.*

⁴⁵ *Id.*

⁴⁶ CMS, Medicare NCD Manual, Pub. 100-03, § 280.4.

⁴⁷ *Id.*

condition, and that the severity of the condition is such that the alternative would be chair or bed confinement.⁴⁸

Given CMS's conclusion that a seat lift mechanism is primarily medical in nature, it stands to reason that a power seat elevation system and a power standing system of a Group 3 PWC (which significantly exceeds a standard seat lift mechanism in application, materials, cost, design, and technological and mechanical complexity) is also primarily medical in nature and, therefore, covered DME.

3. NCD for the iBOT 4000 Mobility System

In 2006, CMS issued an NCD for the INDEPENDENCE iBOT 4000 Mobility System ("iBOT") stating that Medicare covers the "Standard Function" of the system but not its other functions, including a "Balance Function" that involves seat elevation.⁴⁹ The Standard Function is similar to a traditional PWC. The Balance Function of the iBOT enables a user to move from a seated position to an elevated seated position where the four wheels rotate to a vertical position balancing on two wheels with the use of gyroscopes, while the user remains in a seated position. In denying coverage for the Balance Function, CMS reasoned that "[s]eat elevation serves the same purpose as other equipment that assist all persons in reaching items out of reach or having an 'eye-level' conversation with a standing person."⁵⁰ The agency, therefore, determined that the Balance Function is not primarily medical in nature. However, as described in detail below, the NCD for the iBOT should not preclude CMS from determining that the power seat elevation and power standing systems are primarily medical in nature.

IV. Requested Revisions to NCD for MAE

We have attached to this request for reconsideration the NCD for MAE with revisions indicated in red. Criteria 3 and 9 should be amended to clarify that access to the vertical environment in the home is a limiting factor that can warrant a power seat elevation or a power standing system used in conjunction with a Group 3 PWC to enable the beneficiary to perform or participate in MRADLs in the home. (The narrative description of the NCD revisions we propose immediately below can be viewed in redline changes in Appendix 2 of this NCD request.)

Criterion 3 ("If these other limitations exist, can they be ameliorated or compensated sufficiently such that the additional provision of MAE will be reasonably expected to significantly improve the beneficiary's ability to perform or obtain assistance to participate in MRADLs in the home?") should be amended to link the only reference in the NCD on "performance" of MRADLs to "features or accessories" described below in criterion 9. The

⁴⁸ *Id.*

⁴⁹ CMS, Medicare NCD Manual, Pub. 100-03, § 280.15.

⁵⁰ Decision Memorandum from Laurence Wilson et al. on the INDEPENDENCE 4000 iBOT Mobility System – Scope of Benefits § 1862(a)(1)(A) (July 27, 2006), <https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=5&fromdb=true>.

terms “features or accessories” should therefore be added after “If these other limitations exist, can they be ameliorated or compensated sufficiently such that the additional provision of MAE.”

Criterion 9 (“Are the additional features provided by a power wheelchair needed to allow the beneficiary to participate in one or more MRADLs?”) should be amended to link the concept of performance of MRADLs to accessories⁵¹ and to identify power seat elevation and standing systems as medically necessary DME that may assist certain beneficiaries in performing or obtaining assistance to participate in MRADLs in the home. Therefore, the term “or accessories” should be added after the phrase “Are the additional features...” In addition, after “a power wheelchair needed to allow the beneficiary to,” the words “perform or” should be added. Lastly, a new subparagraph should be added after subparagraph (a), stating: “Assess the beneficiary’s vertical environment (i.e., the need for a power seat elevation system or a power standing system) to allow the beneficiary to perform or obtain assistance to participate in MRADLs in the home.”

V. Benefit Category

Power seat elevation and power standing systems used in conjunction with a Group 3 PWC fall squarely within the DME benefit category. Contrary to LCA A52504, both systems primarily serve a medical purpose. The extensive medical benefits of these systems are discussed at length below, under section “VI. Scientific Evidence Supporting the Clinical Indications for Power Seat Elevation and Power Standing Systems.” *The ITEM Coalition implores CMS to include medical officers and consultants with training and experience in wheelchair seating and treatment of Medicare beneficiaries with mobility impairments in the literature review and determination of whether these systems are primarily medical in nature.* In addition, the current NCD for MAE and HCFA Ruling 96-1 support including power seat elevation and power standing systems within the DME benefit category. The NCD for Seat Lifts in stationary chairs is strong precedent for a determination that power seat elevation in Group 3 PWCs is also primarily medical in nature and should be included the DME benefit category.

The NCD for MAE § 280.3 currently supports that power seat elevation and power standing systems are within the DME benefit category. Under “Indications and Limitations of Coverage,” the NCD for MAE indicates that a Medicare beneficiary can qualify for a PWC if the additional features provided by a PWC allow the beneficiary to participate in one or more MRADLs. Item 9 of the clinical criteria algorithm for wheelchair prescribing indicates that “the pertinent features of a power wheelchair compared to a power-operated vehicle are typically

⁵¹ The current version of the NCD for MAE refers to both “performance of” and “participation in” MRADLs (*see* criterion 3 of the 9 criteria). During development of the NCD for MAE, CMS officials took the position that “participation” in MRADLs was confined to movement from point A to point B in order to place the beneficiary in the position where the MRADL occurs, whereas “performance of” MRADLs referred to the beneficiary actually accomplishing the MRADL itself, with or without assistance. Extending the term “performance of” MRADLs to criterion 9 which addresses wheelchair “features”—and we would add, “or accessories”—allows the NCD to consider coverage of features or accessories that address a beneficiary’s need to move vertically to perform an MRADL, once the mobility device places the beneficiary in the position where the MRADL takes place.

controlled by a joystick or alternative input device, *lower seat height for slide transfers*, and the ability to accommodate a variety of seating needs.” (Emphasis added.) The NCD for MAE indicates that criteria such as seat height are pertinent features used to determine eligibility for MAE.

The NCD for Seat Lift § 280.4 demonstrates that a seat elevation system of a Group 3 PWC falls under the DME benefit. CMS has recognized that seat lifts can provide a therapeutic benefit for patients with neuromuscular diseases.⁵² A power seat elevation system of a Group 3 PWC also provides a medical benefit for beneficiaries with permanent disabilities as it raises and lowers a beneficiary with specific limitations while they remain in a seated position. While the seat lift is accepted to be medical in nature, the primary and customary use of the base component (the chair) is nonmedical and non-covered.⁵³

Conversely, the power seat elevation system can only be used as a component of a medically necessary Group 3 PWC and should be considered presumptively medical and, hence, DME. Further, the seat lift function used with a stationary chair raises the beneficiary to an independent, standing position for self-ambulation. In contrast, the power seat elevation system raises the beneficiary’s seated position within the vertical plane to address MRADLs while still allowing the associate Group 3 PWC to move. If standard seat lifts are covered under Medicare, then power seat elevation when used as part of a Group 3 PWC must be covered as well.

The NCD for Seat Lift also supports a BCD for the power standing system of a Group 3 PWC by acknowledging that standing is a medically necessary position. The power standing system has far greater safety benefits than a seat lift, as the beneficiary stands without transferring out of the PWC and is supported while standing, greatly reducing the risk of falls that may occur during transfers and during performance of MRADLs while standing. The seat lift merely moves the beneficiary to a position where they can stand and ambulate on their own. In contrast, the power standing system allows a beneficiary incapable of standing independently to maintain a standing position or ambulate while standing and maintaining a standing position. It also allows a beneficiary to perform or participate in MRADLs.

Finally, the power standing system responds to numerous medical needs of the beneficiary, including, but not limited to, improved musculoskeletal joint mobility and strength, bone density, renal, cardiorespiratory, and digestive health and hygiene. It also serves to lessen the risk of skin pressure injuries (decubitus ulcers), circulatory challenges, and pulmonary limitations. Moreover, the standing system is a component of a Group 3 PWC, which is considered primarily medical in nature and is intended for use by beneficiaries with considerable mobility and neurological complications. CMS should, therefore, recognize the medical benefits of the power standing system used in conjunction with a medically necessary Group 3 PWC.

⁵² CMS, Medicare NCD Manual, Pub. 100-03, § 280.4.

⁵³ 42 U.S.C. § 1395x(n) (“With respect to a seat-lift chair, such term includes only the seat-lift mechanism and does not include the chair.”).

HCFA Ruling 96-1 supports the inclusion of the power seat elevation and power standing systems within the DME benefit. Both are accessories to a PWC that are integral to the wheelchair's function for beneficiaries who need them in order to achieve the "full 'therapeutic benefit'" of a PWC (i.e., DME).⁵⁴ The power seat elevation system enables certain beneficiaries to perform or participate in transfers and other MRADLs. The power standing system supports upright stability that impacts the entire body, providing medical and therapeutic benefits and facilitating the beneficiary's ability to reach and access objects in order to perform and participate in MRADLs. For this reason, HCFA Ruling 96-1 is directly on point as it relates to the BCD of the power standing and power seat elevation systems.

VI. Scientific Evidence Supporting the Clinical Indications for Power Seat Elevation and Power Standing Systems

A. Selection of Evidence

The ITEM Coalition used an intentional and purposeful process to select and organize the evidence for this NCD request. The ITEM Coalition relied heavily on its members with clinical expertise in wheelchair and seating assessment and prescription. An ITEM Coalition member, the Clinician Task Force, took a lead role in assessing the evidence base. The Clinician Task Force is comprised of physical therapists ("PTs") and occupational therapists ("OTs") with specific training and experience in complex rehabilitative PWC evaluations of beneficiaries' mobility, seating, and positioning needs. Another Coalition member, the American Academy of Physical Medicine and Rehabilitation, as well as RESNA-certified Assistive Technology Professionals ("ATPs"), provided valuable input.⁵⁵ Evidence selection was framed using direction from multiple CMS documents, including the Medicare Program Integrity Manual, chapter 13, § 13.5.3, which governs the LCD process, and the Federal Register.⁵⁶ Based on § 13.5.3 of the Medicare Program Integrity Manual, the ITEM Coalition selected evidence that met the following criteria:

- Published in peer-reviewed medical journals;
- Evidence-based consensus statements; and/or
- Clinical guidelines.

Furthermore, the ITEM Coalition examined each study, the study sample, instrumentation, and outcomes for representativeness and reliability to the equipment function and beneficiary population. The ITEM Coalition considered age (people over the age of 65 and under the age of 65 who qualify for Medicare based on disability) and diagnoses (e.g., healthy

⁵⁴ HCFA, *HCFA Ruling No. 96-1* (Sept. 1996), <https://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/Downloads/HCFAR961.pdf>.

⁵⁵ See Appendix D for a listing of individuals and organizations that participated in the development of this NCD request.

⁵⁶ Medicare Program; Revised Process for Making National Coverage Determinations, 78 Fed. Reg. 48,164 (Aug. 7, 2013).

condition, chronic and progressive conditions) as the main criteria for the beneficiary population.⁵⁷ Medicare beneficiaries with mobility impairments due to a neurological condition, myopathy, or congenital skeletal deformity regardless of age are the focus of this request and, therefore, the ITEM Coalition strongly considered this as we reviewed the evidence.

The ITEM Coalition studied the similarity of the instrumentation method and outcomes of the studies for relatedness to the function of the power seat elevation or power standing systems. When presenting evidence, the Coalition focused on the use of original study results with explicit reference to objective methods (e.g., measurements, recordings) and subjective methods (e.g., survey results, subject report). The ITEM Coalition excluded from consideration proprietary information, including non-published study results, unpublished dissertations, and conference proceedings.

Furthermore, the ITEM Coalition used a consensus of expert opinions to select evidence and, once compiled, the narrative was agreed upon by clinical experts in the field.⁵⁸ All articles and sources referenced in this NCD Reconsideration Request are listed in the bibliography. This NCD Reconsideration Request organizes evidence to explain the medical necessity of the power seat elevation and power standing systems consistent with the NCD for MAE and the accompanying Decision Memorandum for MAE that changed wheelchair coverage based on bed or chair confinement to function, specifically identifying toileting, feeding, dressing, grooming, and bathing as “activities necessary to serve a medical purpose in the home.”⁵⁹

B. Power Seat Elevation Evidence

1. Proposed Use of Power Seat Elevation

Some beneficiaries with permanent mobility impairments who use Group 3 PWCs need a power seat elevation system to replace loss of function in the vertical plane and improve their ability to perform or participate in MRADLs. A power seat elevation system that is a component of a medically necessary Group 3 PWC may play a vital role in meeting the medical device needs of certain beneficiaries with permanent mobility impairments. A Group 3 PWC replaces the loss of extremity function by allowing the beneficiary to move between two points in the horizontal plane independently, safely, and in a timely manner throughout the day, but a Group 3 PWC alone does not permit the beneficiary to access items in the vertical plane, which may limit their ability to perform or participate in MRADLs. In order to qualify for a PWC (rather than a

⁵⁷ See, e.g., Cara E. Masselink, Trends in Wheelchair Recommendations in a Dedicated Seating Department, *Assistive Technology* (July 2, 2020), doi: 10.1080/10400435.2020.1772899; Sprigle S, Taylor SJ. Data-mining analysis of the provision of mobility devices in the United States with emphasis on complex rehab technology. *Assist Tech*. 2019;31(3):141-146. DOI: 10.1080/10400435.2017.1402391.

⁵⁸ Experts include Cathy Carver, PT, ATP; Cara E. Masselink, PhD, OTRL, ATP; Nicole LaBerge, PT, ATP; Julie Piriano, PT, ATP/SMS; and Ashley Detterbeck, DPT, ATP, SMS.

⁵⁹ Decision Memorandum from Steve Phurrough et al. on Mobility Assistive Equipment (May 5, 2005), <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=143&NCDId=219&ncdver=2&IsPopup=y&bc=AAAAAAAAIAAA&>.

manual wheelchair) the beneficiary must also have limited upper extremity strength, which may result in a need for technology to assist in vertical access. Power seat elevation can assist beneficiaries with upper extremity strength deficits in transferring to and from the Group 3 PWC.

2. Target Medicare Population for Power Seat Elevation

Although a power seat elevation system may provide benefits to a broad range of PWC users, this request is limited to those Medicare beneficiaries who have a permanent disability and full-time need for a Group 3 PWC. This population of users have more extensive needs related to performance or participation in routine MRADLs. The power seat elevation system allows for the combination of seat elevation with other power seating systems, such as tilt and/or recline, and provides for a greater range of excursion.

Wheelchair users need to transfer regularly to perform or participate in MRADLs and often to level and non-level surfaces. People who perform stand-pivot transfers and have compromised cardiopulmonary systems⁶⁰ or lower extremity impairments⁶¹ are at greater risk for injuries or falls during transfers.⁶² This risk is reduced when moving to a standing position from higher seat heights equal to or greater than 20% of the person's lower leg length.⁶³ Additionally, PWC users who perform lateral transfers with shoulder pain⁶⁴ or regularly transfer to non-level surfaces, especially those that are higher than their standard PWC seat height,⁶⁵ would benefit from power seat elevation to reduce upper extremity effort and reduce risk of potential injury from overuse.⁶⁶

Related to reaching, PWC users with chronic shoulder pain or limitations in active upper extremity range of motion, strength, and/or endurance may benefit from power seat elevation to reduce the arc of range of motion that is required to grasp items overhead, and to the front and

⁶⁰ Nakamura K, Nagasawa Y, Sawaki S, Yokokawa Y, Ohira M. Effect of different seat heights during an incremental sit-to-stand exercise test on peak oxygen uptake in young, healthy women. *J Sports Sci Med*. 2016;15:410-416.

⁶¹ Burdett RG, Habasevich R, Pisciotto J, Simon SR. Biomechanical comparison of rising from two types of chairs. *Phys Ther*. 1985;65(8):1177-1183.

⁶² Tinetti ME, Speechley M, Ginter SF. Risk factors for falls among elderly persons living in the community. *N Engl J Med*. 1988;319(26):1701-1707; Nevitt MC, Cummings SR, Hudes ES. Risk factors for injurious falls: a prospective study. *J Gerontol*. 1991;46(5):M161-170.

⁶³ Weiner DK, Long R, Hughes MA, Chandler J, Studenski S. When older adults face the chair-rise challenge. *J Am Geriatr Soc*. 1993;41:6-10.

⁶⁴ Dalyan M, Cardenas DD, Gerard B. Upper extremity pain after spinal cord injury. *Spinal Cord*. 1999;37:191-195.

⁶⁵ Wang YT, Kim CK, Ford III HT, Ford Jr HT. Reaction force and EMG analyses of wheelchair transfers. *Percept Mot Skills*. 1994;79:763-766; Kim SS, Her JG, Ko TS. Effect of different hand positions on trunk and shoulder kinematics and reaction forces in sitting pivot transfer. *J Phys Ther Sci*. 2015;27:2307-2311.

⁶⁶ Finley MA, McQuade KJ, Rodgers MM. Scapular kinematics during transfers in manual wheelchair users with and without shoulder impingement. *Clin Biomech*. 2005;20:32-40. doi:10.1016/j.clinbiomech.2004.06.011; Nyland J, Quigley P, Huang C, Lloyd J, Harrow J, Nelson A. Preserving transfer independence among individuals with spinal cord injury. *Spinal Cord*. 2000;38:649-657.

side,⁶⁷ especially due to the repetitiveness and frequency of reaching required during MRADLs.⁶⁸ Lastly, PWC users with significant neck or upper back pain,⁶⁹ with limitations in active neck range of motion, spasms, or reflexes that impact static head positioning,⁷⁰ and/or limited vision⁷¹ may benefit from seat elevation to facilitate line of sight necessary for MRADL performance or participation. These characteristics are associated with neurological diagnoses such as SCI, cerebral palsy, and multiple sclerosis that require a Group 3 PWC for mobility and participation in and performance of MRADLs.

3. Evaluation and Assessment Process for Power Seat Elevation

The current LCD contains special conditions for coverage for Group 3 PWCs. Coverage is limited to beneficiaries with a mobility limitation that is due to a neurological condition, myopathy, or congenital skeletal deformity. In addition, these beneficiaries are required to have a specialty evaluation that is performed by a licensed/certified medical professional (LCMP), such as a PT or OT, or practitioner who has specific training and experience in rehabilitation wheelchair evaluations. The LCMP must document the medical necessity for the wheelchair and its special features, which would include power seat elevation if it is being recommended. The PT, OT, or practitioner may have no financial relationship with the supplier, and the wheelchair and power seating systems must be provided by a supplier that employs a RESNA-certified Assistive Technology Professional (ATP) who specializes in wheeled mobility and seating.

A team consisting of a LCMP, the supplier representative (ATP), the beneficiary, and possibly other clinicians or a caregiver will work together through the evaluation and assessment processes to consider the beneficiary's medical needs, clinical conditions, and other factors that drive the specific technology recommendation, such as, but not limited to; daily activities of living in the home environment (referred to in the NCD for MAE as MRADLs), functional needs and capabilities, and transportation needs. In addition, the team will identify the least expensive but medically appropriate technology and consider any contraindications that would prevent the

⁶⁷ 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 Technol*. 2016;28(3):184-189. doi: 10.1080/10400435.2016.1140692.

⁶⁸ Requejo PS, Mulroy SJ, Haubert LL, Newsam CJ, Gronley JK, Perry J. Evidence-based strategies to preserve shoulder function in manual wheelchair users with spinal cord injury. *Top Spinal Cord Inj Rehabil*. 2008;13(4):86-119. doi:10.1310/sci1304-86

⁶⁹ Boninger ML, Cooper RA, Fitzgerald SG, et al. Investigating neck pain in wheelchair users. *Am J Phys Med Rehabil*. 2003;82:197-202. doi: 10.1097/01.PHM.0000054217.17816.DD.

⁷⁰ Kirby RL, Fahie CL, Smith C, Chester EL, MacLeod DA. Neck discomfort of wheelchair users: effect of neck position. *Disabil Rehab*. 2004;26(1):9-15. doi: 10.1080/09638280310001621451; 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 Technol*. 2016;28(3):184-189. doi: 10.1080/10400435.2016.1140692.

⁷¹ Massengale S, Folden D, McConnell P, Stratton L, Whitehead V. Effect of visual perception, visual function, cognition, and personality on power wheelchair user in adults. *Assist Tech*. 2005;17(2):108-121. doi: 10.1080/10400435.2005.10132101; Kirby RL, Fahie CL, Smith C, Chester EL, MacLeod DA. Neck discomfort of wheelchair users: effect of neck position. *Disabil Rehab*. 2004;26(1):9-15. doi: 10.1080/09638280310001621451.

beneficiary from using certain technologies. The clinical and technological decision-making that occurs is documented in the beneficiary's medical record.

4. Medical Indications for Power Seat Elevation

Power seat elevation systems are primarily medical in nature due to the support they provide beneficiaries in their home with performance of or participation in MRADLs—the fundamental coverage criteria for MAE—specifically, transferring in and out of the PWC, and with upper extremity and head movements. This is consistent with the NCD for MAE and the accompanying Decision Memorandum for MAE.⁷² Power seat elevation supports PWC users' performance of tasks and actions required to perform or participate in MRADLs. This aligns with CMS's defined function-based PWC coverage criteria.⁷³ Without power seat elevation, these Group 3 PWC users are at greater risk for repetitive use injuries in the neck, upper back, and shoulders, as well as falls and/or injury during transfers and reach activities.

Additionally, power seat elevation is not functional on its own but must be integrated into a PWC. Power seat elevation is clearly not appropriate in the absence of an illness or injury. In addition, Group 3 PWC seat elevation will not be appropriate for beneficiaries for whom the benefits of seat elevation do not outweigh the additional out-of-pocket costs, and when the power seat elevation system is too complex for the user to operate.⁷⁴

a. Transfers

i. The Importance of Transfers to Beneficiaries Who Are Non-Ambulatory

“Seat elevating devices can facilitate safer and more independent transfers by elevating or lowering the seated height of the wheelchair.”⁷⁵ Safely performing transfers from one surface to another in order to perform or participate in MRADLs in the home is critical for non-ambulatory beneficiaries. A transfer is defined as, “movement from one surface to the other (e.g., wheelchair to bench).”⁷⁶ The ambulatory population starts the transition from one surface to another with a sitting to standing (“STS”) movement to propel the person vertically, which adults

⁷² CMS, Medicare NCD Manual, Pub. 100-03, § 280.3; Decision Memorandum from Steve Phurrough et al. on Mobility Assistive Equipment (May 5, 2005), <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=143&NCDId=219&ncdver=2&IsPopup=y&bc=AAAAAAAAIAAA&>.

⁷³ CMS, Medicare NCD Manual, Pub. 100-03, § 280.3; Decision Memorandum from Steve Phurrough et al. on Mobility Assistive Equipment (May 5, 2005), <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=143&NCDId=219&ncdver=2&IsPopup=y&bc=AAAAAAAAIAAA&>.

⁷⁴ Sonenblum SE, Maurer CL, Hanes CD, Piriano J, Sprigle SH. Everyday use of power adjustable seat height (PASH) systems. *Assist Technol.* 2019. doi: 10.1080/10400435.2019.1634659.

⁷⁵ Arva J, Schmeler MR, Lange ML, Lipka DD, Rosen LE. RESNA position on the application of seat-elevating devices for wheelchair users. *Assist Tech.* 2009; 21(2):69-72. doi: 10.1080/10400430902945587.

⁷⁶ Tsai CY, Hogaboom NS, Boninger ML, Koontz AM. The Relationship between Independent Transfer Skills and Upper Limb Kinetics in Wheelchair Users. *Biomed Res Int.* 2014;1-12. doi.org/10.1155/2014/984526.

were recorded to perform an average of 60 to 66 times per day, independent of the person's age.⁷⁷

Power mobility generally focuses on the user's ability to move in a horizontal, two-dimensional plane while seated in the wheelchair;⁷⁸ however, performance of or participation in MRADLs often requires movement in a vertical plane as well, especially during routine transfers from one surface to another. "Transferring is a means to accomplish MRADLs and therefore it is considered a medical necessity."⁷⁹ Transfers are required in MRADLs to care for oneself, including toileting and bathing.⁸⁰ The *RESNA Position Paper on the Application of Seat-Elevating Devices for Wheelchair Users* substantiates that transfers are medically necessary and an integral part of a wheelchair user's daily routine.⁸¹ Full-time PWC users have been recorded transferring an average of five to nine times per day.⁸² The frequency and consistency of the demand for this task indicates that transfers are a repetitive daily task for PWC users.⁸³

PWC users use variations of two main types of independent transfers: 1) stand-pivot; and 2) lateral. Stand-pivot transfers start with the STS transition, which occurs in four phrases: 1) flexion (leaning forward); 2) momentum transfer (seat-off); 3) extension (coming to the upright position); and 4) stabilization (standing).⁸⁴ To finish the transfer, the subject pivots the feet, then reverses the process to move from the standing position to the seated position.⁸⁵ While the lower extremities bear the weight of the person in a stand-pivot transfer, the upper extremities bear weight and facilitate movement in a lateral transfer.

⁷⁷ Bohannon RW, Barreca SR, Shove ME, Lambert C, Masters LM, Sigouin CS. Documentation of daily sit-to-stands performed by community-dwelling adults. *Physiother Theory Pract.* 2008;24(6):437-442. doi: 10.1080/09593980802511813; Dall PM, Kerr A. Frequency of the sit to stand task: An observational study of free-living adults. *Appl Ergon.* 2010;21:58-61; Yoshioka S, Nagano A, Hay DC, Fukushima S. Peak hip and knee joint moments during a sit-to-stand movement are invariant to the change of seat height within the range of low to normal seat height. *BioMedical Engineering OnLine.* 2014;13(27).

⁷⁸ Arva J, Schmeler MR, Lange ML, Lipka DD, Rosen LE. RESNA position on the application of seat-elevating devices for wheelchair users. *Assist Tech.* 2009;21(2):69-72. doi: 10.1080/10400430902945587.

⁷⁹ *Id.*

⁸⁰ *Id.*; Schiappa V, Piriano J, Bernhardt L, et al. RESNA position on the application of seat elevation devices for power wheelchair users: literature update 2019. September 25, 2019.

[https://www.resna.org/Portals/0/Documents/Position%20Papers/RESNA_App%20of%20Seat%20Elevation%20Dev](https://www.resna.org/Portals/0/Documents/Position%20Papers/RESNA_App%20of%20Seat%20Elevation%20Devices%202019.pdf)ices%202019.pdf. Accessed March 2, 2020.

⁸¹ Arva J, Schmeler MR, Lange ML, Lipka DD, Rosen LE. RESNA position on the application of seat-elevating devices for wheelchair users. *Assist Tech.* 2008;21(2):69-72. doi: 10.1080/10400430902945587.

⁸² Ding D, Leister E, Cooper RA et al. Usage of tilt-in-space, recline, and elevation seating functions in natural environment of wheelchair users. *J Rehabil Res Dev.* 2008;45(7):973-984, doi: 10.1682/JRRD.2007.11.0178; Sonenblum SE, Maurer CL, Hanes CD, Piriano J, Sprigle SH. Everyday use of power adjustable seat height (PASH) systems. *Assist Technol.* 2019. doi: 10.1080/10400435.2019.1634659.

⁸³ Dall PM, Kerr A. Frequency of the sit to stand task: An observational study of free-living adults. *Appl Ergon.* 2010;21:58-61.

⁸⁴ Schenkman M, Berger RA, Riley PO, Mann RW, Hodge WA. Whole-Body Movements During Rising to Standing from Sitting. *Phys Ther.* 1990;70(10):638-651.

⁸⁵ Janssen WGM, Bussmann HBJ, Stam HJ. Determinants of the Sit-to-Stand Movement: A Review. *Phys Ther.* 2002;82(9):866-879.

Lateral transfers start by placing one upper extremity ahead of the body (leading limb) toward the new surface and one upper extremity behind the body (trailing limb). Using bilateral upper extremities and trunk flexion (leaning forward), the person rises on bilateral upper extremities to move the body from one surface to the next, often using multiple incremental forward movements for one transfer.⁸⁶ Each forward movement requires a combination of bilateral upper extremity flexion, abduction, and internal rotation, and associated scapular movements, in which the head of the humerus (glenohumeral) moves toward the acromion.⁸⁷

This requires the person to reach, stretch and stabilize their shoulder joint with significant amounts of pressure since the beneficiary is transferring their full body weight onto that single joint during transfers. This occurs multiple times daily and the pressure is heightened when transfers are made between surfaces of unequal heights.

These repetitive movements can accelerate the development of shoulder muscle strain, nerve root disorders, and osteoarthritis. The complex shoulder and scapular movements close joint spaces and, over time, may result in poor posture with compensatory movements during lateral transfers and worsening shoulder impingement.⁸⁸ Due to the differences in physical and sensorimotor demands during each transfer type, the need for seat elevation to support stand-pivot and lateral transfers will be addressed separately.

ii. Stand-Pivot Transfers

Seat height impacts the biomechanics and success of the STS movement, a key action of the stand-pivot transfer. The STS has been investigated because studies have identified it as a key factor in functional independence.⁸⁹ From a neutral sitting position in a standard chair with feet flat on the floor, the quadriceps muscle experiences the highest load when initiating the rise to standing, and also contributes the most to timing of the movement in older adults.⁹⁰ However,

⁸⁶ Tsai CY, Hogaboom NS, Boninger ML, Koontz AM. The Relationship between Independent Transfer Skills and Upper Limb Kinetics in Wheelchair Users. *Biomed Res Int*. 2014;1-12. doi.org/10.1155/2014/984526; Finley MA, McQuade KJ, Rodgers MM. Scapular kinematics during transfers in manual wheelchair users with and without shoulder impingement. *Clin Biomech*. 2005;20:32-40. doi:10.1016/j.clinbiomech.2004.06.011; Gagnon D, Nadeau S, Noreau L, Eng JJ, Gravel D. Trunk and Upper Extremity Kinematics During Sitting Pivot Transfers Performed by Individuals with Spinal Cord Injury. *Clin Biomech*. 2008;23:279-290, doi:10.1016/j.clinbiomech.2007.09.017.

⁸⁷ Finley MA, McQuade KJ, Rodgers MM. Scapular kinematics during transfers in manual wheelchair users with and without shoulder impingement. *Clin Biomech*. 2005;20:32-40. doi:10.1016/j.clinbiomech.2004.06.011; Gagnon D, Nadeau S, Noreau L, Eng JJ, Gravel D. Trunk and Upper Extremity Kinematics During Sitting Pivot Transfers Performed by Individuals with Spinal Cord Injury. *Clin Biomech*. 2008;23:279-290, doi:10.1016/j.clinbiomech.2007.09.017.

⁸⁸ Finley MA, McQuade KJ, Rodgers MM. Scapular kinematics during transfers in manual wheelchair users with and without shoulder impingement. *Clin Biomech*. 2005;20:32-40. doi:10.1016/j.clinbiomech.2004.06.011.

⁸⁹ Kerr KM, White JA, Barr DA, Mollan RAB. Analysis of the sit—stand—sit movement cycle in normal subjects. *Clin Biomech*. 1997;12(4):236-245.

⁹⁰ Khemlani, MM, Carr JH, Crosbie WJ. Muscle synergies and joint linkages in sit-to-stand under two initial foot positions. *Clin Biomech*. 1999;14:236-246; Lord SR, Murray SM, Chapman K, Munro B, Tiedemann A. Sit-to-stand

the interaction of chair seat height and the person's lower leg length impacts STS performance. In an incremental STS test with healthy young-adult female subjects, researchers found that peak oxygen consumption and peak heart rate values were significantly higher when subjects performed STS from surfaces 20% lower than their total lower leg length than 40% higher than their total lower leg length.⁹¹ In other words, healthy, young-adult females required more oxygenation and developed a higher heart rate during STS as their seat height decreased. This can cause a significant adverse event for someone with a neurological condition and comorbidities of the cardiopulmonary systems.⁹²

In older adults, the impact of seat height is even more pronounced. Standing up from a lower seat height takes longer for older adults and increases the hip and knee joint angles, torque output, and anterior center of pressure.⁹³ Additionally, a study identified reduced respiratory health as a high risk of falls in older adults.⁹⁴ As the STS movement has shown to stress the cardiorespiratory system more at lower seat heights, and reduced respiratory health of older adults has been linked to fall risk, use of a power seat elevation system would reduce fall risk by increasing the seat height from which an older adult stands.

In contrast, a different study found that standing from a higher seat height decreases the stress in muscles surrounding the hips and knees and the range of motion needed in hips and knees to rise to the standing position, concluding that people with lower extremity impairments, such as weakness, pain, or other disabilities, have difficulty with rising from a standard seat height.⁹⁵ An additional study supported those results, finding that 73-86% of older adults with STS impairments (as those who need a PWC would exhibit) needed a seat with a minimum height of 120% of the person's knee height to execute STS successfully.⁹⁶ As 14% of falls in people older than age 75 occurred when rising to stand or sitting down,⁹⁷ and people prone to

performance depends on sensation, speed, balance, and psychological status in addition to strength in older people. *J Gerontol.* 2002;57(8):M539-M543.

⁹¹ Nakamura K, Nagasawa Y, Sawaki S, Yokokawa Y, Ohira M. Effect of different seat heights during an incremental sit-to-stand exercise test on peak oxygen uptake in young, healthy women. *J Sports Sci Med.* 2016;15:410-416.

⁹² Koski K, Luukinen H, Laippala P, Kivela SL. Risk factors for major injurious falls among the home-dwelling elderly by functional abilities. *Gerontology.* 1998;44:232-238.

⁹³ Alexander NB, Gross MM, Medell JL, Hofmeyer MR. Effects of functional ability and training on chair-rise biomechanics in older adults. *J Gerontol.* 2001;56A(9):M538-M547; Hughes MA, Schenkman ML. Chair rise strategy in the functionally impaired elderly. *J Rehabil Res Dev.* 1996;33(4):409-412.

⁹⁴ Koski K, Luukinen H, Laippala P, Kivela SL. Risk factors for major injurious falls among the home-dwelling elderly by functional abilities. *Gerontology.* 1998;44:232-238.

⁹⁵ Burdett RG, Habasevich R, Pisciotto J, Simon SR. Biomechanical comparison of rising from two types of chairs. *Phys Ther.* 1985;65(8):1177-1183.

⁹⁶ Weiner DK, Long R, Hughes MA, Chandler J, Studenski S. When older adults face the chair-rise challenge. *J Am Geriatr Soc.* 1993;41:6-10.

⁹⁷ Tinetti ME, Speechley M, Ginter SF. Risk factors for falls among elderly persons living in the community. *N Engl J Med.* 1988;319(26):1701-1707.

falling were found to take longer to rise to standing,⁹⁸ the ability to adjust one's seat height for more successful STS may increase physiological efficacy and reduce falls during stand-pivot transfers.

iii. Lateral Transfers

Long-term wheelchair users have rated transfers as one of the three most strenuous and intense wheelchair tasks they perform.⁹⁹ Researchers examined the transfer techniques of wheelchair users in relationship to the biomechanics of the upper extremities, finding that during a level transfer the trailing arm supports more body weight than the leading arm.¹⁰⁰ The physical effort of repetitive lateral transfers contributes to pain and injury over time. In a study of 84 people with paraplegia, 52% reported pain during transferring during the first five years of their injury, increasing to 100% by 20 years.¹⁰¹ Pain impacted transfer performance in 36 out of 55 adult respondents with paraplegia or tetraplegia who transferred independently or with minimal assistance.¹⁰²

Other research studied the impact of wheelchair height on upper extremity muscle activity and reaction force during transfers to toilet height (10 cm lower), wheelchair height (level), and bed height (10 cm higher) levels.¹⁰³ The results indicated that transfers to a level surface required the least amount of muscle effort, transfers to the lower surface required more use of the triceps and posterior deltoid muscles, and transfers to the higher surface required more biceps muscle use and elbow flexion and arm abduction range of motion actions.¹⁰⁴ Controlling and stabilizing the person's body mass during the transfer to move was described as a key factor when transferring to the higher and lower surfaces.¹⁰⁵ Researchers described this further, concluding that when level transfers are not possible, transfers to a lower height are preferred, as the position allows for the upper extremity to make smaller force movements and reduce the load on the shoulder.¹⁰⁶ Additionally, the lower hand placement was found to facilitate lower trunk

⁹⁸ Nevitt MC, Cummings SR, Hudes ES. Risk factors for injurious falls: a prospective study. *J Gerontol.* 1991;46(5):M161-170.

⁹⁹ Alm M, Saraste H, Norrbrink C. Shoulder pain in persons with thoracic spinal cord injury: prevalence and characteristics. *J Rehabil Med.* 2008;40:277-283, doi: 10.2340/16501977-0173; Curtis KA, Roach KE, Applegate EB, et al. Development of the Wheelchair User's Shoulder Pain Index (WUSPI). *Paraplegia.* 1995;33(5):290-293.

¹⁰⁰ Tsai CY, Hogaboom NS, Boninger ML, Koontz AM. The Relationship between Independent Transfer Skills and Upper Limb Kinetics in Wheelchair Users. *Biomed Res Int.* 2014;1-12. doi.org/10.1155/2014/984526.

¹⁰¹ Gellman H, Sie I, Waters RL. Late complications of the weight-bearing upper extremity in the paraplegic patient. *Clinical Orthopaedics and Rehabilitation Research.* 1987;233:132-135.

¹⁰² Dalyan M, Cardenas DD, Gerard B. Upper extremity pain after spinal cord injury. *Spinal Cord.* 1999;37:191-195.

¹⁰³ Wang YT, Kim CK, Ford III HT, Ford Jr HT. Reaction force and EMG analyses of wheelchair transfers. *Percept Mot Skills.* 1994;79:763-766.

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

¹⁰⁶ Kim SS, Her JG, Ko TS. Effect of different hand positions on trunk and shoulder kinematics and reaction forces in sitting pivot transfer. *J Phys Ther Sci.* 2015;27:2307-2311.

flexion, which would act as a “dynamic advantage for the movement to lift the hip” and thereby enable lateral movement.¹⁰⁷

Use of power seat elevation may reduce the risk of repetitive use injury to the upper extremities and also improve transfer safety during MRADLs. Transfer mishaps were recorded as the second most common cause of wheelchair-related injuries in people age 35 to 64 and over 65 years of age between 1991 to 2003.¹⁰⁸ Yet, transferring to a bed, toilet, or other surface is necessary for a person’s daily routine and is fundamental to performing or participating in MRADLs. In a study recording usage of power functions in PWCs, 50% of subjects reported using power seat elevation for transfers.¹⁰⁹ In surveys, 67 to 80% of respondents report using seat elevation frequently for transfers.¹¹⁰

Objective results confirmed subjective reports and identified that most transfers took place at a height of less than five inches or greater than nine inches and that the PWC users changed their seat heights between the transfer out of the wheelchair and the return transfer.¹¹¹ This indicates that the PWC users found the seat elevation function a meaningful element of their PWCs that facilitated transfers. Use of power seat elevation during transfer tasks is likely to enable and prolong independence with transfers by improving the person’s biomechanics and thereby reducing upper extremity strain and fall risk during this task.¹¹²

b. Reaching

Reaching is a crucial component of MRADL participation,¹¹³ as this action provides the functional means for which wheelchair users retrieve and transport objects throughout their homes. Key components of motor skills, reaching along with object retrieval, grasping, and manipulating, are core actions required to perform or participate effectively in many

¹⁰⁷ *Id.*

¹⁰⁸ Xiang H, Chany A-M, Smith GA. Wheelchair related injuries treated in US emergency departments. *Inj Prev.* 2006;12:8-11. doi: 10.1136/ip.2005.010033.

¹⁰⁹ Ding D, Leister E, Cooper RA et al. Usage of tilt-in-space, recline, and elevation seating functions in natural environment of wheelchair users. *J Rehabil Res Dev.* 2008;45(7):973-984, doi: 10.1682/JRRD.2007.11.0178.

¹¹⁰ Sonenblum SE, Maurer CL, Hanes CD, Piriano J, Sprigle SH. Everyday use of power adjustable seat height (PASH) systems. *Assist Technol.* 2019. doi: 10.1080/10400435.2019.1634659; Sprigle S. Survey of users of wheelchair seat elevators. Georgia Institute of Technology. 2017. https://smartech.gatech.edu/bitstream/handle/1853/59106/seat_elevator_survey_report.pdf?sequence=1&isAllowed=y. Accessed March 20, 2020.

¹¹¹ Sonenblum SE, Maurer CL, Hanes CD, Piriano J, Sprigle SH. Everyday use of power adjustable seat height (PASH) systems. *Assist Technol.* 2019. doi: 10.1080/10400435.2019.1634659.

¹¹² Schiappa V, Piriano J, Bernhardt L, et al. RESNA position on the application of seat elevation devices for power wheelchair users: literature update 2019. September 25, 2019. [https://www.resna.org/Portals/0/Documents/Position%20Papers/RESNA_App%20of%20Seat%20Elevation%20Dev](https://www.resna.org/Portals/0/Documents/Position%20Papers/RESNA_App%20of%20Seat%20Elevation%20Devices%202019.pdf)ices%202019.pdf. Accessed March 2, 2020.

¹¹³ McCrea PH, Eng JJ, Hodgson AJ. Biomechanics of reaching: clinical implications for individuals with acquired brain injury. *Disabil Rehabil.* 2002;24(10):534-541. doi: 10.1080/09638280110115393.

occupations.¹¹⁴ In the non-disabled population, the upper extremity is used primarily for reaching and grasping.¹¹⁵ Similarly, reaching and carrying items have been identified as two of 21 most important categories reported by wheelchair users through a semi-structured, standardized interview process.¹¹⁶ Rehabilitation professionals recognize this importance for wheelchair users as well, as demonstrated in the “Wheelchair Skills Test” that assesses reach as one of 20 skills critical to the function of wheelchair users.¹¹⁷ Additionally, 75% to 95% of PWC users reported using their power seat elevation system for reaching “often” or “sometimes.”¹¹⁸

Although wheelchair users emphasize reaching as a very important task, they also must reach overhead more than the ambulatory population. Wheelchair users reach overhead five times more often than non-wheelchair users.¹¹⁹ The home environment of many wheelchair users requires reach above shoulder height to locate, explore, and reach many features, including upper kitchen cabinets (average height 54 inches at bottom), items in a freezer over refrigerator (50 to 72 inches tall), an over-the-stove microwave (50 to 54 inches at bottom to 66 inches at top), and clothes hanging on a closet rod (66 inches).¹²⁰ Many thermostats, necessary for wheelchair users to control for thermal regulation, are positioned at 60 inches from the floor, and many light switches are on the wall at 48 inches.¹²¹

When measuring reach to 63.5 inches, researchers found a significant difference in the active range of motion required when subjects were seated in a PWC at 17.5 inches (at the minimum, static height) and the active range of motion needed when seated in a PWC at 25.5

¹¹⁴ American Occupational Therapy Association. (2014). Occupational therapy practice framework: Domain and process (3rd ed.). *American Journal of Occupational Therapy*, 68(Suppl. 1), S1-S48.

¹¹⁵ Nyland J, Quigley P, Huang C, Lloyd J, Harrow J, Nelson A. Preserving transfer independence among individuals with spinal cord injury. *Spinal Cord*. 2000;38:649-657.

¹¹⁶ Mills T, Holm MB, Trefler E, Schmeler M, Fitzgerald S, Boninger M. Development and consumer validation of the Functional Evaluation in a Wheelchair (FEW) instrument. *Disabil Rehabil*. 2002;24(1):38-46. doi: 10.1080/09638280110066334.

¹¹⁷ Kirby RL, Swuste J, Dupuis DJ, MacLeod DA, Monroe R. The Wheelchair Skills Test: A pilot study of a new outcome measure. *Arch Phys Med Rehabil*. 2002;83:10-8. doi:10.1053/apmr.2002.26823.

¹¹⁸ Sonenblum SE, Maurer CL, Hanes CD, Piriano J, Sprigle SH. Everyday use of power adjustable seat height (PASH) systems. *Assist Technol*. 2019. doi: 10.1080/10400435.2019.1634659; Sprigle S. Survey of users of wheelchair seat elevators. Georgia Institute of Technology. 2017. https://smartech.gatech.edu/bitstream/handle/1853/59106/seat_elevator_survey_report.pdf?sequence=1&isAllowed=y. Accessed March 20, 2020.

¹¹⁹ Requejo PS, Mulroy SJ, Haubert LL, Newsam CJ, Gronley JK, Perry J. Evidence-based strategies to preserve shoulder function in manual wheelchair users with spinal cord injury. *Top Spinal Cord Inj Rehabil*. 2008;13(4):86-119. doi:10.1310/sci1304-86.

¹²⁰ Schiappa V, Piriano J, Bernhardt L, et al. RESNA position on the application of seat elevation devices for power wheelchair users: literature update 2019. September 25, 2019; Sonenblum SE, Maurer CL, Hanes CD, Piriano J, Sprigle SH. Everyday use of power adjustable seat height (PASH) systems. *Assist Technol*. 2019. doi: 10.1080/10400435.2019.1634659.

¹²¹ Schiappa V, Piriano J, Bernhardt L, et al. RESNA position on the application of seat elevation devices for power wheelchair users: literature update 2019. September 25, 2019.

inches (positioned at maximum height with power seat elevation).¹²² In this task, all participants abducted their shoulder (reached sideways) equal to or over 60 degrees to reach the object when seated at the minimum height, with an average shoulder abduction of 85.11 degrees.¹²³ However, with the power seat elevation system at maximum height (25.5 inches), the minimum active abduction utilized was 35 degrees, with an average of 53.39 degrees abduction.¹²⁴

Repeated or sustained abduction or flexion over 60 degrees is known to contribute to tendinitis and other musculoskeletal disorders in the shoulder.¹²⁵ Therefore, PWC users are at great risk of pain and injury due to their need to repetitively reach overhead during MRADLs without the vertical support provided through seat elevation. Because wholesale redesign of each Medicare PWC user's home is infeasible to accommodate the seated position, seat elevation is a key equalizer in the pursuit of performance of or participation in MRADLs in the home.

c. Line of Sight's Impact on Neck and Spine Function

PWC users rely on vision to navigate directions, such as when turning corners and driving down hallways, and around obstacles, such as couches and tables, with evidence supporting similarities between driving a PWC and driving a car.¹²⁶ Visual components that contribute significantly to safe PWC driving are visual perception, far visual acuity, visual fields, oculomotor control, specifically pursuits, saccades, and depth perception.¹²⁷ Visual fields in the human population are approximately 90 degrees horizontally to each side, 70 degrees inferiorly, and 60 degrees superiorly.¹²⁸

For PWC users, the upper visual quadrant, or superior visual field, is relied on more than in the ambulatory population due to the differences in eye height and available trunk positions observed by ambulatory people and people seated in PWC.¹²⁹ However, using the visual sense is necessary to locate items during MRADLs that are in cabinets or on shelves, when utilizing the mirror for grooming tasks (e.g., shaving, brushing teeth), and when reading information posted

¹²² 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 Technol*. 2016;28(3):184-189. doi: 10.1080/10400435.2016.1140692.

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ Bernard BP. *Musculoskeletal disorders and workplace factors* (97B141). Cincinnati, OH: US Department of Health and Human Services, National Institute for Occupational Safety and Health; July, 1997.

¹²⁶ Charette C, Routhier F, McFadyen BJ. Visuo-locomotor control in persons with spinal cord injury in a manual or power wheelchair for direction change and obstacle circumvention. *Exp Brain Res*. 2017;235:2669-2678. doi: 10.1007/s00221-017-4994-4.

¹²⁷ Massengale S, Folden D, McConnell P, Stratton L, Whitehead V. Effect of visual perception, visual function, cognition, and personality on power wheelchair user in adults. *Assist Tech*. 2005;17(2):108-121. doi: 10.1080/10400435.2005.10132101.

¹²⁸ Durette DP, Fortuna J. Visual function assessment. In: Durette DP, Gutman SA, eds. *Occupational Therapy for Physical Dysfunction*. 8th ed. Philadelphia:Wolters Kluwer;2020:81-99.

¹²⁹ Kirby RL, Fahie CL, Smith C, Chester EL, MacLeod DA. Neck discomfort of wheelchair users: effect of neck position. *Disabil Rehab*. 2004;26(1):9-15. doi: 10.1080/09638280310001621451.

on walls (e.g., calendars, thermostats), as well as in the use of eye-hand coordination when reaching for objects near the periphery of maximum range of motion, as occurs when cooking on a hot stove or using the oven or a microwave (i.e., meal preparation).¹³⁰

However, superior vision (looking up) is the most restricted quadrant in the visual field of humans at 60 degrees.¹³¹ In instances where vertical line of sight above the visual field is necessary, compensatory body movement strategies increase visual access to the vertical space, and PWC users commonly use cervical extension. Researchers found that wheelchair users extended their cervical spine 11 degrees to look at a seated person, and 27 degrees to look at a standing person.¹³² Furthermore, people with thoracic kyphosis must hyperextend into cervical lordosis to maintain line of sight.¹³³ With a PWC at minimum seat height, people were shown to use an average of 24 degrees cervical extension to look at a computer screen centered at 69.5 inches from the floor; however, with power seat elevation of 8 inches, average cervical extension was reduced to 15 degrees, close to a 10 degree reduction.¹³⁴

Repetitive cervical extension, which occurs when looking up frequently during physical environment navigation and MRADL performance/participation, may lead to pain and injury. PWC users have reported approximately 15% greater neck pain than the general population,¹³⁵ with 66% of 68 subjects reporting neck and upper back pain at some point since the start of using a wheelchair, 60% in the prior month, and 40% in the 24 hours prior to questioning.¹³⁶ Furthermore, 17% more PWC users reported experiencing neck and upper back pain than manual wheelchair users, and 40% of all respondents who experienced pain admitted to limiting their daily activities in response.¹³⁷ Comparatively, approximately 85% of PWC users with power seat elevation across multiple studies reported using this feature for line of sight tasks.¹³⁸

¹³⁰ Schiappa V, Piriano J, Bernhardt L, et al. RESNA position on the application of seat elevation devices for power wheelchair users: literature update 2019. September 25, 2019. [https://www.resna.org/Portals/0/Documents/Position%20Papers/RESNA_App%20of%20Seat%20Elevation%20Dev](https://www.resna.org/Portals/0/Documents/Position%20Papers/RESNA_App%20of%20Seat%20Elevation%20Devices%202019.pdf)ices%202019.pdf. Accessed March 2, 2020.

¹³¹ Dirette DP, Fortuna J. Visual function assessment. In: Dirette DP, Gutman SA, eds. *Occupational Therapy for Physical Dysfunction*. 8th ed. Philadelphia:Wolters Kluwer;2020:81-99.

¹³² Kirby RL, Fahie CL, Smith C, Chester EL, MacLeod DA. Neck discomfort of wheelchair users: effect of neck position. *Disabil Rehab*. 2004;26(1):9-15. doi: 10.1080/09638280310001621451.

¹³³ Diebo BG, Challier V, Henry JK, et al. Predicting cervical alignment required to maintain horizontal gaze based on global spinal alignment, *Spine*, 2016;41(23):1795-1800. doi:10.1097/BRS.0000000000001698.

¹³⁴ 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 Technol*. 2016;28(3):184-189. doi: 10.1080/10400435.2016.1140692.

¹³⁵ Kirby RL, Fahie CL, Smith C, Chester EL, MacLeod DA. Neck discomfort of wheelchair users: effect of neck position. *Disabil Rehab*. 2004;26(1):9-15. doi: 10.1080/09638280310001621451.

¹³⁶ Boninger ML, Cooper RA, Fitzgerald SG, et al. Investigating neck pain in wheelchair users. *Am J Phys Med Rehabil*. 2003;82:197-202. doi: 10.1097/01.PHM.0000054217.17816.DD.

¹³⁷ *Id.*

¹³⁸ Ding D, Leister E, Cooper RA et al. Usage of tilt-in-space, recline, and elevation seating functions in natural environment of wheelchair users. *J Rehabil Res Dev*. 2008;45(7):973-984, doi: 10.1682/JRRD.2007.11.0178; Sonenblum SE, Maurer CL, Hanes CD, Piriano J, Sprigle SH. Everyday use of power adjustable seat height (PASH) systems. *Assist Technol*. 2019. doi: 10.1080/10400435.2019.1634659; Sprigle S. Survey of users of wheelchair seat

d. MRADLs in the Home

PWCs accommodate for loss of mobility in the horizontal plane. However, without power seat elevation to enable movement in a vertical plane, PWC users are unable to adapt their seat-to-floor height to relate to their home physical environment, which was likely constructed for an ambulatory population. To ensure the optimal equipment-environment match, clinical decision-making during wheelchair evaluations involves the close collaboration of the provider (e.g., physician, advanced practice providers, PT, or OT), the supplier (manufacturer or supplier), and the patient/client and their family and/or caregivers.¹³⁹

Without power seat elevation, the stakeholders must balance seat-to-floor height between a low seat-to-floor height that will position the PWC under tables or desks for self-feeding and/or computer access with lower extremity clearance, and a higher seat-to-floor height that will facilitate transfers.¹⁴⁰ Both lower and upper seat height help the non-ambulatory beneficiary perform or participate in multiple MRADLs. PWC users improve function within the home with a dynamic seat height; 79% of respondents with power seat elevation report that they “often” use power seat elevation within the home, with 94% reporting they “often or sometimes” use it.¹⁴¹ Additionally, researchers found that PWC users with power seat elevation were active approximately 18 times an hour, and at an elevation of more than one inch.¹⁴² Specific MRADLs that survey respondents reported using their power seat elevation system for included eating, preparing meals, toileting, and when sitting at various table-top heights, among the other tasks described above, such as transferring, reaching, and to improve line of sight.¹⁴³

elevators. Georgia Institute of Technology. 2017.

https://smartech.gatech.edu/bitstream/handle/1853/59106/seat_elevator_survey_report.pdf?sequence=1&isAllowed=y. Accessed March 20, 2020.

¹³⁹ Eggers SL, Myaskovsky L, Burkitt KH et al. A preliminary model of wheelchair service delivery. *Arch Phys Med Rehabil*. 2009;90:1030-1038. doi:10.1016/j.apmr.2008.12.007.

¹⁴⁰ Sonenblum SE, Maurer CL, Hanes CD, Piriano J, Sprigle SH. Everyday use of power adjustable seat height (PASH) systems. *Assist Technol*. 2019. doi: 10.1080/10400435.2019.1634659; Measuring a power chair. *Mobility Management Magazine*. Oct 1, 2018. <https://mobilitymgmt.com/Articles/2018/10/01/Measurements.aspx>. Accessed April 9, 2020.

¹⁴¹ Sonenblum SE, Maurer CL, Hanes CD, Piriano J, Sprigle SH. Everyday use of power adjustable seat height (PASH) systems. *Assist Technol*. 2019. doi: 10.1080/10400435.2019.1634659; Sprigle S. Survey of users of wheelchair seat elevators. Georgia Institute of Technology. 2017.

https://smartech.gatech.edu/bitstream/handle/1853/59106/seat_elevator_survey_report.pdf?sequence=1&isAllowed=y. Accessed March 20, 2020.

¹⁴² Sonenblum SE, Maurer CL, Hanes CD, Piriano J, Sprigle SH. Everyday use of power adjustable seat height (PASH) systems. *Assist Technol*. 2019. doi: 10.1080/10400435.2019.1634659.

¹⁴³ Schiappa V, Piriano J, Bernhardt L, et al. RESNA position on the application of seat elevation devices for power wheelchair users: literature update 2019. September 25, 2019. https://www.resna.org/Portals/0/Documents/Position%20Papers/RESNA_App%20of%20Seat%20Elevation%20Devices%202019.pdf. Accessed March 2, 2020; Ding D, Leister E, Cooper RA et al. Usage of tilt-in-space, recline, and elevation seating functions in natural environment of wheelchair users. *J Rehabil Res Dev*. 2008;45(7):973-984, doi: 10.1682/JRRD.2007.11.0178; Sprigle S. Survey of users of wheelchair seat elevators. Georgia Institute of Technology. 2017.

C. Power Standing Evidence

1. Proposed Use of Power Standing System

A Group 3 PWC with a power standing system supports MRADL performance/participation by providing the user with the ability to rise to a standing position when the home environment vertically exceeds the seated position.¹⁴⁴ These items may include upper kitchen cabinets (average height 54 inches at bottom), items in a freezer over a refrigerator (50-72 inches tall), an over-the-stove microwave (50-54 inches at bottom to 66 inches at top), and clothes hanging on a closet rod (66 inches).¹⁴⁵ People with spinal cord injury (SCI) and Duchenne's Muscular Dystrophy have expressed appreciation for the increased ease of reaching and moving objects in a standing position¹⁴⁶ and managing a urinal or standing at the toilet.¹⁴⁷ Additionally, standing directly supports MRADL performance/participation through spasticity management.¹⁴⁸ Respondents with Duchenne's Muscular Dystrophy reported more efficient daily care routines that required less transfers.¹⁴⁹ Finally, the use of a power standing system of a Group 3 PWC

https://smartech.gatech.edu/bitstream/handle/1853/59106/seat_elevator_survey_report.pdf?sequence=1&isAllowed=y. Accessed March 20, 2020.

¹⁴⁴ Eng JJ, Levins SM, Townson AF, Mah-Jones D, Bremner J, Huston G. Use of prolonged standing for individuals with spinal cord injuries. *Phys Ther.* 2001;81(8):1392-1399.

¹⁴⁵ Schiappa V, Piriano J, Bernhardt L, et al. RESNA position on the application of seat elevation devices for power wheelchair users: literature update 2019. September 25, 2019.

https://www.resna.org/Portals/0/Documents/Position%20Papers/RESNA_App%20of%20Seat%20Elevation%20Devices%202019.pdf. Accessed March 2, 2020; Sonenblum SE, Maurer CL, Hanes CD, Piriano J, Sprigle SH. Everyday use of power adjustable seat height (PASH) systems. *Assist Technol.* 2019. doi: 10.1080/10400435.2019.1634659.

¹⁴⁶ Antonio TS, Urrutia F, Larrea A, Espín V, Latta MA. (2019) Variations in Vital Signs Associated with the Postural Changes When Using a Stand-up Wheelchair in Patients with Spinal Cord Injury. In: Ahram T.Z., Falcão C. (eds) *Advances in Usability, User Experience and Assistive Technology*. AHFE 2018; Vorster N, Evans K, Murphy N, et al. Powered standing wheelchairs promote independence, health and community involvement in adolescents with Duchenne muscular dystrophy. *Neuromuscul Disord.* 2019;29:221-230. doi: 10.1016/j.nmd.2019.01.010. Antonio et al, 2019.

¹⁴⁷ Vorster N, Evans K, Murphy N, et al. Powered standing wheelchairs promote independence, health and community involvement in adolescents with Duchenne muscular dystrophy. *Neuromuscul Disord.* 2019;29:221-230. doi: 10.1016/j.nmd.2019.01.010; Eng JJ, Levins SM, Townson AF, Mah-Jones D, Bremner J, Huston G. Use of prolonged standing for individuals with spinal cord injuries. *Phys Ther.* 2001;81(8):1392-1399.

¹⁴⁸ Newman M, Barker K. The effect of supported standing in adults with upper motor neurone disorders: a systematic review. *Clin Rehabil.* 2012;26(12):1059-1077. doi: 10.1177/0269215512443373; Kheder A, Nair KPS. Spasticity: pathophysiology, evaluation and management. *Pract Neurol.* 2012;12:289-298. doi:10.1136/practneurol-2011-000155; Dudley-Javoroski S, Shields RK. Muscle and bone plasticity after spinal cord injury: review of adaptations to disuse and to electrical muscle stimulation. *J Rehabil Res. Dev.* 2008;45(2):283-296. doi: 10.1682/JRRD.2007.02.0031.

¹⁴⁹ Vorster N, Evans K, Murphy N, et al. Powered standing wheelchairs promote independence, health and community involvement in adolescents with Duchenne muscular dystrophy. *Neuromuscul Disord.* 2019;29:221-230. doi: 10.1016/j.nmd.2019.01.010.

can address other medical needs of the beneficiary, including, but not limited to, protection of skin and tissue integrity, enhancing pulmonary function, and increasing circulatory function.¹⁵⁰

2. Target Medicare Population for Power Standing

Although standing may provide benefits to a broad range of people with disabilities, this NCD reconsideration request is limited to power standing systems, which, at this time, are only available in PWCs classified as Group 3 or above under the Medicare DME benefit.

The individuals who would most benefit from the power standing system of a Group 3 PWC include beneficiaries who are at risk of losing or have lost passive or active range of motion in unilateral or bilateral lower extremities. Beneficiaries with neurological conditions are particularly at risk of muscle spasticity, spasms, and loss of bone density and can benefit from the power standing system. In addition, the power standing system will benefit individuals with bowel and bladder difficulties, pulmonary limitations, and skin integrity or pressure management problems.

Individuals who have range of motion restrictions in the hip¹⁵¹ and ankle¹⁵² will likely benefit from standing 30 minutes a day three to five days a week,¹⁵³ and there is also evidence of

¹⁵⁰ 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; Antonio TS, Urrutia F, Larrea A, Espín V, Latta MA. (2019) Variations in Vital Signs Associated with the Postural Changes When Using a Stand-up Wheelchair in Patients with Spinal Cord Injury. In: Ahram T.Z., Falcão C. (eds) *Advances in Usability, User Experience and Assistive Technology. AHFE 2018. Advances in Intelligent Systems and Computing*, vol 794; Edwards LC, Layne CS. Effect of dynamic weight bearing on neuromuscular activation after spinal cord injury. *Am J Phys Med Rehabil.* 2007;86(7):499-506; Cotie LM, Geurts CLM, Adams MME, MacDonald MJ. Leg skin temperature with body-weight-supported treadmill and tilt-table standing training after spinal cord injury. *Spinal Cord.* 2011;49:149-153. doi: 10.1038/sc.2010.52.

¹⁵¹ 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.

¹⁵² *Id.*; Ben M, Harvey L, Denis S, et al. Does 12 weeks of regular standing prevent loss of ankle mobility and bone mineral density in people with recent spinal cord injuries? *Aust J Physiother.* 2005;51:251-256; Newman M, Barker K. The effect of supported standing in adults with upper motor neurone disorders: a systematic review. *Clin Rehabil.* 2012;26(12):1059-1077. doi: 10.1177/0269215512443373; Robinson W, Smith R, Aung O, Ada L. No difference between wearing a night splint and standing on a tilt table in preventing ankle contracture early after stroke: a randomised trial. *Aust J Physiother.* 2008;54:33-38.

¹⁵³ 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; Newman M, Barker K. The effect of supported standing in adults with upper motor neurone disorders: a systematic review. *Clin Rehabil.* 2012;26(12):1059-1077. doi: 10.1177/0269215512443373; Robinson W, Smith R, Aung O, Ada L. No difference between wearing a night splint and standing on a tilt table in preventing ankle contracture early after stroke: a randomised trial. *Aust J Physiother.* 2008;54:33-38; Ben M, Harvey L, Denis S, et al. Does 12 weeks of regular standing prevent loss of ankle mobility and bone mineral density in people with recent spinal cord injuries? *Aust J Physiother.* 2005;51:251-256; Paleg G, Livingstone R. Systematic review and clinical recommendations for dosage of supported home-based standing programs for adults with stroke, spinal cord injury and other neurological conditions. *BMC Musculoskelet Disord.* 2015;16(358):1-16. doi: 10.1186/s12891-015-0813-x.

upper trunk and shoulder musculature benefits from the standing posture as well.¹⁵⁴ Similarly, people with lower extremity muscle atrophy, which occurs with loss of ambulation, may improve their lower extremity strength through weight bearing in a standing position.¹⁵⁵ Dynamic movement may further support muscle strength development,¹⁵⁶ which movement from the PWC may provide.

Many people with neurological conditions encounter spasticity and the loss of bone mineral density. Spasticity and spasms may be managed by standing for intervals a minimum of three days a week, although the effects of standing on spasticity appear short-term.¹⁵⁷ Therefore, people with spasticity and/or spasms would benefit from a plan of care that includes daily standing, to improve body functions during MRADL performance/participation.¹⁵⁸ People with acute lower extremity disuse, for example with SCI or cerebral vascular accident (“CVA”)/stroke, would benefit from early intervention and at higher doses, standing one hour, five days a week, to decrease the rate of bone density loss.¹⁵⁹

¹⁵⁴ Riek LM, Ludewig PM, Nawoczenski 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;46:335-343. doi:10.1038/sj.sc.3102140.

¹⁵⁵ Kaplan PE, Roden W, Gilbert E, Richards L, Goldschmidt JW. Reduction of hypercalciuria in tetraplegia after weight-bearing and strengthening exercises. *Paraplegia*. 1981;19:289-293; Kuznetsov AN, Rybalko NV, Daminov VD, Luft AR. Early poststroke rehabilitation using a robotic tilt-table stepper and functional electrical stimulation. *Stroke Res Treat*. 2013;1-9, doi.org/10.1155/2013/946056.

¹⁵⁶ Kim CY, Lee JS, Kim HD, Kim JS. The effect of progressive task-oriented training on supplementary tilt table on lower extremity muscle strength and gait recovery in patients with hemiplegic stroke. *Gait Posture*. 2015;41:425-430; Kim CY, Lee JS, Kim HD, Kim J, Lee IH. Lower extremity muscle activation and function in progressive task-oriented training on the supplementary tilt table during stepping-like movements in patients with acute stroke hemiparesis. *J Electromyogr Kinesiol*. 2015;25:522-530, doi.org/10.1016/j.jelekin.2015.03.004; Netz Y, Argov E, Burstin A, et al. 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 Technol*. 2007;2(1):43-49. doi: 10.1080/17483100601143371.

¹⁵⁷ Adams MM, Hicks AL. Comparison of the effects of body-weight-supported treadmill training and tilt-table standing on spasticity in individuals with chronic spinal cord injury. *J Spinal Cord Med*. 2011;34(5):488-494. doi: 10.1179/2045772311Y.0000000028; 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; Bohannon RW. Tilt table standing for reducing spasticity after spinal cord injury. *Arch Phys Med Rehabil*. 1993;74(10):1121-1122; Odeen I, Knutsson E. Evaluation of the effects of muscle stretch and weight load in patients with spastic paraplegia. *Scand J Rehabil Med*. 1981;13:117-121.

¹⁵⁸ Shields RK, Dudley-Javoroski S. Monitoring standing wheelchair use after spinal cord injury: a case report. *Disabil Rehabil*. 2005;27(3):142-146. doi: 10.1080/09638280400009337.

¹⁵⁹ Alekna V, Tamulaitiene M, Sinevicius T, Juocevicius A. Effect of weight-bearing activities on 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; de Bruin ED, Frey-Rindova P, Herzog RE, Dietz V, Dambacher MA, Stüssi E. Changes in tibia bone properties after spinal cord injury: effects of early intervention. *Arch Phys Med Rehabil*. 1999;80:214-220; Paleg G, Livingstone R. Systematic review and clinical recommendations for dosage of supported home-based standing programs for adults with stroke, spinal cord injury and other neurological conditions. *BMC Musculoskeletal Disord*. 2015;16(358):1-16. doi: 10.1186/s12891-015-0813-x.

Furthermore, beneficiaries who frequently experience bowel and bladder issues, pulmonary or circulatory issues, or difficulty with skin pressure management or have a history of skin injuries will benefit from the power standing system of a Group 3 PWC. Transitioning between sitting and standing positions has shown to increase bowel emptying times,¹⁶⁰ and movement while standing may improve muscle control and bowel continence.¹⁶¹ Additionally, bladder health increases in the standing position rather than sitting¹⁶² as well as with consistent standing.¹⁶³ Similarly, breaking up long periods of sitting, as experienced by many PWC users,¹⁶⁴ with standing¹⁶⁵ normalizes the vital signs of many PWC users.¹⁶⁶ Lastly, people with poor skin integrity, at risk for—or who have encountered—pressure injuries, may benefit from standing, especially if pressure injuries have occurred on the posterior surface of the person.¹⁶⁷

3. Evaluation and Assessment Process for Power Standing System

The current LCD contains special conditions for coverage for Group 3 PWCs. Coverage is limited to beneficiaries with a mobility limitation that is due to a neurological condition, myopathy, or congenital skeletal deformity. In addition, these beneficiaries are required to have a specialty evaluation that is performed by a licensed/certified medical professional (LCMP), such as a PT or OT, or practitioner who has specific training and experience in rehabilitation wheelchair evaluations. The LCMP must document the medical necessity for the wheelchair and its special features, which would include power seat elevation if it is being recommended. The PT, OT, or practitioner may have no financial relationship with the supplier, and the wheelchair and power seating systems must be provided by a supplier that employs a RESNA-certified Assistive Technology Professional (ATP) who specializes in wheeled mobility and seating.

¹⁶⁰ Moore JG, Datz FL, Christian PE, Greenberg E, Alazraki N. Effect of body posture on radionuclide measurements of gastric emptying. *Dig Dis Sci*. 1988;33(12):1592-1595.

¹⁶¹ Netz Y, Argov E, Burstin A, et al. 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 Technol*. 2007;2(1):43-49. doi: 10.1080/17483100601143371.

¹⁶² Ragnarsson KT, Krebs M, Naftchi NE et al. Head-up tilt effect on glomerular filtration rate, renal plasma flow, and mean arterial pressure in spinal man. *Arch Phys Med Rehabil*. 1981;62:306-310.

¹⁶³ Kaplan PE, Roden W, Gilbert E, Richards L, Goldschmidt JW. Reduction of hypercalciuria in tetraplegia after weight-bearing and strengthening exercises. *Paraplegia*. 1981;19:289-293.

¹⁶⁴ Sonenblum SE, Maurer CL, Hanes CD, Piriano J, Sprigle SH. Everyday use of power adjustable seat height (PASH) systems. *Assist Technol*. 2019. doi: 10.1080/10400435.2019.1634659.

¹⁶⁵ Dunstan DW, Kingwell BA, Larsen R, et al. Breaking up prolonged sitting reduces postprandial glucose and insulin responses. *Diabetes care*. 2012;35:976-983, doi: 10.2337/dc11-1931.

¹⁶⁶ Antonio TS, Urrutia F, Larrea A, Espín V, Latta MA. (2019) Variations in Vital Signs Associated with the Postural Changes When Using a Stand-up Wheelchair in Patients with Spinal Cord Injury. In: Ahram T.Z., Falcão C. (eds) *Advances in Usability, User Experience and Assistive Technology*. AHFE 2018; Edwards LC, Layne CS. Effect of dynamic weight bearing on neuromuscular activation after spinal cord injury. *Am J Phys Med Rehabil*. 2007;86(7):499-506; Kuznetsov AN, Rybalko NV, Daminov VD, Luft AR. Early poststroke rehabilitation using a robotic tilt-table stepper and functional electrical stimulation. *Stroke Res Treat*. 2013;1-9, doi.org/10.1155/2013/946056.

¹⁶⁷ 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.

A team consisting of a LCMP, the supplier representative (ATP), the beneficiary, and possibly other clinicians or a caregiver will work together through the evaluation and assessment processes to consider the beneficiary's medical needs, clinical conditions, and other factors that drive the specific technology recommendation, such as, but not limited to; daily activities of living, (referred to in the NCD for MAE as MRADLs) the home environment, functional needs and capabilities, and transportation needs. In addition, the team will rule out less expensive technology and consider any contraindications that would prevent the beneficiary from using certain technologies. The clinical and technological decision-making that occurs is documented in the beneficiary's medical record. In the case of power standing systems in particular, the clinician will evaluate the beneficiary's history of standing or capacity to stand. In some situations, this might require tests to ensure that the beneficiary is safe to stand for the recommended frequency and duration.

4. Medical Indications for Power Standing System

A power standing system used in conjunction with a Group 3 PWC improves or ameliorates many deficits that these PWC users experience. The power standing system improves joint mobility and reduces muscle spasticity and spasms.¹⁶⁸ Standing increases muscle strength and helps reduce bone density loss.¹⁶⁹ Standing improves bladder function and

¹⁶⁸ 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; Newman M, Barker K. The effect of supported standing in adults with upper motor neurone disorders: a systematic review. *Clin Rehabil.* 2012;26(12):1059-1077. doi: 10.1177/0269215512443373; Ben M, Harvey L, Denis S, et al. Does 12 weeks of regular standing prevent loss of ankle mobility and bone mineral density in people with recent spinal cord injuries? *Aust J Physiother.* 2005;51:251-256; Odeen I, Knutsson, E. Evaluation of the effects of muscle stretch and weight load in patients with spastic paraplegia. *Scand J Rehabil Med.* 1981;13:117-121; Bohannon RW. Tilt table standing for reducing spasticity after spinal cord injury. *Arch Phys Med Rehabil.* 1993;74(10):1121-1122; Adams MM, Hicks AL. Comparison of the effects of body-weight-supported treadmill training and tilt-table standing on spasticity in individuals with chronic spinal cord injury. *J Spinal Cord Med.* 2011; 34(5):488-494. doi: 10.1179/2045772311Y.0000000028.

¹⁶⁹ Newman M, Barker K. The effect of supported standing in adults with upper motor neurone disorders: a systematic review. *Clin Rehabil.* 2012;26(12):1059-1077. doi: 10.1177/0269215512443373.; Kuznetsov AN, Rybalko NV, Daminov VD, Luft AR. Early poststroke rehabilitation using a robotic tilt-table stepper and functional electrical stimulation. *Stroke Res Treat.* 2013;1-9. doi.org/10.1155/2013/946056; Kaplan PE, Roden W, Gilbert E, Richards L, Goldschmidt JW. Reduction of hypercalciuria in tetraplegia after weight-bearing and strengthening exercises. *Paraplegia.* 1981;19:289-293; Alekna V, Tamulaitiene M, Sinevicius T, Juocevicius A. Effect of weight-bearing activities on 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.; de Bruin ED, Frey-Rindova P, Herzog RE, Dietz V, Dambacher MA, Stüssi E. Changes in tibia bone properties after spinal cord injury: effects of early intervention. *Arch Phys Med Rehabil.* 1999;80:214-220.

facilitates digestive and bowel function.¹⁷⁰ Standing improves cardiovascular and respiratory functions.¹⁷¹ Studies of standing interventions support standing as a medically necessary component of overall health, the effects of which cannot be duplicated by other postures including tilt or recline in PWC users.¹⁷²

Although static standing devices contribute to the health of the beneficiary, movement while standing has been shown to result in greater gains.¹⁷³ Beneficiaries who are eligible for Group 3 PWC systems present with restricted or absent ability to ambulate. Therefore, for beneficiaries who are appropriate candidates for the power standing system, the system provides the ability to use standing in a passive or dynamic manner to manage their musculoskeletal, bowel, bladder, cardiovascular, pulmonary, and integumentary system body functions; reduce skin and tissue integrity concerns; and enable MRADL performance/participation.

a. The Musculoskeletal System

Individuals with SCI, who are commonly Group 3 and higher PWC users, are likely to encounter musculoskeletal deficits, such as limited range of motion, spasticity, decreased

¹⁷⁰ Ragnarsson KT, Krebs M, Naftchi NE et al. Head-up tilt effect on glomerular filtration rate, renal plasma flow, and mean arterial pressure in spinal man. *Arch Phys Med Rehabil.* 1981;62:306-310.; Kaplan PE, Roden W, Gilbert E, Richards L, Goldschmidt JW. Reduction of hypercalciuria in tetraplegia after weight-bearing and strengthening exercises. *Paraplegia.* 1981;19:289-293; Kwok S, Harvey L, Glinsky J, Bowden JL, Coggrave M, Tussler D. Does regular standing improve bowel function in people with spinal cord injury? A randomized crossover trial. *Spinal Cord.* 2015;53:36-41. doi: 10.1038/sc.2014.189.; Hoenig H, Murphy T., et al., Case study to evaluate a standing table for managing constipation. *SCI Nurs.* 2001;18(2):74–77.; Moore JG, Datz FL, Christian PE, Greenberg E, Alazraki N. Effect of body posture on radionuclide measurements of gastric emptying. *Dig Dis Sci.* 1988;33(12):1592-1595; Netz Y, Argov E, Burstin A, et al. 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 Technol.* 2007;2(1):43-49. doi: 10.1080/17483100601143371.

¹⁷¹ Antonio TS, Urrutia F, Larrea A, Espín V, Latta MA. (2019) Variations in Vital Signs Associated with the Postural Changes When Using a Stand-up Wheelchair in Patients with Spinal Cord Injury. In: Ahram T.Z., Falcão C. (eds) *Advances in Usability, User Experience and Assistive Technology.* AHFE 2018. *Advances in Intelligent Systems and Computing*, vol 794; Edwards LC, Layne CS. Effect of dynamic weight bearing on neuromuscular activation after spinal cord injury. *Am J Phys Med Rehabil.* 2007;86(7):499-506.

¹⁷² 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.

¹⁷³ Kim CY, Lee JS, Kim HD, Kim JS. The effect of progressive task-oriented training on supplementary tilt table on lower extremity muscle strength and gait recovery in patients with hemiplegic stroke. *Gait Posture.* 2015;41:425-430; Kim CY, Lee JS, Kim HD, Kim J, Lee IH. Lower extremity muscle activation and function in progressive task-oriented training on the supplementary tilt table during stepping-like movements in patients with acute stroke hemiparesis. *J Electromyogr Kinesiol.* 2015;25:522-530, doi.org/10.1016/j.jelekin.2015.03.004; Kuznetsov AN, Rybalko NV, Daminov VD, Luft AR. Early poststroke rehabilitation using a robotic tilt-table stepper and functional electrical stimulation. *Stroke Res Treat.* 2013;1-9, doi.org/10.1155/2013/946056; Netz Y, Argov E, Burstin A, et al. 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 Technol.* 2007;2(1):43-49. doi: 10.1080/17483100601143371; Moore JG, Datz FL, Christian PE, Greenberg E, Alazraki N. Effect of body posture on radionuclide measurements of gastric emptying. *Dig Dis Sci.* 1988;33(12):1592-1595.

strength, and/or bone density, based on the nature of the coverage criteria.¹⁷⁴ A power standing system of a Group 3 PWC can alleviate these problems. Standing has been shown to increase joint mobility, decrease spasticity, and increase muscle strength.¹⁷⁵ A power standing system of a Group 3 PWC may also decrease the rate of bone density loss.¹⁷⁶ Evidence of these medical effects is presented in the following sections of this NCD request.

i. Joint Mobility

Studies addressing joint mobility demonstrate that standing impacts upper and lower extremity range of motion.¹⁷⁷ When comparing shoulder position during sitting, during weight relief through bilateral upper extremities, during sit pivot transfers, and standing in a standing frame, people with paraplegia showed less pressure and damage to the shoulder and scapular joints when in the standing position.¹⁷⁸ People with SCI frequently report shoulder pain,¹⁷⁹ and

¹⁷⁴ Levi R, Hultling C, Nash MS, Seiger A. The Stockholm spinal cord injury study: 1. Medical problems in a regional SCI population. *Paraplegia*. 1995;33:308-315.

¹⁷⁵ Newman M, Barker K. The effect of supported standing in adults with upper motor neurone disorders: a systematic review. *Clin Rehabil*. 2012;26(12):1059-1077. doi: 10.1177/0269215512443373; 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; Ben M, Harvey L, Denis S, et al. Does 12 weeks of regular standing prevent loss of ankle mobility and bone mineral density in people with recent spinal cord injuries? *Aust J Physiother*. 2005;51:251-256; Odeen I, Knutsson E. Evaluation of the effects of muscle stretch and weight load in patients with spastic paraplegia. *Scand J Rehabil Med*. 1981;13:117-121; Bohannon RW. Tilt table standing for reducing spasticity after spinal cord injury. *Arch Phys Med Rehabil*. 1993;74(10):1121-1122; Adams MM, Hicks AL. Comparison of the effects of body-weight-supported treadmill training and tilt-table standing on spasticity in individuals with chronic spinal cord injury. *J Spinal Cord Med*. 2011;34(5):488-494. doi: 10.1179/2045772311Y.0000000028; Kuznetsov AN, Rybalko NV, Daminov VD, Luft AR. Early poststroke rehabilitation using a robotic tilt-table stepper and functional electrical stimulation. *Stroke Res Treat*. 2013;1-9. doi.org/10.1155/2013/946056; Kaplan PE, Roden W, Gilbert E, Richards L, Goldschmidt JW. Reduction of hypercalciuria in tetraplegia after weight-bearing and strengthening exercises. *Paraplegia*. 1981;19:289-293.

¹⁷⁶ Alekna V, Tamulaitiene M, Sinevicius T, Juocevicius A. Effect of weight-bearing activities on 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.; de Bruin ED, Frey-Rindova P, Herzog RE, Dietz V, Dambacher MA, Stüssi E. Changes in tibia bone properties after spinal cord injury: effects of early intervention. *Arch Phys Med Rehabil*. 1999;80:214-220.

¹⁷⁷ Ben M, Harvey L, Denis S, et al. Does 12 weeks of regular standing prevent loss of ankle mobility and bone mineral density in people with recent spinal cord injuries? *Aust J Physiother*. 2005;51:251-256.; 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.; Riek LM, Ludewig PM, Nawoczenski 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;46:335-343. doi:10.1038/sj.sc.3102140.; Robinson W, Smith R, Aung O, Ada L. No difference between wearing a night splint and standing on a tilt table in preventing ankle contracture early after stroke: a randomised trial. *Aust J Physiother*. 2008;54:33-38.

¹⁷⁸ Riek LM, Ludewig PM, Nawoczenski 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;46:335-343. doi:10.1038/sj.sc.3102140.

¹⁷⁹ Alm M, Saraste H, Norrbrink C. Shoulder pain in persons with thoracic spinal cord injury: prevalence and characteristics. *J Rehabil Med*. 2008;40:277-283, doi: 10.2340/16501977-0173.

the increased glenohumeral space in the shoulder joint seen in the standing position may improve postural alignment and counter the effects of prolonged sitting.¹⁸⁰

Consistent supported standing may reduce the risk of joint contracture over time by maintaining or improving range of motion throughout the lower extremity.¹⁸¹ Contractures are dangerous because they lead to further disability, pain and frequently require surgical intervention to permanent release of the contracture, and may result in irreversible loss of function.¹⁸² Hip and ankle range of motion significantly improved in six people with muscular sclerosis in a three-week study comparing standing to a non-weight bearing home exercise program.¹⁸³ Similarly, researchers reported high evidence that supported standing as an intervention that would maintain calf muscle and soft tissue length.¹⁸⁴ Standing was as effective as night-time splinting in people after a CVA,¹⁸⁵ and standing slowed the decrease in ankle range of motion compared to non-standing.¹⁸⁶ Alternatively, researchers found that standing improved knee and ankle range of motion, although not at a statistically significant level,¹⁸⁷ and a single subject study with adolescents with Duchenne's Muscular Dystrophy only found positive changes in hip range of motion in three out of four participants during and immediately after standing.¹⁸⁸ The differences in range of motion may be attributed to the person's position in standing, as stretching to a joint's full range of motion will increase muscle length.¹⁸⁹

ii. Muscle Tone

Standing can decrease spasticity (the presence of increased muscle tone).¹⁹⁰ Spasticity often has detrimental results on joint range of motion, ultimately leading to joint contractures, a

¹⁸⁰ Riek LM, Ludewig PM, Nawoczenski 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;46:335-343. doi:10.1038/sj.sc.3102140.

¹⁸¹ Newman M, Barker K. The effect of supported standing in adults with upper motor neurone disorders: a systematic review. *Clin Rehabil*. 2012;26(12):1059-1077. doi: 10.1177/0269215512443373.

¹⁸² Dehail P, Gaudreault N, Zhou H, et al. Joint contractures and acquired deforming hypertonia in older people: which determinants? *Ann Phys Rehabil Med*. 2019;62:435-441.

¹⁸³ 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.

¹⁸⁴ Newman M, Barker K. The effect of supported standing in adults with upper motor neurone disorders: a systematic review. *Clin Rehabil*. 2012;26(12):1059-1077. doi: 10.1177/0269215512443373.

¹⁸⁵ Robinson W, Smith R, Aung O, Ada L. No difference between wearing a night splint and standing on a tilt table in preventing ankle contracture early after stroke: a randomised trial. *Aust J Physiother*. 2008;54:33-38.

¹⁸⁶ Ben M, Harvey L, Denis S, et al. Does 12 weeks of regular standing prevent loss of ankle mobility and bone mineral density in people with recent spinal cord injuries? *Aust J Physiother*. 2005;51:251-256.

¹⁸⁷ Kunkel CF, Scremin E, Eisenberg B, Garcia JF, Roberts S, Martinez S. Effect of "standing" on spasticity, contracture, and osteoporosis in paralyzed males. *Arch Phys Med Rehabil*. 1993;74:73-78.

¹⁸⁸ Townsend EL, Bibeau C, Holmes TM. Supported standing in boys with Duchenne Muscular Dystrophy. *Pediatr Phys Ther*. 2016;28(3):320-329. doi: 10.1097/PEP.0000000000000251.

¹⁸⁹ Newman M, Barker K. The effect of supported standing in adults with upper motor neurone disorders: a systematic review. *Clin Rehabil*. 2012;26(12):1059-1077. doi: 10.1177/0269215512443373.

¹⁹⁰ Adams MM, Hicks AL. Comparison of the effects of body-weight-supported treadmill training and tilt-table standing on spasticity in individuals with chronic spinal cord injury. *J Spinal Cord Med*. 2011;34(5):488-494. doi:

condition in which joint movement is severely restricted.¹⁹¹ Spasticity was reported in 68% of 353 study subjects with SCI, with 41% of those reporting that the spasticity restricted their activity participation.¹⁹² Spasticity was the most reported symptom to occur after discharge from initial hospitalization, and 53% of participants reported joint/muscular symptoms in the last week (e.g., pain, stiffness).¹⁹³ Over time, spasticity impacts the person's physical-motor and functional status. Spasticity changes people's ability to care for themselves and be cared for by others by impacting how they are positioned, move, and transfer.¹⁹⁴

Also, MRADLs are affected because muscle tightness inhibits adequate bathing and drying in limited joint spaces, and it increases the difficulty of threading clothing over limbs.¹⁹⁵ Many people with spasticity develop pressure injuries and/or experience pain that requires treatment,¹⁹⁶ and moderate and severe spasticity has been related to greater health care utilization.¹⁹⁷ If left untreated, spasticity may shorten the muscles and tendons, limiting range of motion, and contributing to contracture development.¹⁹⁸ Additionally, the presence of age-related comorbidities, such as impaired vision, impaired cognition, neurological disease, obesity, and cardiorespiratory issues, appears to increase the risk of joint contracture in people after the age of 79.¹⁹⁹

10.1179/2045772311Y.0000000028.; 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.; Bohannon RW, Barreca SR, Shove ME, Lambert C, Masters LM, Sigouin CS. Documentation of daily sit-to-stands performed by community-dwelling adults. *Physiother Theory Pract.* 2008;24(6):437-442. doi: 10.1080/09593980802511813.; Odeen I, Knutsson E. Evaluation of the effects of muscle stretch and weight load in patients with spastic paraplegia. *Scand J Rehabil Med.* 1981;13:117-121.

¹⁹¹ Dehail P, Gaudreault N, Zhou H, et al. Joint contractures and acquired deforming hypertonia in older people: which determinants? *Ann Phys Rehabil Med.* 2019;62:435-441.

¹⁹² Levi R, Hultling C, Nash MS, Seiger A. The Stockholm spinal cord injury study: 1. Medical problems in a regional SCI population. *Paraplegia.* 1995;33:308-315.

¹⁹³ *Id.*

¹⁹⁴ Kheder A, Nair KPS. Spasticity: pathophysiology, evaluation and management. *Pract Neurol.* 2012;12:289-298. doi:10.1136/practneurol-2011-000155.

¹⁹⁵ *Id.*; Newman M, Barker K. The effect of supported standing in adults with upper motor neurone disorders: a systematic review. *Clin Rehabil.* 2012;26(12):1059-1077. doi: 10.1177/0269215512443373.

¹⁹⁶ Kheder A, Nair KPS. Spasticity: pathophysiology, evaluation and management. *Pract Neurol.* 2012;12:289-298. doi:10.1136/practneurol-2011-000155; Tyry T, Salter A, Largent J, Marrie RA. The impact of spasticity severity on healthcare utilization among MS patients: a large-scale six-year follow-up study. *J Neurol Sci.* 2013;333(S1):e376-e378. doi: 10.1016/j.jns.2013.07.1371.

¹⁹⁷ Tyry T, Salter A, Largent J, Marrie RA. The impact of spasticity severity on healthcare utilization among MS patients: a large-scale six-year follow-up study. *J Neurol Sci.* 2013;333(S1):e376-e378. doi: 10.1016/j.jns.2013.07.1371.

¹⁹⁸ Kheder A, Nair KPS. Spasticity: pathophysiology, evaluation and management. *Pract Neurol.* 2012;12:289-298. doi:10.1136/practneurol-2011-000155; Newman M, Barker K. The effect of supported standing in adults with upper motor neurone disorders: a systematic review. *Clin Rehabil.* 2012;26(12):1059-1077. doi: 10.1177/0269215512443373.

¹⁹⁹ van Shaardenburg D, Van den Brande KJS, Ligthart GJ, Breedveld FC, Hazes JMW. Musculoskeletal disorders and disability in persons aged 85 and over: a community survey. *Ann Rheum Dis.* 1994. 53:807-811.

Spasticity and involuntary muscle activity, such as reflexes and spasms, may decrease with consistent standing, although research studies measure spasticity using a variety of methods, which makes comparisons difficult. Researchers mechanically measured spasticity, finding that resistance to passive ankle movement decreased by 15% after subjects were standing in dorsiflexion when tested at slow speed resistance, and 32% and 26% after subjects were standing in dorsiflexion and plantar flexion, respectively, when tested at fast speed resistance, when compared to stretching.²⁰⁰

Additionally, researchers have documented decreased measurements of Modified Ashworth Scale scores (a measure of muscle tone) after standing interventions.²⁰¹ Although Kunkel et al. did not report change in spasticity in subjects who stood in a standing frame, their instrument only graded two levels of increased tone, while the Modified Ashworth Scale defines six;²⁰² therefore, the Kunkel study may not have been sensitive to change. Subjectively, people who participate in consistent standing programs report a decrease in muscle spasms²⁰³ and spasticity,²⁰⁴ and have changed their routines by dressing and bathing after standing rather than sitting to decrease spasms during activities of daily living.²⁰⁵

Furthermore, standing on a dynamic surface may augment the impact of passive standing on spasticity by overriding reflex hyperactivity that induces spasms during perturbations.²⁰⁶ In a comparison study, four weeks of bodyweight supported treadmill training resulted in a decrease of flexor spasms, while tilt-table standing decreased extensor spasms.²⁰⁷ Additionally, Boutilier et al. found that standing on a moving surface immediately reduced spasticity, with the greatest

²⁰⁰ Odeen I, Knutsson E. Evaluation of the effects of muscle stretch and weight load in patients with spastic paraplegia. *Scand J Rehabil Med.* 1981;13:117-121.

²⁰¹ 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; Bohannon RW. Tilt table standing for reducing spasticity after spinal cord injury. *Arch Phys Med Rehabil.* 1993;74(10):1121-1122.

²⁰² Bohannon RW, Smith MB. Interrater reliability of a modified Ashworth scale of muscle spasticity. *Phys Ther.* 1987;67(2):206-207. doi: 10.1093/ptj/67.2.206.

²⁰³ Bohannon RW. Tilt table standing for reducing spasticity after spinal cord injury. *Arch Phys Med Rehabil.* 1993;74(10):1121-1122; Eng JJ, Levins SM, Townson AF, Mah-Jones D, Bremner J, Huston G. Use of prolonged standing for individuals with spinal cord injuries. *Phys Ther.* 2001;81(8):1392-1399.

²⁰⁴ Bohannon RW. Tilt table standing for reducing spasticity after spinal cord injury. *Arch Phys Med Rehabil.* 1993;74(10):1121-1122; Dunn RB, Walter JS, Lucero Y, et al. Follow-up assessment of standing mobility device users. *Assist Technol.* 1998;10(2):84-93. doi: 10.1080/10400435.1998.10131966; Walter JS, Sola PG, Sacks J, Lucero Y, Langbein E, Weaver F. Indications for a home standing program for individuals with spinal cord injury. *J Spinal Cord Med.* 1999;18(1):152-158. doi: 10.1080/10790268.1999.11719564.

²⁰⁵ Shields RK, Dudley-Javoroski S. Monitoring standing wheelchair use after spinal cord injury: a case report. *Disabil Rehabil.* 2005;27(3):142-146. doi: 10.1080/09638280400009337.

²⁰⁶ Boutilier G, Sawatzky BJ, Grant C, Wiefelspuett S, Finlayson H. Spasticity changes in SCI following a dynamic standing program using the Segway. *Spinal Cord.* 2012;50:595-598. doi: 10.1038/sc.2012.23; Horak FB, Earhart GM, Dietz V. Postural responses to combinations of head and body displacements: vestibular-somatosensory interactions. *Exp Brain Res.* 2001;141:410-414. doi: 10.1007/s00221-001-0915-6.

²⁰⁷ Adams MM, Hicks AL. Comparison of the effects of body-weight-supported treadmill training and tilt-table standing on spasticity in individuals with chronic spinal cord injury. *J Spinal Cord Med.* 2011;34(5):488-494. doi: 10.1179/2045772311Y.0000000028.

change in spasticity between the first and second visits noted in the participant that also actively used a standing frame.²⁰⁸ It is hypothesized that the head and extremity positions prompted by dynamic movement may override the pathways of spasticity, impacting a decrease in muscle tone.²⁰⁹ Although a person using a standing system of a Group 3 PWC while moving will maintain a static lower extremity position, their head and upper extremities will accommodate the momentum from the movement, which may override the pathways of spasticity through the central nervous system.²¹⁰

b. Strength

Standing interventions show potential to improve lower extremity strength in affected limbs. Randomized trials with people acutely post-CVA show that standing compared to no standing, standing with movement,²¹¹ and/or functional electrical stimulation (“FES”)²¹² improved affected lower extremity muscle strength more than no standing, but not as much as when standing was combined with movement and/or FES.²¹³ Additionally, people with chronic SCI have anecdotally²¹⁴ and by manual muscle test²¹⁵ increased lower extremity muscle strength after standing interventions. Furthermore, exercises in standing devices demonstrated increased strength in hip and knee extensors and abductors, and all ankle muscles, in institutionalized older

²⁰⁸ Boutilier G, Sawatzky BJ, Grant C, Wiefelspuett S, Finlayson H. Spasticity changes in SCI following a dynamic standing program using the Segway. *Spinal Cord*. 2012;50:595-598. doi: 10.1038/sc.2012.23.

²⁰⁹ Horak FB, Earhart GM, Dietz V. Postural responses to combinations of head and body displacements: vestibular-somatosensory interactions. *Exp Brain Res*. 2001;141:410-414. doi: 10.1007/s00221-001-0915-6.

²¹⁰ Edwards LC, Layne CS. Effect of dynamic weight bearing on neuromuscular activation after spinal cord injury. *Am J Phys Med Rehabil*. 2007;86(7):499-506.

²¹¹ Kim CY, Lee JS, Kim HD, Kim JS. The effect of progressive task-oriented training on supplementary tilt table on lower extremity muscle strength and gait recovery in patients with hemiplegic stroke. *Gait Posture*. 2015;41:425-430; Kim CY, Lee JS, Kim HD, Kim J, Lee IH. Lower extremity muscle activation and function in progressive task-oriented training on the supplementary tilt table during stepping-like movements in patients with acute stroke hemiparesis. *J Electromyogr Kinesiol*. 2015;25:522-530, doi.org/10.1016/j.jelekin.2015.03.004; Kuznetsov AN, Rybalko NV, Daminov VD, Luft AR. Early poststroke rehabilitation using a robotic tilt-table stepper and functional electrical stimulation. *Stroke Res Treat*. 2013;1-9, doi.org/10.1155/2013/946056.

²¹² Kuznetsov AN, Rybalko NV, Daminov VD, Luft AR. Early poststroke rehabilitation using a robotic tilt-table stepper and functional electrical stimulation. *Stroke Res Treat*. 2013;1-9, doi.org/10.1155/2013/946056.

²¹³ Kim CY, Lee JS, Kim HD, Kim JS. The effect of progressive task-oriented training on supplementary tilt table on lower extremity muscle strength and gait recovery in patients with hemiplegic stroke. *Gait Posture*. 2015;41:425-430; Kim CY, Lee JS, Kim HD, Kim J, Lee IH. Lower extremity muscle activation and function in progressive task-oriented training on the supplementary tilt table during stepping-like movements in patients with acute stroke hemiparesis. *J Electromyogr Kinesiol*. 2015;25:522-530, doi.org/10.1016/j.jelekin.2015.03.004; Kuznetsov AN, Rybalko NV, Daminov VD, Luft AR. Early poststroke rehabilitation using a robotic tilt-table stepper and functional electrical stimulation. *Stroke Res Treat*. 2013;1-9, doi.org/10.1155/2013/946056.

²¹⁴ Edwards LC, Layne CS. Effect of dynamic weight bearing on neuromuscular activation after spinal cord injury. *Am J Phys Med Rehabil*. 2007;86(7):499-506.

²¹⁵ Kaplan PE, Roden W, Gilbert E, Richards L, Goldschmidt JW. Reduction of hypercalciuria in tetraplegia after weight-bearing and strengthening exercises. *Paraplegia*. 1981;19:289-293.

adults (average age of 86) with chronic neurological diseases.²¹⁶ Unfortunately, no studies measured trunk and/or upper extremity muscle strength. While standing using a power standing system will not accommodate gross lower extremity movement due to the anterior knee supports, people standing using a Group 3 PWC system will experience external forces as it is moving, requiring trunk and limb adjustments to maintain balance, as well as spontaneously move upper extremities and trunk when reaching and manipulating items during MRADLs, which are expected to impact the strength of the Group 3 PWC user more than passive standing.

c. Bone Density

With the onset of paresis and disuse, bone mineral density (also known as BMD) begins to decrease. Within the first few months after SCI, BMD declines two to four percent per month.²¹⁷ This trend continues for two to eight years,²¹⁸ eventually decreasing 50% to 60% more than the BMD of people without SCI.²¹⁹ In the first year after a CVA, similar decreases in BMD occur.²²⁰ Researchers attribute the decrease in BMD to lack of mechanical loading that occurs with muscular contractions and weight bearing.²²¹ Disuse of the bone results in changes in bone structure²²² that contribute to a doubling of fracture risk for people with SCI over the general population,²²³ and predicts hip or wrist fracture in 25% and 33%, respectively, of the population of people with CVA.²²⁴ The fractures often occur during the person's typical routine MRADLs, such as dressing, bathing, transferring to/from the wheelchair.²²⁵ Due to the high

²¹⁶ Netz Y, Argov E, Burstin A, et al. 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 Technol.* 2007;2(1):43-49. doi: 10.1080/17483100601143371.

²¹⁷ Wilmet E, Ismail AA, Heilporn A, Welraeds D, Bergmann P. Longitudinal study of the bone mineral content and of soft tissue composition after spinal cord section. *Paraplegia.* 1995;33(11):674-677.

²¹⁸ Eser P, de Bruin ED, Telley I, Lechner HE, Knecht H, Stüssi E. Effect of electrical stimulation-induced cycling on bone mineral density in spinal cord-injured patients. *Eur J Clin Invest.* 2003;33(5):412-419.

²¹⁹ *Id.*; Shields RK, Dudley-Javoroski S, Boaldin KM, Corey TA, Fog DB, Ruen JM. Peripheral quantitative computed tomography: measurement sensitivity in persons with and without spinal cord injury. *Arch Phys Med Rehabil.* 2006;87(10):1376-1381.

²²⁰ Beaupre GS, Lew HL. Bone-density changes after stroke. *Am J Phys Med Rehabil.* 2006;85:464-472. doi: 10.1097/01.phm.0000214275.69286.7a; Lazoura O, Groumas N, Antoniadou E, et al. Bone mineral density alterations in upper and lower extremities 12 months after stroke measured by peripheral quantitative computed tomography and DXA. *J Clin Densitom.* 2008;11(4):511-517. doi: 10.1016/j.jocd.2008.05.097.

²²¹ Dudley-Javoroski S, Shields RK. Muscle and bone plasticity after spinal cord injury: review of adaptations to disuse and to electrical muscle stimulation. *J Rehabil Res. Dev.* 2008;45(2):283-296. doi: 10.1682/JRRD.2007.02.0031.

²²² *Id.*

²²³ Vestergaard P, Krogh K, Rejnmark L, Mosekilde L. Fracture rates and risk factors for fractures in patients with spinal cord injury. *Spinal Cord.* 1998;36:790-796.

²²⁴ Ashe MC, Fehling P, Eng JJ, Khan KM, McKay HA. Bone geometric response to chronic disuse following stroke: a pQCT study. *J Musculoskelet Neuronal Interact.* 2006;6(3):226-233; Beaupre GS, Lew HL. Bone-density changes after stroke. *Am J Phys Med Rehabil.* 2006;85:464-472. doi: 10.1097/01.phm.0000214275.69286.7a.

²²⁵ Dudley-Javoroski S, Shields RK. Muscle and bone plasticity after spinal cord injury: review of adaptations to disuse and to electrical muscle stimulation. *J Rehabil Res. Dev.* 2008;45(2):283-296. doi: 10.1682/JRRD.2007.02.0031.

incidence of injury, health care utilization, and post-acute care required post-fracture, preventing the deterioration of bone density is necessary in non-ambulatory populations.

The scientific background on BMD supports that bone formation²²⁶ and loss²²⁷ is a complex and multifactorial process in which the dosage and load are important factors. Animal studies have shown that the type of bone formed in response to loading depends on the speed and size of the request (i.e., demand on the bone),²²⁸ with smaller requests for bone strength, which correlated to that experienced during typical activity, resulting in strong lamellar bone and larger requests, overloading the limb by about 30%, resulting in the quicker-forming woven bone.²²⁹

Additionally, short, frequent loading at a high strain resulted in statistically significant greater change in bone volume over moderate and low strain.²³⁰ However, many of the animal studies²³¹ examine bone change by autopsy, and measuring BMD in humans with SCI has been “fraught with difficulty.”²³² When measuring BMD, the trabecular bone is more sensitive to change than the cortical bone.²³³ However, the instrument often used in studies measuring BMD, dual-energy X-ray absorptiometry (“DEXA”), cannot differentiate between the cortical and trabecular bone, so some positive changes may be overlooked.²³⁴ Despite these difficulties, a range of methods for assessing BMD change exist, and the DEXA system remains the international standard for measuring osteoarthritis.²³⁵

²²⁶ Mosley JR, Lanyon LE. Strain rate as a controlling influence on adaptive modeling in response to dynamic loading of the ulna in growing male rats. *Bone*. 1998;23(4):313-318.

²²⁷ de Bruin ED, Frey-Rindova P, Herzog RE, Dietz V, Dambacher MA, Stüssi E. Changes in tibia bone properties after spinal cord injury: effects of early intervention. *Arch Phys Med Rehabil*. 1999;80:214-220.

²²⁸ Dudley-Javoroski S, Shields RK. Muscle and bone plasticity after spinal cord injury: review of adaptations to disuse and to electrical muscle stimulation. *J Rehabil Res. Dev*. 2008;45(2):283-296. doi: 10.1682/JRRD.2007.02.0031; Lee KCL, Maxwell A, Lanyon LE. Validation of a technique for studying functional adaptation of the mouse ulna in response to mechanical loading. *Bone*. 2002;31(3):1-9.

²²⁹ Lee KCL, Maxwell A, Lanyon LE. Validation of a technique for studying functional adaptation of the mouse ulna in response to mechanical loading. *Bone*. 2002;31(3):1-9.

²³⁰ Mosley JR, Lanyon LE. Strain rate as a controlling influence on adaptive modeling in response to dynamic loading of the ulna in growing male rats. *Bone*. 1998;23(4):313-318.

²³¹ Lee KCL, Maxwell A, Lanyon LE. Validation of a technique for studying functional adaptation of the mouse ulna in response to mechanical loading. *Bone*. 2002;31(3):1-9; Mosley JR, Lanyon LE. Strain rate as a controlling influence on adaptive modeling in response to dynamic loading of the ulna in growing male rats. *Bone*. 1998;23(4):313-318.

²³² Dudley-Javoroski S, Shields RK. Muscle and bone plasticity after spinal cord injury: review of adaptations to disuse and to electrical muscle stimulation. *J Rehabil Res. Dev*. 2008;45(2):288. doi: 10.1682/JRRD.2007.02.0031.

²³³ Snyder WS, editor. Report of the task group on reference man. Oxford: Pergamon; 1975. Page 288.

²³⁴ Dudley-Javoroski S, Shields RK. Muscle and bone plasticity after spinal cord injury: review of adaptations to disuse and to electrical muscle stimulation. *J Rehabil Res. Dev*. 2008;45(2):283-296. doi: 10.1682/JRRD.2007.02.0031.

²³⁵ Beaupre GS, Lew HL. Bone-density changes after stroke. *Am J Phys Med Rehabil*. 2006;85:464-472. doi: 10.1097/01.phm.0000214275.69286.7a.

Accordingly, studies report consistent results relating levels of BMD with dosage of standing.²³⁶ In people with SCI, daily standing resulted in small gains in femur BMD, measured by DEXA, that did not register as clinically or statistically significant.²³⁷ However, since people with paresis are known to lose BMD in the first years post-onset,²³⁸ the rate of BMD loss may be a more important measure. Studies involving people recently post-SCI found that participation in regular standing lost BMD in total body, hips, and legs²³⁹ and the trabecular bone²⁴⁰ at a statistically slower rate than controls who did not stand, independent of level of injury, gender, and other factors.²⁴¹ Comparatively, standing one to three hours a week does not appear to change BMD.²⁴² However, rates of BMD loss were insignificant between people who participated in standing five times per week and those performing cycling with FES three times a week and standing two times a week, although older age and higher BMD prior to the injury predicted quicker BMD loss.²⁴³

²³⁶ Paleg G, Livingstone R. Systematic review and clinical recommendations for dosage of supported home-based standing programs for adults with stroke, spinal cord injury and other neurological conditions. *BMC Musculoskeletal Disord.* 2015;16(358):1-16. doi: 10.1186/s12891-015-0813-x.

²³⁷ Ben M, Harvey L, Denis S, et al. Does 12 weeks of regular standing prevent loss of ankle mobility and bone mineral density in people with recent spinal cord injuries? *Aust J Physiother.* 2005;51:251-256; Goktepe AS, Tugcu I, Yilmaz B, Alaca R, Gunduz S. Does standing protect bone density in patients with chronic spinal cord injury? *J Spinal Cord Med.* 2008;31(2):197-201. doi: 10.1080/10790268.2008.11760712.

²³⁸ Beaupre GS, Lew HL. Bone-density changes after stroke. *Am J Phys Med Rehabil.* 2006;85:464-472. doi: 10.1097/01.phm.0000214275.69286.7a; Frey-Rindova P, de Bruin ED, Stüssi E, Dambacher MA, Dietz V. Bone mineral density in upper and lower extremities during 12 months after spinal cord injury measured by peripheral quantitative computed tomography. *Spinal Cord.* 2000;38:28-32; Eser P, de Bruin ED, Telley I, Lechner HE, Knecht H, Stüssi E. Effect of electrical stimulation-induced cycling on bone mineral density in spinal cord-injured patients. *Eur J Clin Invest.* 2003;33(5):412-419; Lazoura O, Groumas N, Antoniadou E, et al. Bone mineral density alterations in upper and lower extremities 12 months after stroke measured by peripheral quantitative computed tomography and DXA. *J Clin Densitom.* 2008;11(4):511-517. doi: 10.1016/j.jocd.2008.05.097; Shields RK, Dudley-Javoroski S, Boaldin KM, Corey TA, Fog DB, Ruen JM. Peripheral quantitative computed tomography: measurement sensitivity in persons with and without spinal cord injury. *Arch Phys Med Rehabil.* 2006;87(10):1376-1381; Wilmet E, Ismail AA, Heilporn A, Welraeds D, Bergmann P. Longitudinal study of the bone mineral content and of soft tissue composition after spinal cord section. *Paraplegia.* 1995;33(11):674-677.

²³⁹ Alekna V, Tamulaitiene M, Sinevicius T, Juocevicius A. Effect of weight-bearing activities on 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.

²⁴⁰ de Bruin ED, Frey-Rindova P, Herzog RE, Dietz V, Dambacher MA, Stüssi E. Changes in tibia bone properties after spinal cord injury: effects of early intervention. *Arch Phys Med Rehabil.* 1999;80:214-220.

²⁴¹ Alekna V, Tamulaitiene M, Sinevicius T, Juocevicius A. Effect of weight-bearing activities on 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.

²⁴² Frey-Rindova P, de Bruin ED, Stüssi E, Dambacher MA, Dietz V. Bone mineral density in upper and lower extremities during 12 months after spinal cord injury measured by peripheral quantitative computed tomography. *Spinal Cord.* 2000;38:28-32; Townsend EL, Bibeau C, Holmes TM. Supported standing in boys with Duchenne Muscular Dystrophy. *Pediatr Phys Ther.* 2016;28(3):320-329. doi: 10.1097/PEP.0000000000000251.

²⁴³ Eser P, de Bruin ED, Telley I, Lechner HE, Knecht H, Stüssi E. Effect of electrical stimulation-induced cycling on bone mineral density in spinal cord-injured patients. *Eur J Clin Invest.* 2003;33(5):412-419.

d. Bladder and Bowel Management

The power standing system of a Group 3 PWC can aid bladder and bowel management. Healthy bladder and bowel management are important contributors to overall wellbeing. Standing eases bladder voiding.²⁴⁴ The power standing system may facilitate digestive and bowel function in all PWC users.²⁴⁵

i. Bladder Management

Standing may improve bladder health and ease of bladder management. Bladder management for people with mobility limitations may require adaptive equipment, such as a bedside commode, assistance of others for transferring and bowel hygiene,²⁴⁶ or a reliance on a catheter that they may manage themselves or with the help of others. People with SCI and CVA are likely to use various methods of bladder management depending on their level of disability.²⁴⁷ The physical dysfunction and other barriers to voiding and hygiene result in known problems, including UTIs,²⁴⁸ urolithiasis,²⁴⁹ and renal function impairment.²⁵⁰ The risk for a kidney stone has been documented as greatest in the first three to six months following an

²⁴⁴ Ragnarsson KT, Krebs M, Naftchi NE et al. Head-up tilt effect on glomerular filtration rate, renal plasma flow, and mean arterial pressure in spinal man. *Arch Phys Med Rehabil.* 1981;62:306-310.

²⁴⁵ Kwok S, Harvey L, Glinsky J, Bowden JL, Coggrave M, Tussler D. Does regular standing improve bowel function in people with spinal cord injury? A randomized crossover trial. *Spinal Cord.* 2015;53:36-41. doi: 10.1038/sc.2014.189.; Hoenig H, Murphy T. et al., Case study to evaluate a standing table for managing constipation. *SCI Nurs.* 2001;18(2):74-77.; Moore JG, Datz FL, Christian PE, Greenberg E, Alazraki N. Effect of body posture on radionuclide measurements of gastric emptying. *Dig Dis Sci.* 1988;33(12):1592-1595; Netz Y, Argov E, Burstin A, et al. 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 Technol.* 2007;2(1):43-49. doi: 10.1080/17483100601143371.

²⁴⁶ Hicken BL, Putzke JD, Richards JS. Bladder management and quality of life after spinal cord injury. *Am J Phys Med Rehabil.* 2001;80:916-922.

²⁴⁷ Chen Y, DeVivo MJ, Roseman JM. Current trend and risk factors for kidney stones in persons with spinal cord injury: a longitudinal study. *Spinal Cord.* 2000;38:346-353; Hansen RB, Biering-Sørensen F, Kristensen JK. Urinary calculi following traumatic spinal cord injury. *Scand J Urol Nephrol.* 2007;41(2):115-119. doi: 10.1080/00365590600991383; Yan T, Liu C, Li Y, Xiao W, Li Y, Wang S. Prevalence and predictive factors of urinary tract infection among patients with stroke: a meta-analysis. *Am J Infect Control.* 2018;46:402-409, doi.org/10.1016/j.ajic.2017.10.001.

²⁴⁸ Levi R, Hultling C, Nash MS, Seiger A. The Stockholm spinal cord injury study: 1. Medical problems in a regional SCI population. *Paraplegia.* 1995;33:308-315; Mahoney JS, Engebretson JC, Cook KF, Hart KA, Robinson-Whelen S, Sherwood AM. Spasticity experience domains in persons with spinal cord injury. *Arch Phys Med Rehabil.* 2007;88:287-294, doi:10.1016/j.apmr.2006.12.029; Yan T, Liu C, Li Y, Xiao W, Li Y, Wang S. Prevalence and predictive factors of urinary tract infection among patients with stroke: a meta-analysis. *Am J Infect Control.* 2018;46:402-409, doi.org/10.1016/j.ajic.2017.10.001.

²⁴⁹ Levi R, Hultling C, Nash MS, Seiger A. The Stockholm spinal cord injury study: 1. Medical problems in a regional SCI population. *Paraplegia.* 1995;33:308-315; Hansen RB, Biering-Sørensen F, Kristensen JK. Urinary calculi following traumatic spinal cord injury. *Scand J Urol Nephrol.* 2007;41(2):115-119. doi: 10.1080/00365590600991383.

²⁵⁰ Levi R, Hultling C, Nash MS, Seiger A. The Stockholm spinal cord injury study: 1. Medical problems in a regional SCI population. *Paraplegia.* 1995;33:308-315.

SCI,²⁵¹ increasing as SCI severity increases,²⁵² and for older adults.²⁵³ A survey of 22,349 community-dwelling adults found greater odds of hypertension, myocardial infarction, or CVA in people who had experienced a kidney stone than those who had not.²⁵⁴ UTIs can cause fever, disorientation and confusion, incontinence and urgency, changes in mental status, and falls.²⁵⁵ These are all activities that could cause hospitalizations, nursing home stays, or home health care needs. CVA is associated with a 19% risk of developing a UTI, which increases as people age.²⁵⁶ In people with SCI, secondary problems may arise with a UTI, including increased spasticity and spasms²⁵⁷ and ultimately more hospitalizations.²⁵⁸

Voiding in the standing position may facilitate relaxation and, therefore, enable urinary flow and bladder emptying in males more than sitting.²⁵⁹ This may be due to increased pressure on the bladder in the standing position.²⁶⁰ In people with SCI, the glomerular filtration rate, a measure of kidney function, was observed as near normal in standing, but not in the supine position.²⁶¹ Additionally, researchers found that standing resulted in decreased hypercalciuria (calcium in the urine, which may enable secondary conditions such as kidney stones) in populations of people with SCI both within six months and farther out from injury, although a more marked decrease was noted in the group with a more recent injury.²⁶² Lastly, 20% of

²⁵¹ Chen Y, DeVivo MJ, Roseman JM. Current trend and risk factors for kidney stones in persons with spinal cord injury: a longitudinal study, *Spinal Cord*, 2000;38:346-353; Hansen RB, Biering-Sørensen F, Kristensen JK. Urinary calculi following traumatic spinal cord injury. *Scand J Urol Nephrol*. 2007;41(2):115-119. doi: 10.1080/00365590600991383.

²⁵² Chen Y, DeVivo MJ, Roseman JM. Current trend and risk factors for kidney stones in persons with spinal cord injury: a longitudinal study, *Spinal Cord*, 2000;38:346-353.

²⁵³ Domingos F, Serra A. Nephrolithiasis is associated with an increased prevalence of cardiovascular disease. *Nephrol Dial Transplant*. 2011;26:864-868. doi: 10.1093/ndt/gfq501.

²⁵⁴ *Id.*

²⁵⁵ Rowe TA, Juthani-Mehta M. Urinary tract infection in older adults. *Aging Health*. 2013;9(5):519-528; Wojszel ZB, Toczyńska-Silkiewicz M. Urinary tract infections in a geriatric sub-acute ward-health correlates and atypical presentations. *Eur Geriatr Med*. 2018;9:659-667.

²⁵⁶ Yan T, Liu C, Li Y, Xiao W, Li Y, Wang S. Prevalence and predictive factors of urinary tract infection among patients with stroke: a meta-analysis. *Am J Infect Control*. 2018;46:402-409, doi.org/10.1016/j.ajic.2017.10.001.

²⁵⁷ Mahoney JS, Engebretson JC, Cook KF, Hart KA, Robinson-Whelen S, Sherwood AM. Spasticity experience domains in persons with spinal cord injury. *Arch Phys Med Rehabil*. 2007;88:287-294, doi:10.1016/j.apmr.2006.12.029.

²⁵⁸ Hicken BL, Putzke JD, Richards JS. Bladder management and quality of life after spinal cord injury. *Am J Phys Med Rehabil*. 2001;80:916-922.

²⁵⁹ Özgürbüz N, Eser I. Effects of voiding in standing and sitting positions on uroflowmetric parameters and post-void residual urine in boys. *Urol Nurs*. 2018;38(2):67-72. doi:10.7257/1053-816X.2018.38.2.67.

²⁶⁰ Gould CV, Umscheid CA, Agarwal RK, Kuntz G, Pegues DA. Healthcare Infection Control Practices Advisory C. Guideline for prevention of catheter-associated urinary tract infections 2009. *Infect Control Hosp Epidemiol*. 2010;31(4):319-326, doi:10.1086/651091.

²⁶¹ Ragnarsson KT, Krebs M, Naftchi NE et al. Head-up tilt effect on glomerular filtration rate, renal plasma flow, and mean arterial pressure in spinal man. *Arch Phys Med Rehabil*. 1981;62:306-310.

²⁶² Kaplan PE, Roden W, Gilbert E, Richards L, Goldschmidt JW. Reduction of hypercalciuria in tetraplegia after weight-bearing and strengthening exercises. *Paraplegia*. 1981;19:289-293.

people with chronic SCI report that standing aided bladder function and emptying²⁶³ and resulted in lower amounts of UTIs.²⁶⁴

ii. Digestion and Bowel Management

Poor digestion and bowel motility may result in constipation, a condition that affects up to 50% of senior Medicare beneficiaries, which is 23% to 48% more than estimates of prevalence for the adult, non-senior population.²⁶⁵ Constipation may be associated with hemorrhoids, irritable bowel syndrome, or intestinal impaction or obstruction, and the treatment of constipation has been estimated at \$250 per patient.²⁶⁶ While medications were commonly used to treat constipation, 0.6% of diagnoses led to hospitalization, costing \$2,993 per patient in 2007 for an average three-day stay.²⁶⁷

Although age has not been associated with gastric emptying speed,²⁶⁸ altered body function (e.g., that which occurs with diagnoses such as SCI)²⁶⁹ and use of narcotics²⁷⁰ have been related to slower bowel motility. Examination of bowel issues in people with SCI validate slower bowel motility, finding constipation, requiring bowel surgery to correct in 12% of cases due to bowel obstruction, hematochezia (fresh, red blood in stools) and melena (black stools),²⁷¹ as well as frequent reports of gas bubbles.²⁷² Therefore, people with diagnoses that may

²⁶³ Dunn RB, Walter JS, Lucero Y, et al. Follow-up assessment of standing mobility device users. *Assist Technol.* 1998;10(2):84-93. doi: 10.1080/10400435.1998.10131966; Eng JJ, Levins SM, Townson AF, Mah-Jones D, Bremner J, Huston G. Use of prolonged standing for individuals with spinal cord injuries. *Phys Ther.* 2001;81(8):1392-1399; Walter JS, Sola PG, Sacks J, Lucero Y, Langbein E, Weaver F. Indications for a home standing program for individuals with spinal cord injury. *J Spinal Cord Med.* 1999;18(1):152-158. doi: 10.1080/10790268.1999.11719564.

²⁶⁴ Walter JS, Sola PG, Sacks J, Lucero Y, Langbein E, Weaver F. Indications for a home standing program for individuals with spinal cord injury. *J Spinal Cord Med.* 1999;18(1):152-158. doi: 10.1080/10790268.1999.11719564.

²⁶⁵ Bouras EP, Tangalos EG. Chronic constipation in the elderly. *Gastroenterol Clin N Am.* 2009;38:463-480. doi: 10.1016/j.gtc.2009.06.001; Rao SSC & Go JT. Update on the management of constipation in the elderly: new treatment options. *Clin Interv Aging.* 2010;5:163:171.

²⁶⁶ Singh G, Lingala V, Wang H, et al. Use of health care resources and cost of care for adults with constipation. *J Clin Gastroenterol Hepatol.* 2007;5:1053-1058, doi:10.1016/j.cgh.2007.04.019.

²⁶⁷ *Id.*

²⁶⁸ Bonner JJ, Vajjah P, Abduljalil K, et al. Does age affect gastric emptying time? A model-based meta-analysis of data from premature neonates through to adults. *Biopharm Drug Dispos.* 2015;36:245-257. doi: 10.1002/bdd.1937.

²⁶⁹ Rasmussen MM, Krogh K, Clemmensen D, Bluhme H, Rawashdeh Y, Christensen P. Colorectal transport during defecation in subjects with supraconal spinal cord injury. *Spinal Cord.* 2013;51:683-687. doi: 10.1038/sc.2013.58.

²⁷⁰ Hoenig H, Murphy T. et al., Case study to evaluate a standing table for managing constipation. *SCI Nurs.* 2001;18(2):74-77.

²⁷¹ Levi R, Hultling C, Nash MS, Seiger A. The Stockholm spinal cord injury study: 1. Medical problems in a regional SCI population. *Paraplegia.* 1995;33:308-315.

²⁷² Mahoney JS, Engebretson JC, Cook KF, Hart KA, Robinson-Whelen S, Sherwood AM. Spasticity experience domains in persons with spinal cord injury. *Arch Phys Med Rehabil.* 2007;88:287-294, doi:10.1016/j.apmr.2006.12.029.

predispose to bowel problems or have a history of digestive or bowel issues should consider interventions that will increase motility.

Pharmacological and non-pharmacological intervention options exist to aid bowel motility. People with SCI often use suppositories and enemas to aid gastric emptying.²⁷³ However, in ambulatory persons, transitioning between sitting and standing was found to improve emptying times 51% over lying down and 35% over sitting.²⁷⁴ Similar results were found in a case study on a 62-year-old male, finding that standing five times a week almost doubled the frequency of bowel movements and reduced the time spent on care by ten minutes.²⁷⁵ Additionally, residents with severe neurological conditions improved control of bowel movements through a supported standing intervention 30 minutes a day, five times a week, for 12 weeks.²⁷⁶ Subjective reports of people with SCI who participate in standing interventions appear to agree that standing improves overall bowel function,²⁷⁷ which was significantly related to the frequency and time spent standing.²⁷⁸

PWC users often spend more than eight hours seated in their PWC,²⁷⁹ and criticisms of static, stationary standing frames and tilt tables include a lack of assistance with or time to transfer between the wheelchair and the device²⁸⁰ and a lack of physical space to store extra equipment.²⁸¹ A power standing system of a Group 3 PWC provides people with the opportunity

²⁷³ Levi R, Hultling C, Nash MS, Seiger A. The Stockholm spinal cord injury study: 1. Medical problems in a regional SCI population. *Paraplegia*. 1995;33:308-315.

²⁷⁴ Moore JG, Datz FL, Christian PE, Greenberg E, Alazraki N. Effect of body posture on radionuclide measurements of gastric emptying. *Dig Dis Sci*. 1988;33(12):1592-1595.

²⁷⁵ Hoenig H, Murphy T. et al., Case study to evaluate a standing table for managing constipation. *SCI Nurs*. 2001;18(2):74-77.

²⁷⁶ Netz Y, Argov E, Burstin A, et al. 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 Technol*. 2007;2(1):43-49. doi: 10.1080/17483100601143371.

²⁷⁷ Eng JJ, Levins SM, Townson AF, Mah-Jones D, Bremner J, Huston G. Use of prolonged standing for individuals with spinal cord injuries. *Phys Ther*. 2001;81(8):1392-1399; Kwok S, Harvey L, Glinsky J, Bowden JL, Coggrave M, Tussler D. Does regular standing improve bowel function in people with spinal cord injury? A randomized crossover trial. *Spinal Cord*. 2015;53:36-41. doi: 10.1038/sc.2014.189.

²⁷⁸ Dunn RB, Walter JS, Lucero Y, et al. Follow-up assessment of standing mobility device users. *Assist Technol*. 1998;10(2):84-93. doi: 10.1080/10400435.1998.10131966; Walter JS, Sola PG, Sacks J, Lucero Y, Langbein E, Weaver F. Indications for a home standing program for individuals with spinal cord injury. *J Spinal Cord Med*. 1999;18(1):152-158. doi: 10.1080/10790268.1999.11719564.

²⁷⁹ Sonenblum SE, Maurer CL, Hanes CD, Piriano J, Sprigle SH. Everyday use of power adjustable seat height (PASH) systems. *Assist Technol*. 2019. doi: 10.1080/10400435.2019.1634659.

²⁸⁰ Eng JJ, Levins SM, Townson AF, Mah-Jones D, Bremner J, Huston G. Use of prolonged standing for individuals with spinal cord injuries. *Phys Ther*. 2001;81(8):1392-1399; Walter JS, Sola PG, Sacks J, Lucero Y, Langbein E, Weaver F. Indications for a home standing program for individuals with spinal cord injury. *J Spinal Cord Med*. 1999;18(1):152-158. doi: 10.1080/10790268.1999.11719564.

²⁸¹ Walter JS, Sola PG, Sacks J, Lucero Y, Langbein E, Weaver F. Indications for a home standing program for individuals with spinal cord injury. *J Spinal Cord Med*. 1999;18(1):152-158. doi: 10.1080/10790268.1999.11719564.

to perform multiple STS transitions throughout the day that has shown to increase bowel motility, without requiring assistance from others or storage of another device.

e. Cardiovascular and Respiratory

Sitting for extended periods of time has been linked to numerous health problems, including cardiovascular disease.²⁸² Periods of standing and light exercise to break up sitting has shown to combat the negative impact of sitting.²⁸³ People in PWCs are known to use their PWC for over eight hours a day,²⁸⁴ and without a power standing system, that time is spent in a seated position. Moving from a sitting to a standing position and assuming the standing position for a period of time increased the heart rate of people with SCI²⁸⁵ and produced vital signs closer to normal.²⁸⁶ Subjective reports express that more than a third of people with SCI who stand report improvements in breathing,²⁸⁷ possibly due to the change in posture allowing for greater expansion of the rib cage when inhaling.²⁸⁸

f. Standing and Pressure Management

Pressure management and skin integrity are crucial for PWC users, due to the cumulative risk for pressure injuries from immobility, motor, and/or sensory impairments.²⁸⁹ Group 3 PWC users often use a combination of tilt, recline, and power elevating leg rests to manage pressure distribution. Standing and reclining have shown to distribute weight across the seat at end

²⁸² Brown WJ, Miller YD, Miller R. Sitting time and work patterns as indicators of overweight and obesity in Australian adults. *Int J Obes*. 2003;27(11):1340-1346. doi: 10.1038/sj.ijo.0802426; Healy GN, Winkler EAH, Owen N, Anuradha S, Dunstan DW. Replacing sitting time with standing or stepping: associations with cardio-metabolic risk biomarkers. *Eur Heart J*. 2015;36:2643-2649. doi:10.1093/eurheartj/ehv308; Matthews CE, Chen KY, Freedson PS, et al. Amount of time spent in sedentary behaviors in the United States, 2003-2004. *Am J Epidemiol*. 2008;167(7):875-881. doi:10.1093/aje/kwm390.

²⁸³ Dunstan DW, Kingwell BA, Larsen R, et al. Breaking up prolonged sitting reduces postprandial glucose and insulin responses. *Diabetes care*. 2012;35:976-983, doi: 10.2337/dc11-1931.

²⁸⁴ Sonenblum SE, Maurer CL, Hanes CD, Piriano J, Sprigle SH. Everyday use of power adjustable seat height (PASH) systems. *Assist Technol*. 2019. doi: 10.1080/10400435.2019.1634659.

²⁸⁵ Antonio TS, Urrutia F, Larrea A, Espín V, Latta MA. (2019) Variations in Vital Signs Associated with the Postural Changes When Using a Stand-up Wheelchair in Patients with Spinal Cord Injury. In: Ahrum T.Z., Falcão C. (eds) *Advances in Usability, User Experience and Assistive Technology*. AHFE 2018. Advances in Intelligent Systems and Computing, vol 794. Springer, Cham; 2019:818-823.

²⁸⁶ Antonio TS, Urrutia F, Larrea A, Espín V, Latta MA. (2019) Variations in Vital Signs Associated with the Postural Changes When Using a Stand-up Wheelchair in Patients with Spinal Cord Injury. In: Ahrum T.Z., Falcão C. (eds) *Advances in Usability, User Experience and Assistive Technology*. AHFE 2018. Advances in Intelligent Systems and Computing, vol 794. Springer, Cham; 2019:818-823.

²⁸⁷ Eng JJ, Levins SM, Townson AF, Mah-Jones D, Bremner J, Huston G. Use of prolonged standing for individuals with spinal cord injuries. *Phys Ther*. 2001;81(8):1392-1399.

²⁸⁸ Torres-Castro R, Richards D, Barraza F, et al. Effects of wheelchair use on pulmonary function and muscular respiratory strength in subjects with spinal cord injury: a case series. *Jour Resp Cardiov Phy Ther*. 2016;5(1):21-25.

²⁸⁹ Flett HM, Delparte JJ, Scovil CY, Higgins J, Laramée MT, Burns AS. Determining pressure injury risk on admission to inpatient spinal cord injury rehabilitation: a comparison of the FIM, Spinal Cord Injury Pressure Ulcer Scale, and Braden Scale. *Arch Phys Med Rehabil*. 2019;100:1881-1887.

range.²⁹⁰ In addition, standing provides pressure relief at the seat and the back.²⁹¹ Increased moisture (such as sweating or incontinence) on the skin can contribute to skin breakdown and pressure injuries by reducing the tensile strength of the skin/tissue.²⁹² In a complementary manner, people reported skin integrity benefits from standing²⁹³ and fewer pressure injuries.²⁹⁴ This could be explained by decreases in epidermal temperature found in people with SCI when standing.²⁹⁵

VII. Distinguishing Power Seat Elevation and Standing Systems From Other Covered and Non-Covered Items

A. Power Seat Elevation Systems

1. Distinguishing Power Seat Elevation From Currently Covered Items

a. Comparison of Power Seat Elevation to Tilt and Recline Power Features

The power tilt and/or recline feature is an “accessory” to a complex rehabilitative PWC that, like power seat elevation, is integral to and used in conjunction with a PWC. Power tilt shifts the orientation of the person posteriorly in a seated position, while maintaining the same hip and knee angles. The power recline feature brings the person’s trunk posterior while opening up the hip and knee angle. Both positions are used primarily for pressure management, although they may aid in the performance of or participation in MRADLs. A power seat elevation system may be used in conjunction with a power tilt, power recline, or combination power tilt/recline system on a medically necessary Group 3 PWC, although the primary function of power seat elevation is to facilitate MRADL participation. A power seat elevation system does not perform any of the same functions as a power tilt or power recline system, nor does it provide any of the same or similar medical benefits of either of these medically necessary components of a PWC.

However, the power tilt and/or recline feature is considered to be covered DME, meeting the standard of being primarily medical in nature, while power seat elevation is not considered

²⁹⁰ 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.

²⁹¹ *Id.*

²⁹² Bergstrom N, Braden B. A prospective study of pressure sore risk among institutionalized elderly. *J Am Geriatr Soc* 1992; 40: 747–758.

²⁹³ Eng JJ, Levins SM, Townson AF, Mah-Jones D, Bremner J, Huston G. Use of prolonged standing for individuals with spinal cord injuries. *Phys Ther.* 2001;81(8):1392-1399.

²⁹⁴ Dunn RB, Walter JS, Lucero Y, et al. Follow-up assessment of standing mobility device users. *Assist Technol.* 1998;10(2):84-93. doi: 10.1080/10400435.1998.10131966; Walter JS, Sola PG, Sacks J, Lucero Y, Langbein E, Weaver F. Indications for a home standing program for individuals with spinal cord injury. *J Spinal Cord Med.* 1999;18(1):152-158. doi: 10.1080/10790268.1999.11719564.

²⁹⁵ Cotie LM, Geurts CLM, Adams MME, MacDonald MJ. Leg skin temperature with body-weight-supported treadmill and tilt-table standing training after spinal cord injury. *Spinal Cord.* 2011;49:149-153. doi: 10.1038/sc.2010.52.

primarily medical in nature and, therefore, not covered DME. CMS and its contractors have offered no meaningful rationale for this disparate treatment of these mobility technologies.

b. Comparison of Power Seat Elevation to Seat Lifts

A power seat elevation system and the seat lift mechanism incorporated in a lift chair both support STS movements; however, the similarities end there. A power seat elevation system moves the seat of the wheelchair vertically, raising or lowering the seat height for a taller surface from which to stand, while the seat lift mechanism tilts the seated person forward until they are weight bearing through their lower extremities. Additionally, the power seat elevation system supports greater function for the wheelchair user beyond STS, such as during MRADL performance/participation, and employs complex technology to seamlessly integrate into the Group 3 PWC base. The seat lift mechanism, in contrast, is primarily used for the STS movement and uses simple technology. However, the seat lift is accepted to be medical in nature, although the primary and customary use of the base component (the stationary chair) is nonmedical and non-covered. Conversely, the power seat elevation system can only be used on a medically necessary PWC and should be similarly considered presumptively medical and, therefore, DME.

The NCD for Seat Lift allows for coverage of a seat lift mechanism in certain situations:

Reimbursement may be made for the rental or purchase of a medically necessary seat lift when prescribed by a physician for a patient with severe arthritis of the hip or knee and patients with muscular dystrophy or other neuromuscular disease when it has been determined the patient can benefit therapeutically from use of the device.²⁹⁶

In establishing medical necessity for the seat lift, the evidence must demonstrate that the “item is included in the physician’s course of treatment, that it is likely to effect improvement, or arrest or retard deterioration in the patient’s condition, and the severity of the condition is such that the alternative would be chair or bed confinement.”²⁹⁷ The NCD further states, “Coverage of seat lifts is limited to those types which operate smoothly, can be controlled by the patient, and effectively assist a patient in standing up and sitting down without other assistance.”²⁹⁸ Additionally, the LCD for Seat Lift Mechanisms states that a seat lift mechanism is covered if the beneficiary is “completely incapable of standing up from a regular armchair or any chair in their home.”²⁹⁹

²⁹⁶ CMS, Medicare NCD Manual, Pub. 100-03, § 280.4.

²⁹⁷ *Id.*

²⁹⁸ *Id.*

²⁹⁹ Noridian Healthcare Solutions, LLC & CGS Administrators, LLC, *Local Coverage Determination: Seat Lift Mechanisms (L33801)*, <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33801&ver=22&Date=06%2f21%2f2020&DocID=L33801&bc=hAAAAAgAAAA&> (Last modified Jan. 1, 2020).

Beneficiaries with permanent disabilities and significant medical conditions, such as, but not limited to, amyotrophic lateral sclerosis, cerebral palsy, CVA, multiple sclerosis, muscular dystrophy, spina bifida, SCI, or traumatic brain injury, who use a Group 3 PWC to ameliorate their mobility limitation may also have a need for a power system that operates smoothly, can be controlled by the beneficiary, and effectively assists them in raising and lowering their position along the vertical continuum, when prescribed by their physician. As Medicare covers seat lift mechanisms to aid the STS movement for people using stationary chairs during their daily routine, a power seat elevation system, which facilitates STS movement for Group 3 PWC users and enables greater MRADL performance/participation beyond STS movement, should also be covered.

2. Distinguishing Power Seat Elevation From Non-Covered Items

A power seat elevation system used in conjunction with a Group 3 PWC is not the same as other items deemed not primarily medical in nature, such as a bathtub lift; bed lifters (bed elevators); and an elevator or stairway elevators (commonly referred to as stair lifts), as outlined in the NCD for DME.³⁰⁰ It is also not the same as the iBOT, as described in the NCD for iBOT.³⁰¹ Lastly, a power seat elevation system used in conjunction with a Group 3 PWC substantially differs from devices used to merely assist beneficiaries in grabbing items that are out of reach of the beneficiary, commonly referred to as “grabbers” or “reachers.”

a. Bathtub Lift

A bathtub lift is a stand-alone device used to raise and lower an individual into and out of the bathtub. It is not a component of a medically necessary PWC. The PWC allows the beneficiary to get to the bathroom, and the power seat elevation system of the Group 3 PWC allows the seat to be adjusted to the appropriate height to transfer safely from the wheelchair to another surface, such as a bathtub lift, shower chair, or tub bench, to engage in the activity of bathing in the customary location of the home.

b. Bed Lifters/Bed Elevator

Bed lifters/bed elevators are more commonly called “bed risers” in the marketplace. They consist of four non-adjustable pieces of plastic, metal, or wood that, when used under the posts of a bed, raise the bed from the floor between three inches and eight inches, depending on the brand. Others designed for under-bed storage raise the bed 20 inches to 24 inches. This may be of benefit to some; however, neither are primarily medical in nature. For anyone that transfers to and from the bed to a wheelchair at a low, static seat height, transfers may be more difficult, require a greater level of assistance, and increase the risk for injury from a fall during the transfer activity. A power seat elevation system used in conjunction with a Group 3 PWC

³⁰⁰ CMS, Medicare NCD Manual, Pub. 100-3, § 280.1.

³⁰¹ *Id.* § 280.15.

allows the seat to be adjusted along the vertical continuum, which may be at a different height when transferring from the bed than transferring to the bed, to maximize transfer biomechanics, independence, and safety.

c. Elevators and Stairway Elevators (Stair Lifts)

Elevators and stairway elevators allow a beneficiary to move from one floor of the home to another, where the bedroom and/or bathroom may be located, and may be of assistance to a beneficiary with mobility impairments who uses a wheelchair. However, an elevator, stairway elevator, or stair lift are all stand-alone items with consensus among the general population that their primary and customary use is non-medical and, as such, would not be deemed medical equipment. A power seat elevation system is not a stand-alone device; it is a critical component of a medically necessary Group 3 PWC. It does not function in the same manner as an elevator, stairway elevator, or stair lift, nor does it serve the same purpose. Finally, it cannot be used by anyone in the absence of an illness or injury, as required by the definition of DME found in 42 C.F.R. § 414.202.

d. iBOT

The NCD for the iBOT Mobility System has limited applicability because it focuses on the unique features of the iBOT, an innovative mobility device that uses gyroscopes and six wheels to help the user to perform a variety of functions not available in traditional mobility technology. CMS's reasoning for denying coverage for the iBOT's Balance Function should not be extended to the power seat elevation system of a Group 3 PWC, which has different functional and clinical benefits from the iBOT's Balance Function. A power seat elevation system used in conjunction with a Group 3 PWC is not the same as or similar to the operation or function of the iBOT.

The iBOT is a stand-alone powered mobility device where the beneficiary remains in the seated position and is moved up and down to various heights that includes a balance function to maintain stability of the device in the elevated position through the use of gyroscopes. It does not allow many of the benefits of a power seat elevation system, including the addition of other powered seat functions (i.e., power tilt and/or power recline) to provide postural stability; manage tone, spasticity or reflex activity; accommodate for varied asymmetrical postures, limitations in joint range of motion, muscle length or deformity; or provide the mechanical means for a beneficiary with a disability to perform a weight shift to minimize the risk of pressure injury on the seated surface. Unlike a power seat elevation system, the iBOT does not allow the beneficiary to transfer to or from the device at any point along the vertical continuum other than its lowest, static seat height position rendering it ineffective for improving transfer biomechanics, safety, and independence.

A Group 3 PWC with a seat elevation system may operate similarly to the iBOT in one aspect that was not identified as "non-covered" in the iBOT NCD. The iBOT provides mobility on smooth surfaces, inclines at home, work, and in other environments, and in its 4-Wheel

Function position, provides movement across a variety of surfaces in the elevated position. With the advances in today's technology, the power seat elevation system of a Group 3 PWC now provides safe mobility in the elevated position at the same minimum top end speed of 3.0 miles per hour required for all PWCs, allowing the user to access the vertical and horizontal environments at an equivalent of standard walking speed.

e. Grabbers/Reachers

A grabber/reacher is a stand-alone, hand-held device that is not a component of a medically necessary PWC. While these devices may provide marginal benefits to certain beneficiaries in extending reach, they are not embedded in a PWC and merely provide enhanced reaching abilities alone. They do nothing to improve beneficiaries' ability to transfer from one surface to another to perform MRADLs. They do not offer the medical benefits of reduction in secondary injury, prevention of falls, and similar medical benefits.

B. Power Standing Systems

1. Distinguishing Power Standing From Currently Covered Items

a. Comparison of Standing to Tilt and Recline Power Systems

Given that power tilt and recline have been deemed to be primarily medical in nature, CMS should similarly conclude that a power standing system used in conjunction with a Group 3 PWC is primarily medical in nature and, therefore, covered DME.³⁰²

i. Pressure Management

A person in the seated position typically experiences pressure primarily on the pelvis, buttocks, ischial tuberosities, and sacrum, as well as the scapula (shoulder blades), back region, and heels.³⁰³ As a person transitions to the upright standing posture, an integrated standing system is similar to power tilt in that it enables pressure redistribution away from the buttocks, sacrum, and pelvis.³⁰⁴ However, power tilt and power recline cannot provide pressure redistribution away from a person's shoulder blades or back, whereas a power standing system does provide pressure redistribution away from the person's trunk and back. As assessed in Sprigle et al., tilt and recline did offer increased pressure redistribution to the seat, however, not

³⁰² To be sure, the ITEM Coalition continues to believe that tilt and recline power systems are primary medical in nature and are medically necessary and reasonable for certain Medicare beneficiaries. Accordingly, Medicare coverage of tilt and recline power systems is appropriate.

³⁰³ Yalcin E, Akyuz M, Onder B, Unalan H, Degirmenci I. Skin thickness on bony prominences measured by ultrasonography in patients with spinal cord injury. *J Spinal Cord Med.* 2013;36(3):225-230. DOI: 10.1179/2045772312Y.0000000088; Lange ML. Wheelchair Seating and Selection. In: Dirette DP, Gutman SA, eds. *Occupational Therapy for Physical Dysfunction.* 8th ed. Philadelphia:Wolters Kluwer; 2020:81-99.

³⁰⁴ 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.

to the back rest.³⁰⁵ Standing was the only method that relieves pressure to both the seated surface and back.³⁰⁶

ii. Toileting

Reclining assists with toileting but in different ways than power standing systems. A recline feature facilitates repositioning of the PWC user's back by opening the hip angle for intermittent catheterization and toileting activities of daily living. Similarly, a power standing system allows for urinating in an upright position, supporting optimal bladder emptying when the person stands in the forward upright position in the complex rehabilitative PWC due to the bladder's weight.³⁰⁷ A person is able to utilize a toilet or urinal in the standing position, without a separate transfer out of their wheelchair to complete toileting needs. As the standing position enables toileting in a gravity assisted position, the standing position is more effective than a reclined position for this task. Furthermore, a power standing system allows a person to alternate and reposition from sitting to standing to improve bowel function necessary for toileting activities. Additionally, standing assists with digestion and decreasing constipation.³⁰⁸ Other studies have reported that food empties from the stomach best when individuals alternate between sitting and standing, and worst when individuals just sit, stand, or lie.³⁰⁹ Tilt and recline do not facilitate digestion, constipation, or bowel function.

iii. Edema and Circulation

Reclining can improve lower extremity edema and circulation when combined with the power accessory elevating legrests.³¹⁰ Similarly, researchers found that repeated and progressive standing may improve functional circulation.³¹¹ Additionally, when the maximal expiratory pressure of the lungs was assessed in different positions, researchers found that it was significantly decreased in the seated position, compared with the standing position.³¹² A power standing system is, therefore, able to improve circulation similar to the recline feature, but additionally improves respiration.

³⁰⁵ *Id.*

³⁰⁶ *Id.*

³⁰⁷ Gould CV, Umscheid CA, Agarwal RK, Kuntz G, Pegues DA. Healthcare Infection Control Practices Advisory C. Guideline for prevention of catheter-associated urinary tract infections 2009. *Infect Control Hosp Epidemiol.* 2010;31(4):319–326. doi:10.1086/651091.

³⁰⁸ Moore JG, Datz FL, Christian PE, Greenberg E, Alazraki N. Effect of body posture on radionuclide measurements of gastric emptying. *Dig Dis Sci.* 1988;33(12):1592-1595.

³⁰⁹ *Id.*

³¹⁰ Dicianno BE, Arva J, Lieberman JM, et al. RESNA position on the application of tilt, recline, and elevating legrests for wheelchairs. *Assist Tech.* 2009;21(1):13-22. doi: 10.1080/10400430902945769.

³¹¹ Paleg GS, Smith BA, Glickman LB. Systematic review and evidence-based clinical recommendations for dosing of pediatric supported standing programs. *Pediatr Phys Ther.* 2013;25:232-247. doi: 10.1097/PEP.0b013e318299d5e7.

³¹² Torres-Castro R, Richards D, Barraza F, et al. Effects of wheelchair use on pulmonary function and muscular respiratory strength in subjects with spinal cord injury: a case series. *Jour Resp Cardio Phys Ther.* 2016;5(1):21-25.

CMS and its contractors consider a PWC tilt and recline feature to be primarily medical in nature and, thereby, covered DME. Their failure also to consider a power standing system of a Group 3 PWC as primarily medical in nature is unsupported by a formidable body of medical evidence and should be corrected in a revised NCD for MAE.

2. Distinguishing Power Standing From Non-Covered Items

A power standing system used in conjunction with a Group 3 PWC is not a separate standing frame, tilt table, or other standing device, as it allows mobility in the standing position. This system also differs from other non-covered devices, including high-speed packages on a PWC, the iBOT, and grabbers/reachers.

a. Standing Frames

A standing frame is a separate device of DME that allows a person to transition from either sitting or supine to a stationary, forward upright standing position. These devices require a person to transfer out of and back into the wheelchair. Once the transfer has been completed into the separate standing frame, the person then transitions to the upright standing position and often requires the assistance of a caregiver to do so, as the device is either cranked or pneumatically activated to achieve an upright posture. The standing frame with a person in it cannot be moved to access multiple areas of the home due to the size and/or maneuverability of the frame. This is different than a power standing system of a Group 3 PWC, which does in fact allow a person to transition independently to and from sitting to standing and to perform or participate in MRADLs while standing and accessing all areas of the home.

b. Tilt Tables

A tilt table is a separate DME device that allows a person to transition from supine to a forward upright standing position. These devices again require a person to transfer into and out of the wheelchair in order to be used. Once the transfer onto the tilt table has been completed, the person is dependent on a caregiver to achieve an upright standing position. A tilt table is often larger than a standing system, and when a person is in the tilt table, it cannot be moved to access multiple areas of the home. This is different than the power standing system of a Group 3 PWC, which does in fact allow a person to complete MRADLs while standing and accessing all areas of the home.

c. Use of Standing Frames and Tilt Tables in the Home

While standing frames and tilt tables allow for weight bearing and the medical benefits of being in an upright posture, transfers in and out of these devices are often difficult for the beneficiary and often require assistance to operate them. In contrast, the beneficiary independently directs the power standing system of a Group 3 PWC, coming in and out of the standing position safely without transferring out of the equipment and without the need for additional assistance.

d. Standing Manual Wheelchairs

A power standing system of a Group 3 PWC is not the same as a standing system in a manual wheelchair in the same way that the clinical indicators for a beneficiary to qualify for a Group 3 PWC as compared to a manual wheelchair are not the same. The primary differences are intended to address the differing needs of Group 3 PWC beneficiaries, as compared to manual wheelchair beneficiaries. The system on a Group 3 PWC requires batteries, electronics, and separate actuators or motors in order to function and compensate for the beneficiary's inability to move on his or her own.

Further, beneficiaries are unable to propel themselves while in a standing position using a standing manual wheelchair. Manual wheelchairs are self-propelled by a person using the upper or lower extremities and allow a person to perform or participate in MRADLs while in the seated position. The standing system of a manual wheelchair is activated with a lever and is a gas-powered spring, pneumatic, or power operated mechanism. The system enables a person to transition from the sitting position to an upright standing posture while in the manual wheelchair; however, once standing, the person is unable to reach the wheels to propel and, therefore, is unable to move about from the upright position and that may limit the ability to complete MRADLs.

Similar to a Group 3 PWC with a power standing system, the beneficiary does not have to transfer out of the manual wheelchair in order to use the system. In the case of a standing manual wheelchair, the beneficiary may require grip strength or hand function, upper body strength, and trunk stability for operation.

e. High Speed Motor Package on a PWC

A high-speed package on a PWC is a good example of a PWC accessory that is not primarily medical in nature. The increased speed of a high-speed package as an accessory does not offer a medical benefit to the beneficiary. The power standing system of a Group 3 PWC, however, provides medical benefits for pressure redistribution, bowel and bladder function, circulatory and respiratory function, as well as increased safety, independence, and timeliness of the completion of MRADLs in the standing position.

f. iBOT

The NCD for the iBOT should not preclude CMS from determining that the Group 3 PWC standing system is primarily medical in nature and is a covered DME benefit. A power standing system of a Group 3 PWC is not similar to the iBOT. The iBOT is a powered device; however, the beneficiary remains in the seated position and is moved up and down to various heights while they are seated. The iBOT does not allow a beneficiary to achieve a forward upright standing position, and because a beneficiary cannot stand while in it, it does not allow for the medical benefits of pressure redistribution, bowel and bladder function, circulatory and

respiratory function, or the increased safety, independence and efficiency to complete MRADLs in the standing position.

The power standing system of a Group 3 PWC goes beyond simply assisting beneficiaries with “reaching items out of reach or having an “eye-level” conversation with a standing person,” as the iBOT Decision Memorandum notes.³¹³ Power standing enables non-ambulatory beneficiaries to perform or participate in essential MRADLs, including grooming, dressing, hygiene, and meal preparation. Moreover, the physical benefits of attaining a vertical standing position through the standing system have a direct therapeutic impact on beneficiaries with mobility impairments.

An extensive body of evidence shows that the standing system results in improved mobility and lower limb function in individuals with preserved muscle strength in the lower limbs, improves range of motion, reduces the risk of contractures, promotes BMD, and has a positive impact on cardio-metabolic health.³¹⁴ The power standing system is not primarily a convenience item. It has direct therapeutic benefits for beneficiaries with mobility-related conditions. As a result, CMS’s coverage determination for the iBOT Balance Function is extremely narrow in applicability and should not be extended to the power standing system of a Group 3 PWC.

g. Grabbers/Reachers

As stated above, grabbers/reachers are stand-alone, hand-held devices that are used to merely assist beneficiaries in grabbing items that are out of reach of the beneficiary. While grabbers/reachers may provide marginal benefits in allowing beneficiaries to reach objects, they are not embedded in a PWC, nor do they offer the medical benefits of pressure redistribution, improved bowel and bladder function, improved circulatory and respiratory function, or the ability to complete MRADLs in the standing position.

VIII. Additional Steps and Future Considerations: Coding Changes and Revisions to Contractor Determinations

While this reconsideration request is specific to the NCD for MAE, once the needed modifications to the NCD for MAE occur, CMS officials should instruct the DME MACs to make further changes and modifications. Specifically, it will be necessary to revise corresponding LCDs and related LCAs to strike existing language with respect to power seat

³¹³ Decision Memorandum from Laurence Wilson et al. on the INDEPENDENCE 4000 iBOT Mobility System – Scope of Benefits § 1862(a)(1)(A) (July 27, 2006), <https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=5&fromdb=true>.

³¹⁴ Arva J, et al., *RESNA Position on the Application of Wheelchair Standing Devices*, Assistive Technology, 21:161-168 (2009), doi: 10.1080/10400430903175622; Dicianno BE, Morgan A, Lieberman J, Rosen L. Rehabilitation Engineering & Assistive Technology Society (RESNA) Position on the Application of Wheelchair Standing Devices: 2013 Current State of the Literature. *Assist Tech*. 2016;28(1):57-62. doi: 10.1080/10400435.2015.1113837.

elevation and standing systems and develop new coverage requirements, activate existing HCPCS billing codes (or consider modifications to code definitions/characteristics), and determine fee schedule amounts for power seat elevation and power standing systems. The ITEM Coalition stands ready to assist CMS and its contractors with these necessary changes. The Clinician Task Force, an ITEM Coalition member, prepared a draft LCD governing power seat elevation and power standing systems for CMS's and the DME MAC Medical Directors' consideration. The draft LCD is attached hereto as Appendix C.

IX. Conclusion

The medical benefits of seat elevation and standing systems in Group 3 PWCs 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 activities of daily living and causes countless medical complications and secondary conditions that are almost entirely avoidable with access to power seat elevation and standing systems in Group 3 PWCs. Seat elevation is critical to MRADL participation and performance, the standard for medical coverage of Medicare mobility equipment. Seat elevation improves transfers and reaching and reduces or eliminates neck and spine injuries from PWC use. The physiological benefits of standing are widely known and often promoted throughout society, and these benefits are not confined to ambulatory individuals. 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.

Both systems will 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, paid homecare providers or personal assistants. While the technology has evolved, these systems have now been available as integral components of PWCs for 25 years and are covered by many payers, other than the Medicare program. Medicare beneficiaries with disabilities and other medical condition are being harmed by the lack of access to important Group 3 PWC accessories. Now is the time for Medicare—the largest health care payer in the country—to finally cover power seat elevation and standing systems in Group 3 PWCs.

In sum and to reiterate, this NCD request for reconsideration seeks to secure coverage of power seat elevation and power standing systems in Group 3 power wheelchairs for certain Medicare beneficiaries with mobility impairments in order to perform or participate in MRADLs in the home. We seek reconsideration of the National Coverage Determination for Mobility Assistive Equipment to (1) establish a benefit category determination that both power seat elevation and power standing systems in Group 3 power wheelchairs are “primarily medical in nature” and, therefore, covered durable medical equipment under the Medicare program, and (2) explicitly recognize coverage of these systems for beneficiaries with a medical or functional

need for vertical movement in a Group 3 power wheelchair in order to perform or obtain assistance to participate in MRADLs in the home.

APPENDICES

Appendix A: Bibliography

Appendix B: NCD for MAE Redline with Proposed Modifications to Clarify the Benefit Category Determination and, Therefore, Coverage of Power Seat Elevation and Power Standing Systems in Complex Rehabilitative PWCs

Appendix C: Suggested Draft Local Coverage Determination for Medicare Coverage of Power Seat Elevation and Power Standing Systems in Group 3 Power Wheelchairs

Appendix D: List of Participating Individuals, Organizations, and Subgroup Membership of the ITEM Coalition on this Initiative

Appendix E: Evidence-Based Articles that Comprise the Bibliography

Appendix A: Bibliography

1. Adams MM, Hicks AL. Comparison of the effects of body-weight-supported treadmill training and tilt-table standing on spasticity in individuals with chronic spinal cord injury. *J Spinal Cord Med.* 2011;34(5):488-494. doi: 10.1179/2045772311Y.0000000028.
2. Alekna V, Tamulaitiene M, Sinevicius T, Juocevicius A. Effect of weight-bearing activities on 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.
3. Alexander NB, Gross MM, Medell JL, Hofmeyer MR. Effects of functional ability and training on chair-rise biomechanics in older adults. *J Gerontol.* 2001;56A(9):M538-M547.
4. Alm M, Saraste H, Norrbrink C. Shoulder pain in persons with thoracic spinal cord injury: prevalence and characteristics. *J Rehabil Med.* 2008;40:277-283, doi: 10.2340/16501977-0173.
5. Antonio TS, Urrutia F, Larrea A, Espín V, Latta MA. (2019) Variations in Vital Signs Associated with the Postural Changes When Using a Stand-up Wheelchair in Patients with Spinal Cord Injury. In: Ahram T.Z., Falcão C. (eds) *Advances in Usability, User Experience and Assistive Technology.* AHFE 2018. *Advances in Intelligent Systems and Computing*, vol 794.
6. Arva J, Schmeler MR, Lange ML, Lipka DD, Rosen LE. RESNA position on the application of seat-elevating devices for wheelchair users. *Assist Tech.* 2009;21(2):69-72. doi: 10.1080/10400430902945587.
7. Arva J, et al., RESNA Position on the Application of Wheelchair Standing Devices, *Assistive Technology*, 21:161-168 (2009), doi: 10.1080/10400430903175622.
8. Ashe MC, Fehling P, Eng JJ, Khan KM, McKay HA. Bone geometric response to chronic disuse following stroke: a pQCT study. *J Musculoskelet Neuronal Interact.* 2006;6(3):226-233.
9. 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.
10. Beaupre GS, Lew HL. Bone-density changes after stroke. *Am J Phys Med Rehabil.* 2006;85:464-472. doi: 10.1097/01.phm.0000214275.69286.7a.

11. Ben M, Harvey L, Denis S, et al. Does 12 weeks of regular standing prevent loss of ankle mobility and bone mineral density in people with recent spinal cord injuries? *Aust J Physiother.* 2005;51:251-256.
12. Bergstrom N, Braden B. A prospective study of pressure sore risk among institutionalized elderly. *J Am Geriatr Soc* 1992; 40: 747–758.
13. Bernard BP. *Musculoskeletal disorders and workplace factors (97B141)*. Cincinnati, OH: US Department of Health and Human Services, National Institute for Occupational Safety and Health; July, 1997.
14. Bohannon RW, Barreca SR, Shove ME, Lambert C, Masters LM, Sigouin CS. Documentation of daily sit-to-stands performed by community-dwelling adults. *Physiother Theory Pract.* 2008;24(6):437-442. doi: 10.1080/09593980802511813.
15. Bohannon RW, Smith MB. Interrater reliability of a modified Ashworth scale of muscle spasticity. *Phys Ther.* 1987;67(2):206-207. doi: 10.1093/ptj/67.2.206.
16. Bohannon RW. Tilt table standing for reducing spasticity after spinal cord injury. *Arch Phys Med Rehabil.* 1993;74(10):1121-1122.
17. Boninger ML, Cooper RA, Fitzgerald SG, et al. Investigating neck pain in wheelchair users. *Am J Phys Med Rehabil.* 2003;82:197-202. doi: 10.1097/01.PHM.0000054217.17816.DD.
18. Bonner JJ, Vajjah P, Abduljalil K, et al. Does age affect gastric emptying time? A model-based meta-analysis of data from premature neonates through to adults. *Biopharm Drug Dispos.* 2015;36:245-257. doi: 10.1002/bdd.1937.
19. Bouras EP, Tangelos EG. Chronic constipation in the elderly. *Gastroenterol Clin N Am.* 2009;38:463-480. doi: 10.1016/j.gtc.2009.06.001 new treatment options. *Clin Interv Aging.* 2010;5:163:171.
20. Boutilier G, Sawatzky BJ, Grant C, Wiefelspuett S, Finlayson H. Spasticity changes in SCI following a dynamic standing program using the Segway. *Spinal Cord.* 2012;50:595-598. doi: 10.1038/sc.2012.23.
21. Brown WJ, Miller YD, Miller R. Sitting time and work patterns as indicators of overweight and obesity in Australian adults. *Int J Obes.* 2003;27(11):1340-1346. doi: 10.1038/sj.ijo.0802426.
22. Burdett RG, Habasevich R, Pisciotta J, Simon SR. Biomechanical comparison of rising from two types of chairs. *Phys Ther.* 1985;65(8):1177-1183.

23. Charette C, Routhier F, McFadyen BJ. Visuo-locomotor control in persons with spinal cord injury in a manual or power wheelchair for direction change and obstacle circumvention. *Exp Brain Res*. 2017;235:2669-2678. doi: 10.1007/s00221-017-4994-4.
24. Chen Y, DeVivo MJ, Roseman JM. Current trend and risk factors for kidney stones in persons with spinal cord injury: a longitudinal study, *Spinal Cord*, 2000;38:346-353.
25. Cotie LM, Geurts CLM, Adams MME, MacDonald MJ. Leg skin temperature with body-weight-supported treadmill and tilt-table standing training after spinal cord injury. *Spinal Cord*. 2011;49:149-153. doi: 10.1038/sc.2010.52.
26. Curtis KA, Roach KE, Applegate EB, et al. Development of the Wheelchair User's Shoulder Pain Index (WUSPI). *Paraplegia*. 1995;33(5)290-293.
27. Dall PM, Kerr A. Frequency of the sit to stand task: An observational study of free-living adults. *Appl Ergon*. 2010;21:58-61.
28. Dalyan M, Cardenas DD, Gerard B. Upper extremity pain after spinal cord injury. *Spinal Cord*. 1999;37:191-195.
29. de Bruin ED, Frey-Rindova P, Herzog RE, Dietz V, Dambacher MA, Stüssi E. Changes in tibia bone properties after spinal cord injury: effects of early intervention. *Arch Phys Med Rehabil*. 1999;80:214-220.
30. Dehail P, Gaudreault N, Zhou H, et al. Joint contractures and acquired deforming hypertonia in older people: which determinants? *Ann Phys Rehabil Med*. 2019;62:435-441.
31. Dicianno BE, Arva J, Lieberman JM, et al. RESNA position on the application of tilt, recline, and elevating legrests for wheelchairs. *Assist Tech*. 2009;21(1);13-22. doi: 10.1080/10400430902945769.
32. Dicianno BE, Morgan A, Lieberman J, Rosen L. Rehabilitation Engineering & Assistive Technology Society (RESNA) Position on the Application of Wheelchair Standing Devices: 2013 Current State of the Literature. *Assist Tech*. 2016;28(1):57-62. doi: 10.1080/10400435.2015.1113837.
33. Diebo BG, Challier V, Henry JK, et al. Predicting cervical alignment required to maintain horizontal gaze based on global spinal alignment, *Spine*, 2016;41(23):1795-1800. doi:10.1097/BRS.0000000000001698.

34. Ding D, Leister E, Cooper RA et al. Usage of tilt-in-space, recline, and elevation seating functions in natural environment of wheelchair users, *J Rehabil Res Dev*. 2008;45(7):973-984, doi: 10.1682/JRRD.2007.11.0178.
35. Dirette DP, Fortuna J. Visual function assessment. In: Dirette DP, Gutman SA, eds. *Occupational Therapy for Physical Dysfunction*. 8th ed. Philadelphia:Wolters Kluwer;2020:81-99.
36. Domingos F, Serra A. Nephrolithiasis is associated with an increased prevalence of cardiovascular disease. *Nephrol Dial Transplant*. 2011;26:864-868. doi: 10.1093/ndt/gfq501.
37. Dudley-Javoroski S, Shields RK. Muscle and bone plasticity after spinal cord injury: review of adaptations to disuse and to electrical muscle stimulation. *J Rehabil Res Dev*. 2008;45(2):283-296. doi: 10.1682/JRRD.2007.02.0031.
38. Dunn RB, Walter JS, Lucero Y, et al. Follow-up assessment of standing mobility device users. *Assist Technol*. 1998;10(2):84-93. doi: 10.1080/10400435.1998.10131966.
39. Dunstan DW, Kingwell BA, Larsen R, et al. Breaking up prolonged sitting reduces postprandial glucose and insulin responses. *Diabetes care*. 2012;35:976-983, doi: 10.2337/dc11-1931.
40. Edwards LC, Layne CS. Effect of dynamic weight bearing on neuromuscular activation after spinal cord injury. *Am J Phys Med Rehabil*. 2007;86(7):499-506.
41. Eggers SL, Myaskovsky L, Burkitt KH et al. A preliminary model of wheelchair service delivery. *Arch Phys Med Rehabil*. 2009;90:1030-1038. doi:10.1016/j.apmr.2008.12.007.
42. Eng JJ, Levins SM, Townson AF, Mah-Jones D, Bremner J, Huston G. Use of prolonged standing for individuals with spinal cord injuries. *Phys Ther*. 2001;81(8):1392-1399.
43. Eser P, de Bruin ED, Telley I, Lechner HE, Knecht H, Stüssi E. Effect of electrical stimulation-induced cycling on bone mineral density in spinal cord-injured patients. *Eur J Clin Invest*. 2003;33(5):412-419.
44. Finley MA, McQuade KJ, Rodgers MM. Scapular kinematics during transfers in manual wheelchair users with and without shoulder impingement. *Clin Biomech*. 2005;20:32-40. doi:10.1016/j.clinbiomech.2004.06.011.

45. Flett HM, Delparte JJ, Scovil CY, Higgins J, Laramée MT, Burns AS. Determining pressure injury risk on admission to inpatient spinal cord injury rehabilitation: a comparison of the FIM, Spinal Cord Injury Pressure Ulcer Scale, and Braden Scale. *Arch Phys Med Rehabil.* 2019;100:1881-1887.
46. Frey-Rindova P, de Bruin ED, Stüssi E, Dambacher MA, Dietz V. Bone mineral density in upper and lower extremities during 12 months after spinal cord injury measured by peripheral quantitative computed tomography. *Spinal Cord.* 2000;38:28-32.
47. Gagnon D, Nadeau S, Noreau L, Eng JJ, Gravel D. Trunk and Upper Extremity Kinematics During Sitting Pivot Transfers Performed by Individuals with Spinal Cord Injury. *Clin Biomech.* 2008;23:279-290, doi:10.1016/j.clinbiomech.2007.09.017.
48. Gellman H, Sie I, Waters RL. Late complications of the weight-bearing upper extremity in the paraplegic patient. *Clinical Orthopaedics and Rehabilitation Research.* 1987;233:132-135.
49. Goktepe AS, Tugcu I, Yilmaz B, Alaca R, Gunduz S. Does standing protect bone density in patients with chronic spinal cord injury? *J Spinal Cord Med.* 2008;31(2):197-201. doi: 10.1080/10790268.2008.11760712.
50. Gould CV, Umscheid CA, Agarwal RK, Kuntz G, Pegues DA. Healthcare Infection Control Practices Advisory C. Guideline for prevention of catheter-associated urinary tract infections 2009. *Infect Control Hosp Epidemiol.* 2010;31(4):319–326, doi:10.1086/651091.
51. Hansen RB, Biering-Sørensen F, Kristensen JK. Urinary calculi following traumatic spinal cord injury. *Scand J Urol Nephrol.* 2007;41(2):115-119. doi: 10.1080/00365590600991383.
52. Healy GN, Winkler EAH, Owen N, Anuradha S, Dunstan DW. Replacing sitting time with standing or stepping: associations with cardio-metabolic risk biomarkers. *Eur Heart J.* 2015;36:2643-2649. doi:10.1093/eurheartj/ehv308.
53. Hicken BL, Putzke JD, Richards JS. Bladder management and quality of life after spinal cord injury. *Am J Phys Med Rehabil.* 2001;80:916-922.
54. Hoenig H, Murphy T, et al. Case study to evaluate a standing table for managing constipation. *SCI Nurs.* 2001;18(2):74–77.
55. Horak FB, Earhart GM, Dietz V. Postural responses to combinations of head and body displacements: vestibular-somatosensory interactions. *Exp Brain Res.* 2001;141:410-414. doi: 10.1007/s00221-001-0915-6.

56. Hughes MA, Schenkman ML. Chair rise strategy in the functionally impaired elderly. *J Rehabil Res Dev.* 1996;33(4):409-412.
57. Janssen WGM, Bussmann HBJ, Stam HJ. Determinants of the Sit-to-Stand Movement: A Review. *Phys Ther.* 2002;82(9):866-879.
58. Kaplan PE, Roden W, Gilbert E, Richards L, Goldschmidt JW. Reduction of hypercalciuria in tetraplegia after weight-bearing and strengthening exercises. *Paraplegia.* 1981;19:289-293.
59. Kerr KM, White JA, Barr DA, Mollan RAB. Analysis of the sit—stand—sit movement cycle in normal subjects. *Clin Biomech.* 1997;12(4):236-245.
60. Kheder A, Nair KPS. Spasticity: pathophysiology, evaluation and management. *Pract Neurol.* 2012;12:289-298. doi:10.1136/practneurol-2011-000155.
61. Khemlani, MM, Carr JH, Crosbie WJ. Muscle synergies and joint linkages in sit-to-stand under two initial foot positions. *Clin Biomech.* 1999;14:236-246.
62. Kim CY, Lee JS, Kim HD, Kim J, Lee IH. Lower extremity muscle activation and function in progressive task-oriented training on the supplementary tilt table during stepping-like movements in patients with acute stroke hemiparesis. *J Electromyogr Kinesiol.* 2015;25:522-530, doi.org/10.1016/j.jelekin.2015.03.004.
63. Kim CY, Lee JS, Kim HD, Kim JS. The effect of progressive task-oriented training on supplementary tilt table on lower extremity muscle strength and gait recovery in patients with hemiplegic stroke. *Gait Posture.* 2015;41:425-430.
64. Kim SS, Her JG, Ko TS. Effect of different hand positions on trunk and shoulder kinematics and reaction forces in sitting pivot transfer. *J Phys Ther Sci.* 2015;27:2307-2311.
65. Kirby RL, Fahie CL, Smith C, Chester EL, MacLeod DA. Neck discomfort of wheelchair users: effect of neck position. *Disabil Rehab.* 2004;26(1):9-15. doi:10.1080/09638280310001621451.
66. Kirby RL, Swuste J, Dupuis DJ, MacLeod DA, Monroe R. The Wheelchair Skills Test: A pilot study of a new outcome measure. *Arch Phys Med Rehabil.* 2002;83:10-8. doi:10.1053/apmr.2002.26823.
67. Koski K, Luukinen H, Laippala P, Kivela SL. Risk factors for major injurious falls among the home-dwelling elderly by functional abilities. *Gerontology.* 1998;44:232-238.

68. Krause JS, Saunders LL. Health, Secondary Conditions, and Life Expectancy After Spinal Cord Injury, *Arch Phys Med Rehabil* 2011; 92:1770-5, doi:10.1016/j.apmr.2011.05.024.
69. Kunkel CF, Scremin E, Eisenberg B, Garcia JF, Roberts S, Martinez S. Effect of “standing” on spasticity, contracture, and osteoporosis in paralyzed males. *Arch Phys Med Rehabil*. 1993;74:73-78.
70. Kuznetsov AN, Rybalko NV, Daminov VD, Luft AR. Early poststroke rehabilitation using a robotic tilt-table stepper and functional electrical stimulation. *Stroke Res Treat*. 2013;1-9, doi.org/10.1155/2013/946056.
71. Kwok S, Harvey L, Glinsky J, Bowden JL, Coggrave M, Tussler D. Does regular standing improve bowel function in people with spinal cord injury? A randomized crossover trial. *Spinal Cord*. 2015;53:36-41. doi: 10.1038/sc.2014.189.
72. Lange ML. Wheelchair Seating and Selection. In: Dirette DP, Gutman SA, eds. *Occupational Therapy for Physical Dysfunction*. 8th ed. Philadelphia:Wolters Kluwer; 2020:81-99.
73. Lazoura O, Groumas N, Antoniadou E, et al. Bone mineral density alterations in upper and lower extremities 12 months after stroke measured by peripheral quantitative computed tomography and DXA. *J Clin Densitom*. 2008;11(4):511-517. doi: 10.1016/j.jocd.2008.05.097.
74. Lee KCL, Maxwell A, Lanyon LE. Validation of a technique for studying functional adaptation of the mouse ulna in response to mechanical loading. *Bone*. 2002;31(3):1-9.
75. Levi R, Hultling C, Nash MS, Seiger A. The Stockholm spinal cord injury study: 1. Medical problems in a regional SCI population. *Paraplegia*. 1995;33:308-315.
76. Lord SR, Murray SM, Chapman K, Munro B, Tiedemann A. Sit-to-stand performance depends on sensation, speed, balance, and psychological status in addition to strength in older people. *J Gerontol*. 2002;57(8):M539-M543.
77. Mahoney JS, Engebretson JC, Cook KF, Hart KA, Robinson-Whelen S, Sherwood AM. Spasticity experience domains in persons with spinal cord injury. *Arch Phys Med Rehabil*. 2007;88:287-294, doi:10.1016/j.apmr.2006.12.029.
78. Masselink C, Trends in Wheelchair Recommendations in a Dedicated Seating Department, Assistive Technology (July 2, 2020), doi: 10.1080/10400435.2020.1772899.

79. Massengale S, Folden D, McConnell P, Stratton L, Whitehead V. Effect of visual perception, visual function, cognition, and personality on power wheelchair user in adults. *Assist Tech*. 2005;17(2):108-121. doi: 10.1080/10400435.2005.10132101.
80. Matthews CE, Chen KY, Freedson PS, et al. Amount of time spent in sedentary behaviors in the United States, 2003-2004. *Am J Epidemiol*. 2008;167(7):875-881. doi:10.1093/aje/kwm390.
81. McCrea PH, Eng JJ, Hodgson AJ. Biomechanics of reaching: clinical implications for individuals with acquired brain injury. *Disabil Rehabil*. 2002;24(10):534-541. doi: 10.1080/09638280110115393.
82. Measuring a power chair. *Mobility Management Magazine*. Oct 1, 2018. <https://mobilitymgmt.com/Articles/2018/10/01/Measurements.aspx>. Accessed April 9, 2020.
83. Mills T, Holm MB, Trefler E, Schmeler M, Fitzgerald S, Boninger M. Development and consumer validation of the Functional Evaluation in a Wheelchair (FEW) instrument. *Disabil Rehabil*. 2002;24(1):38-46. doi: 10.1080/09638280110066334.
84. Moore JG, Datz FL, Christian PE, Greenberg E, Alazraki N. Effect of body posture on radionuclide measurements of gastric emptying. *Dig Dis Sci*. 1988;33(12):1592-1595.
85. Mosley JR, Lanyon LE. Strain rate as a controlling influence on adaptive modeling in response to dynamic loading of the ulna in growing male rats. *Bone*. 1998;23(4):313-318.
86. Nakamura K, Nagasawa Y, Sawaki S, Yokokawa Y, Ohira M. Effect of different seat heights during an incremental sit-to-stand exercise test on peak oxygen uptake in young, healthy women. *J Sports Sci Med*. 2016;15:410-416.
87. Netz Y, Argov E, Burstin A, et al. 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 Technol*. 2007;2(1):43-49. doi: 10.1080/17483100601143371.
88. Nevitt MC, Cummings SR, Hudes ES. Risk factors for injurious falls: a prospective study. *J Gerontol*. 1991;46(5):M161-170.
89. Newman M, Barker K. The effect of supported standing in adults with upper motor neurone disorders: a systematic review. *Clin Rehabil*. 2012;26(12):1059-1077. doi: 10.1177/0269215512443373.

90. Nyland J, Quigley P, Huang C, Lloyd J, Harrow J, Nelson A. Preserving transfer independence among individuals with spinal cord injury. *Spinal Cord*. 2000;38:649-657.
91. Odeen I, Knutsson E. Evaluation of the effects of muscle stretch and weight load in patients with spastic paraplegia. *Scand J Rehabil Med*. 1981;13:117-121.
92. Özgürbüz N, Eser I. Effects of voiding in standing and sitting positions on uroflowmetric parameters and post-void residual urine in boys. *Urol Nurs*. 2018;38(2):67-72. doi:10.7257/1053-816X.2018.38.2.67.
93. Paleg G, Livingstone R. Systematic review and clinical recommendations for dosage of supported home-based standing programs for adults with stroke, spinal cord injury and other neurological conditions. *BMC Musculoskelet Disord*. 2015;16(358):1-16. doi: 10.1186/s12891-015-0813-x.
94. Paleg GS, Smith BA, Glickman LB. Systematic review and evidence-based clinical recommendations for dosing of pediatric supported standing programs. *Pediatr Phys Ther*. 2013;25:232-247. doi: 10.1097/PEP.0b013e318299d5e7.
95. Ragnarsson KT, Krebs M, Naftchi NE et al. Head-up tilt effect on glomerular filtration rate, renal plasma flow, and mean arterial pressure in spinal man. *Arch Phys Med Rehabil*. 1981;62:306-310.
96. Rao SSC & Go JT. Update on the management of constipation in the elderly: new treatment options. *Clin Interv Aging*. 2010;5:163:171.
97. Rasmussen MM, Krogh K, Clemmensen D, Bluhme H, Rawashdeh Y, Christensen P. Colorectal transport during defecation in subjects with supraconal spinal cord injury. *Spinal Cord*. 2013;51:683-687. doi: 10.1038/sc.2013.58.
98. Requejo PS, Mulroy SJ, Haubert LL, Newsam CJ, Gronley JK, Perry J. Evidence-based strategies to preserve shoulder function in manual wheelchair users with spinal cord injury. *Top Spinal Cord Inj Rehabil*. 2008;13(4)86-119. doi:10.1310/sci1304-86.
99. Riek LM, Ludewig PM, Nawoczenski 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;46:335-343. doi:10.1038/sj.sc.3102140.
100. Robinson W, Smith R, Aung O, Ada L. No difference between wearing a night splint and standing on a tilt table in preventing ankle contracture early after stroke: a randomised trial. *Aust J Physiother*. 2008;54:33-38.

101. Rowe TA, Juthani-Mehta M. Urinary tract infection in older adults. *Aging Health*. 2013;9(5):519-528.
102. 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 Technol*. 2016;28(3):184-189. doi: 10.1080/10400435.2016.1140692.
103. Schenkman M, Berger RA, Riley PO, Mann RW, Hodge WA. Whole-Body Movements During Rising to Standing from Sitting. *Phys Ther*. 1990;70(10):638-651.
104. Schiappa V, Piriano J, Bernhardt L, et al. RESNA position on the application of seat-elevation devices for power wheelchair users: literature update (2019). September 25, 2019.
https://www.resna.org/Portals/0/Documents/Position%20Papers/RESNA_App%20of%20Seat%20Elevation%20Devices%202019.pdf. Accessed March 2, 2020.
105. Shields RK, Dudley-Javoroski S. Monitoring standing wheelchair use after spinal cord injury: a case report. *Disabil Rehabil*. 2005;27(3):142-146. doi: 10.1080/09638280400009337.
106. Shields RK, Dudley-Javoroski S, Boaldin KM, Corey TA, Fog DB, Ruen JM. Peripheral quantitative computed tomography: measurement sensitivity in persons with and without spinal cord injury. *Arch Phys Med Rehabil*. 2006;87(10):1376-1381.
107. Singh G, Lingala V, Wang H, et al. Use of health care resources and cost of care for adults with constipation. *J Clin Gastroenterol Hepatol*. 2007;5:1053-1058, doi:10.1016/j.cgh.2007.04.019.
108. Snyder WS, editor. Report of the task group on reference man. Oxford: Pergamon; 1975.
109. Sonenblum SE, Maurer CL, Hanes CD, Piriano J, Sprigle SH. Everyday use of power adjustable seat height (PASH) systems. *Assist Technol*. 2019. doi: 10.1080/10400435.2019.1634659.
110. Sprigle S. Survey of users of wheelchair seat elevators. Georgia Institute of Technology. 2017.
https://smartech.gatech.edu/bitstream/handle/1853/59106/seat_elevator_survey_report.pdf?sequence=1&isAllowed=y. Accessed March 20, 2020.
111. 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.

112. Sprigle S, Taylor SJ. Data-mining analysis of the provision of mobility devices in the United States with emphasis on complex rehab technology. *Assist Tech*. 2019;31(3):141-146. DOI: 10.1080/10400435.2017.1402391.
113. Tinetti ME, Speechley M, Ginter SF. Risk factors for falls among elderly persons living in the community. *N Engl J Med*. 1988;319(26):1701-1707.
114. Torres-Castro R, Richards D, Barraza F, et al. Effects of wheelchair use on pulmonary function and muscular respiratory strength in subjects with spinal cord injury: a case series. *Jour Resp Cardio Phys Ther*. 2016;5(1):21-25.
115. Townsend EL, Bibeau C, Holmes TM. Supported standing in boys with Duchenne Muscular Dystrophy. *Pediatr Phys Ther*. 2016;28(3):320-329. doi: 10.1097/PEP.0000000000000251.
116. Tsai CY, Hogaboom NS, Boninger ML, Koontz AM. The Relationship between Independent Transfer Skills and Upper Limb Kinetics in Wheelchair Users. *Biomed Res Int*. 2014;1-12. doi.org/10.1155/2014/984526.
117. Tyry T, Salter A, Largent J, Marrie RA. The impact of spasticity severity on healthcare utilization among MS patients: a large-scale six-year follow-up study. *J Neurol Sci*. 2013;333(S1):e376-e378. doi: 10.1016/j.jns.2013.07.1371.
118. van Shaardenburg D, Van den Brande KJS, Ligthart GJ, Breedveld FC, Hazes JMW. Musculoskeletal disorders and disability in persons aged 85 and over: a community survey. *Ann Rheum Dis*. 1994. 53:807-811.
119. Vestergaard P, Krogh K, Rejnmark L, Mosekilde L. Fracture rates and risk factors for fractures in patients with spinal cord injury. *Spinal Cord*. 1998;36:790-796.
120. Vorster N, Evans K, Murphy N, et al. Powered standing wheelchairs promote independence, health and community involvement in adolescents with Duchenne muscular dystrophy. *Neuromuscul Disord*. 2019;29:221-230. doi: 10.1016/j.nmd.2019.01.010.
121. Walter JS, Sola PG, Sacks J, Lucero Y, Langbein E, Weaver F. Indications for a home standing program for individuals with spinal cord injury. *J Spinal Cord Med*. 1999;18(1):152-158. doi: 10.1080/10790268.1999.11719564.
122. Wang YT, Kim CK, Ford III HT, Ford Jr. HT. Reaction force and EMG analyses of wheelchair transfers. *Percept Mot Skills*. 1994;79:763-766.

123. Weiner DK, Long R, Hughes MA, Chandler J, Studenski S. When older adults face the chair-rise challenge. *J Am Geriatr Soc.* 1993;41:6-10.
124. Wilmet E, Ismail AA, Heilporn A, Welraeds D, Bergmann P. Longitudinal study of the bone mineral content and of soft tissue composition after spinal cord section. *Paraplegia.* 1995;33(11):674-677.
125. Wojszel ZB, Toczyńska-Silkiewicz M. Urinary tract infections in a geriatric sub-acute ward-health correlates and atypical presentations. *Eur Geriatr Med.* 2018;9:659-667.
126. Xiang H, Chany A-M, Smith GA. Wheelchair related injuries treated in US emergency departments. *Inj Prev.* 2006;12:8-11. doi: 10.1136/ip.2005.010033.
127. Yalcin E, Akyuz M, Onder B, Unalan H, Degirmenci I. Skin thickness on bony prominences measured by ultrasonography in patients with spinal cord injury. *J Spinal Cord Med.* 2013;36(3):225-230. DOI: 10.1179/2045772312Y.0000000088.
128. Yan T, Liu C, Li Y, Xiao W, Li Y, Wang S. Prevalence and predictive factors of urinary tract infection among patients with stroke: a meta-analysis. *Am J Infect Control.* 2018;46:402-409, doi.org/10.1016/j.ajic.2017.10.001.
129. Yoshioka S, Nagano A, Hay DC, Fukashiro S. Peak hip and knee joint moments during a sit-to-stand movement are invariant to the change of seat height within the range of low to normal seat height. *BioMedical Engineering OnLine.* 2014;13(27).

Appendix B:
NCD for MAE Redline with Proposed Modifications to Clarify the Benefit Category Determination and, Therefore, Coverage of Power Seat Elevation and Power Standing Systems in Complex Rehabilitative PWCs

National Coverage Determination (NCD) for Mobility Assistive Equipment (MAE) (280.3)

A. General

The Centers for Medicare & Medicaid Services (CMS) addresses numerous items that it terms “mobility assistive equipment” (MAE) and includes within that category canes, crutches, walkers, manual wheelchairs, power wheelchairs, and scooters. This list, however, is not exhaustive.

Medicare beneficiaries may require mobility assistance for a variety of reasons and for varying durations because the etiology of the disability may be due to a congenital cause, injury, or disease. Thus, some beneficiaries experiencing temporary disability may need mobility assistance on a short-term basis, while in contrast, those living with chronic conditions or enduring disabilities will require mobility assistance on a permanent basis.

Medicare beneficiaries who depend upon mobility assistance are found in varied living situations. Some may live alone and independently while others may live with a caregiver or in a custodial care facility. The beneficiary's environment is relevant to the determination of the appropriate form of mobility assistance that should be employed. For many patients, a device of some sort is compensation for the mobility deficit. Many beneficiaries experience co-morbid conditions that can impact their ability to safely utilize MAE independently or to successfully regain independent function even with mobility assistance.

The functional limitation as experienced by a beneficiary depends on the beneficiary's physical and psychological function, the availability of other support, and the beneficiary's living environment. A few examples include muscular spasticity, cognitive deficits, the availability of a caregiver, and the physical layout, surfaces, and obstacles that exist in the beneficiary's living environment.

B. Nationally Covered Indications

Effective May 5, 2005, CMS finds that the evidence is adequate to determine that MAE is reasonable and necessary for beneficiaries who have a personal mobility deficit sufficient to impair their participation in mobility-related activities of daily living (MRADLs) such as toileting, feeding, dressing, grooming, and bathing in customary locations within the home. Determination of the presence of a mobility deficit will be made by an algorithmic process, Clinical Criteria for MAE Coverage, to provide the appropriate MAE to correct the mobility deficit.

Clinical Criteria for MAE Coverage

The beneficiary, the beneficiary's family or other caregiver, or a clinician, will usually initiate the discussion and consideration of MAE use. Sequential consideration of the questions below provides clinical guidance for the coverage of equipment of appropriate type and complexity to restore the beneficiary's ability to participate in MRADLs such as toileting, feeding, dressing, grooming, and bathing in customary locations in the home. These questions correspond to the numbered decision points on the accompanying flow chart. In individual cases where the beneficiary's condition clearly and unambiguously precludes the reasonable use of a device, it is not necessary to undertake a trial of that device for that beneficiary.

1. Does the beneficiary have a mobility limitation that significantly impairs his/her ability to participate in one or more MRADLs in the home? A mobility limitation is one that:
 - a. Prevents the beneficiary from accomplishing the MRADLs entirely, or,
 - b. Places the beneficiary at reasonably determined heightened risk of morbidity or mortality secondary to the attempts to participate in MRADLs, or,
 - c. Prevents the beneficiary from completing the MRADLs within a reasonable time frame.

2. Are there other conditions that limit the beneficiary's ability to participate in MRADLs at home?
 - a. Some examples are significant impairment of cognition or judgment and/or vision.
 - b. For these beneficiaries, the provision of MAE might not enable them to participate in MRADLs if the comorbidity prevents effective use of the wheelchair or reasonable completion of the tasks even with MAE.

3. If these other limitations exist, can they be ameliorated or compensated sufficiently such that the additional provision of MAE, **features or accessories** will be reasonably expected to significantly improve the beneficiary's ability to perform or obtain assistance to participate in MRADLs in the home?
 - a. A caregiver, for example a family member, may be compensatory, if consistently available in the beneficiary's home and willing and able to safely operate and transfer the beneficiary to and from the wheelchair and to transport the beneficiary using the wheelchair. The caregiver's need to use a wheelchair to assist the beneficiary in the MRADLs is to be considered in this determination.

b. If the amelioration or compensation requires the beneficiary's compliance with treatment, for example medications or therapy, substantive non-compliance, whether willing or involuntary, can be grounds for denial of MAE coverage if it results in the beneficiary continuing to have a significant limitation. It may be determined that partial compliance results in adequate amelioration or compensation for the appropriate use of MAE.

4. Does the beneficiary or caregiver demonstrate the capability and the willingness to consistently operate the MAE safely?

a. Safety considerations include personal risk to the beneficiary as well as risk to others. The determination of safety may need to occur several times during the process as the consideration focuses on a specific device.

b. A history of unsafe behavior in other venues may be considered.

5. Can the functional mobility deficit be sufficiently resolved by the prescription of a cane or walker?

a. The cane or walker should be appropriately fitted to the beneficiary for this evaluation.

b. Assess the beneficiary's ability to safely use a cane or walker.

6. Does the beneficiary's typical environment support the use of wheelchairs including scooters/power-operated vehicles (POVs)?

a. Determine whether the beneficiary's environment will support the use of these types of MAE.

b. Keep in mind such factors as physical layout, surfaces, and obstacles, which may render MAE unusable in the beneficiary's home.

7. Does the beneficiary have sufficient upper extremity function to propel a manual wheelchair in the home to participate in MRADLs during a typical day? The manual wheelchair should be optimally configured (seating options, wheelbase, device weight, and other appropriate accessories) for this determination.

a. Limitations of strength, endurance, range of motion, coordination, and absence or deformity in one or both upper extremities are relevant.

b. A beneficiary with sufficient upper extremity function may qualify for a manual wheelchair. The appropriate type of manual wheelchair, i.e. light weight, etc., should be determined based on the beneficiary's physical characteristics and anticipated intensity of use.

c. The beneficiary's home should provide adequate access, maneuvering space and

surfaces for the operation of a manual wheelchair.

- d. Assess the beneficiary's ability to safely use a manual wheelchair.

NOTE: If the beneficiary is unable to self-propel a manual wheelchair, and if there is a caregiver who is available, willing, and able to provide assistance, a manual wheelchair may be appropriate.

8. Does the beneficiary have sufficient strength and postural stability to operate a POV/scooter?

- a. A POV is a 3- or 4-wheeled device with tiller steering and limited seat modification capabilities. The beneficiary must be able to maintain stability and position for adequate operation.

- b. The beneficiary's home should provide adequate access, maneuvering space and surfaces for the operation of a POV.

- c. Assess the beneficiary's ability to safely use a POV/scooter.

9. Are the additional features **or accessories** provided by a power wheelchair needed to allow the beneficiary to **perform or** participate in one or more MRADLs?

- a. The pertinent features of a power wheelchair compared to a POV are typically control by a joystick or alternative input device, lower seat height for slide transfers, and the ability to accommodate a variety of seating needs.

- b. **Assess the beneficiary's vertical environment (i.e., the need for a power seat elevation system or a power standing system) to allow the beneficiary to perform or obtain assistance to participate in MRADLs in the home.**

- c. The type of wheelchair and options provided should be appropriate for the degree of the beneficiary's functional impairments.

- d. The beneficiary's home should provide adequate access, maneuvering space and surfaces for the operation of a power wheelchair.

- e. Assess the beneficiary's ability to safely use a power wheelchair.

NOTE: If the beneficiary is unable to use a power wheelchair, and if there is a caregiver who is available, willing, and able to provide assistance, a manual wheelchair is appropriate. A caregiver's inability to operate a manual wheelchair can be considered in covering a power wheelchair so that the caregiver can assist the beneficiary.

[Flow chart]

C. Nationally Non-Covered Indications

Medicare beneficiaries not meeting the clinical criteria for prescribing MAE as outlined above, and as documented by the beneficiary's physician, would not be eligible for Medicare coverage of the MAE.

D. Other

All other durable medical equipment (DME) not meeting the definition of MAE as described in this instruction will continue to be covered, or noncovered, as is currently described in the NCD Manual, in Section 280, Medical and Surgical Supplies. Also, all other sections not altered here and the corresponding policies regarding MAEs which have not been discussed here remain unchanged.

Appendix C:
**Suggested Draft Local Coverage Determination for Medicare Coverage of Power Seat
Elevation and Power Standing Systems in Group 3 Power Wheelchairs**

Once the Centers for Medicare and Medicaid Services grants the ITEM Coalition's request to modify the National Coverage Determination for Mobility Assistance Equipment (NCD for MAE) to include coverage of seat elevation and standing systems in Group 3 power wheelchairs, the following verbiage should be added to the Local Coverage Determination on Wheelchair Options and Accessories (L33792) after the section on "Power Tilt and/or Recline Systems," in order to effectuate the revised NCD for MAE:

POWER SEAT ELEVATION SYSTEM (E2300):

A power seat elevation system used in conjunction with a Group 3 PWC will be covered if criterion 1, 2, and 3 are met and if criterion 4, 5 or 6 is met:

1. The beneficiary meets the coverage criteria for a Group 3 PWC described in the Power Mobility Devices ("PMD") LCD; and
2. A specialty evaluation that was performed by a licensed/certified medical professional, such as a physical therapist ("PT"), occupational therapist ("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 Assistive Technology Professional ("ATP") who specializes in wheelchairs and who has direct, in-person involvement in the wheelchair selection for the beneficiary.
4. The beneficiary does not have the ability to transfer independently from a static seat height, but by adjusting the seat height the beneficiary is able to:
 - transfer in a standing or supported standing position; or
 - transfer across otherwise unequal seat heights; or
5. The beneficiary is at high risk for repetitive strain injury or has limited range of reach of the upper extremities, which prohibits performance of or participation in MRADLs from a static seat height due to limited upper extremity strength, limited upper extremity active range of motion, deformity, or short stature; or
6. The beneficiary has limitations in vision, in neck range of motion, in neck strength, and/or presence of motor control impairments and/or posture induced

neck reflex activity that prohibits performance of or participation in MRADLs from a static seat height.

POWER STANDING (E2301):

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

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 muscle 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

**Appendix D:
List of Participating Individuals, Organizations, and Subgroup Membership of the ITEM
Coalition on this Initiative**

ITEM Coalition Steering Committee

Amputee Coalition
Christopher & Dana Reeve Foundation
Spina Bifida Association

The ALS Association
Paralyzed Veterans of America
United Spinal Association

Participants

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Executive Director, Clinician Task Force

Tim Casey
General Counsel & Chief Compliance Officer, Numotion

Don Clayback
Executive Director, National Coalition for Assistive & Rehab Technology

Ronald Connelly, JD
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Dan Fedor
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Seth Johnson
Senior Vice President of Government Affairs, Pride Mobility Products Corp.

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Karen Roy, LCSW
Brand Ambassador, Numotion

Thomas Ryan
President and CEO, American Association for Homecare

Anjali Shah, MD
*Associate Professor, Department of Physical Medicine and Rehabilitation, UT
Southwestern Medical Center*

Reva Singh, JD MA
*Director of Advocacy and Government Affairs, American Academy of Physical Medicine
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President and Chief Executive Officer, United Spinal Association

Doug Westerdahl
Regional Vice President, Numotion

Jay Witter
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Subgroup Membership

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Alexandra Bennewith (Co-Chair)
Leela Baggett
Don Clayback
Amy Cunniffe
John Goetz
Seth Johnson
Jim Mead
Joe Nahra
Karen Roy
Peter Thomas
Jay Witter

Clinical/Coverage Analysis Group

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Cara Masselink (Co-Chair)
Leela Baggett
Lorri Bernhardt
Don Clayback
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Rita Stanley
Jim Stephenson
Jeremy Stone
Peter Thomas
Todd Walling
Alexis Ward

**Appendix E:
Evidence-Based Articles that Comprise the Bibliography**