



August 12, 2019

**SUBMITTED ELECTRONICALLY VIA [www.regulations.gov](http://www.regulations.gov)**

Seema Verma  
Administrator  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244

Re: **CMS-6082-NC; Request for Information: Reducing Administrative Burden to Put Patients over Paperwork**

Dear Administrator Verma:

The undersigned members of the Independence through Enhancement of Medicare and Medicaid (“ITEM”) Coalition appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services’ (“CMS”) request for information (“RFI”) regarding reducing administrative burden through the Patients over Paperwork initiative.

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, hearing and speech impairments, cerebral palsy, visual impairments, spinal cord injuries, brain injury, stroke, spina bifida, myositis, limb loss, Osteogenesis Imperfecta (OI), and other life-altering conditions.

The ITEM Coalition shares CMS’ goal of reducing unnecessary administrative burden for patients and providers, and we appreciate the Centers’ commitment to achieving this goal. We believe that the proposals outlined below will have a significant impact on the ability of health care professionals to spend more time providing truly patient-centered care, especially for individuals with disabilities and other complex needs in need of assistive devices and technologies. We urge CMS to consider adopting these proposals and to continue pursuing policies that decrease regulatory barriers to access and empower providers to maximize their time spent providing care to patients.

## **I. Access to Seat Elevation and Standing Feature in Powered Wheelchairs**

*Durable Medical Equipment Medicare Administrator Contractor (DME MAC) decisions preventing coverage of critical power wheelchair features are a significant barrier to access and contradict national CMS policy. CMS should revisit the contractor's decisions and promulgate a coverage policy that reduces barriers to access.*

Seat elevation and “standing feature” in power wheelchairs are two functions that can be critical to the independent living and wellbeing of Medicare beneficiaries with mobility impairments. However, due to publication of a “policy article” issued by the DME MACs that contradicts CMS policy, these functions are not covered within the durable medical equipment (“DME”) benefit category. This policy unnecessarily restricts access to medically necessary benefits due to red tape determinations and should be revisited in order to better align this policy with national CMS policy on coverage of power wheelchairs.

The seat elevation feature is an accessory to power wheelchairs, embedded in the mobility device itself, that assists an individual to raise and lower him- or herself in the seated position through the use of an electromechanical lift system. This feature is critical in assisting individuals with transfers from a wheelchair to a commode, bed, or other surface, and to allow for independence in the performance of hygiene, grooming, dressing, and other mobility-related activities of daily living (“MRADLs”). The standing feature of a power wheelchair allows an individual to transition from a seated position to a standing position without the need to transfer from the wheelchair, allowing the individual to independently perform MRADLs and offering the individual numerous medical benefits that come with standing.

Performance of MRADLs is the standard for coverage of power wheelchairs and accessories under the national coverage determination (“NCD”) for mobility assistance equipment (“MAE”). Without these features, Medicare beneficiaries have limited options to achieve performance of MRADLs, and beneficiaries may require the assistance of another individual, limiting independent function in the home.

The Medicare DME MACs have taken the position (with no rationale for their conclusion and no citation to medical literature) that these features are non-covered because they are “not primarily medical in nature.”<sup>1</sup> Because this is a Benefit Category Determination (“BCD”) rather than a local coverage determination (“LCD”), the DME MACs have not had to comply with the rigorous clinical evidence standards required for LCDs,<sup>2</sup> nor is there a clear legal pathway available for challenging this decision.

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<sup>1</sup> See, e.g., Local Coverage Article for Wheelchair Options/Accessories – Policy Article A52504, published by CGS Administrators and Noridian Healthcare Solutions (revised Jan. 1, 2018).

<sup>2</sup> Medicare guidance requires that LCDs, which address medical necessity under Section 1862(a), be supported by “the strongest evidence available.” CMS Pub. 100-08, Ch. 13 § 13.7.1.

In addition, CMS has clarified (in HCFA Ruling 96-1) that accessories to wheelchairs and other items of DME that are integral to their function are part of the DME benefit.<sup>3</sup> Both standing feature and seat elevation would clearly meet the HCFA 96-1 standard for a subset of Medicare beneficiaries with mobility impairment. Finally, CMS has issued an NCD<sup>4</sup> allowing coverage for seat lifts for stationary chairs in the home, recognizing that seat lifts can provide a therapeutic benefit for patients with neuromuscular diseases or severe arthritis of the hip and knee who have trouble standing from a seated position. There is no meaningful distinction between coverage of a seat lift in a stationary chair and coverage of seat elevation embedded in a power wheelchair. In addition, the standing feature has even greater therapeutic benefit than a seat lift because standing helps to improve cardio-metabolic health, bone density, and other physiologic systems in non-ambulatory individuals.

The position taken by the DME MACs that seat elevation and standing feature do not primarily serve a medical purpose is inconsistent with CMS policy as articulated in Ruling 96-1 and the NCD on MAE. Although contractors have some latitude to develop policy, they must follow NCDs and other aspects of Medicare law, and may not take a position contrary to national CMS policy.<sup>5</sup> This regulatory confusion not only presents a burden for patients who are refused access to this critical benefit, but to providers who must advocate for coverage for their patients and treat additional secondary conditions that may develop that could be avoided with the use of these features (i.e., falls, skin ulcers, diminished bone density, etc.)

***The ITEM Coalition recommends that CMS use its administrative authority to revise its policies relating to Medicare coverage of seat elevation and standing feature for power wheelchair users.*** The current benefit category determination is inconsistent with national Medicare coverage policy and represents an example of red tape (instituted not by CMS staff, but by regional contractors) causing an unnecessary barrier to necessary care for non-ambulatory Medicare beneficiaries. In order to better align contradictory regulations and serve Medicare beneficiaries, CMS should reconsider the existing BCD that prevents coverage of seat elevation and standing feature in power wheelchairs, clarify that these features are, in fact, “primarily medical in nature” and therefore considered DME, and develop a coverage policy that will allow beneficiaries to appropriately access these features when reasonable and necessary.

## **II. Access to Titanium Wheelchairs**

*A regulatory change by the administrative contractors overseeing durable medical equipment policy has eliminated beneficiary access to titanium manual wheelchairs. Titanium wheelchairs are lighter, stronger, and preferred by patients compared to other manual wheelchair materials, but they entail an incremental cost. CMS should revise this administrative determination to increase patient access to medically necessary and appropriate titanium manual wheelchairs.*

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<sup>3</sup> The HCFA ruling reads, in part, “To the extent that a wheelchair seating system or other equipment may or may not function properly or 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.”

<sup>4</sup> NCD 280.4 (effective May 1, 1989).

<sup>5</sup> CMS Pub. 100-08 § 13.1.1.

Titanium manual wheelchairs are extremely strong and lightweight, and are appropriate for a subset of Medicare beneficiaries with long term mobility impairments. Such devices allow beneficiaries improved mobility and decreased risk of secondary injury to the upper body as a result of long term wheelchair use. Beneficiaries with a history of certain upper-extremity issues including pain or dysfunction can benefit from the use of a lighter wheelchair frame, and titanium chairs often provide significant improvement in an individual's ability to perform MRADLs. Titanium chairs are especially necessary and appropriate for those with conditions such as compromised cardiopulmonary systems, upper-extremity weaknesses, decreases in upper-extremity range of motion, decreased endurance for propulsion, spasticity, and orthopedic conditions.

In 2016, the four DME MACs issued a joint publication<sup>6</sup> that no longer allows suppliers to bill separate codes or use an advanced beneficiary notice of noncoverage (ABN) to provide patients with titanium or titanium-alloy wheelchairs. The publication announced that all manual wheelchair codes, including the ultra-lightweight manual wheelchair code (K0005 – Ultralightweight Wheelchair), are inclusive of: (1) all materials (specifically, titanium) and (2) patient weight capacities in excess of 250 pounds. The DME MACs claim that a recent review of the K0108 (Wheelchair Component or Accessory, not Otherwise Specified) HCPCS code identified increased billing for titanium components in wheelchairs. The DME MACs stated in their joint publication that the HCPCS codes for manual wheelchairs, including the K0005 code, cover titanium wheelchairs, and that suppliers may no longer additionally charge CMS using the K0108 code to account for the cost of titanium materials used in the wheelchair.

As a result of this regulatory modification, Medicare beneficiaries cannot obtain access to lightweight, titanium wheelchairs because the added expense to suppliers of the titanium upgrade is not covered by the existing K0005 HCPCS code. Additionally, due to the DME MACs' decision, beneficiaries can no longer even opt to pay out of pocket, utilizing an ABN, to cover the cost of the titanium upgrade. Before the DME MACs changed the regulatory requirements, covering costs with ABNs had been standard practice for suppliers who had their K0108 code claims denied. By changing the coding practices surrounding titanium wheelchairs, CMS has effectively removed beneficiaries' choice to acquire a titanium wheelchair through the Medicare program that better meets their needs.

***The ITEM Coalition recommends that CMS revise the decision by the DME MACs to eliminate the K0108 code and empower patients to access medically necessary and clinically appropriate titanium wheelchairs.*** Such an action would help reinstate beneficiary access to these critical assistive devices, which is currently obstructed by administrative decisions constituting significant regulatory overreach. Failing that, CMS should at least reinstate the ability for beneficiaries to opt to pay out-of-pocket for titanium upgrades using an ABN.

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<sup>6</sup> Manual Wheelchairs Constructed of Titanium – Correct Coding, published by CGS Administrators (December 15, 2016).

### **III. Low Vision Aid Exclusion**

*CMS has currently interpreted the Medicare statute to include an overly narrow reading of the “eyeglass exclusion.” CMS should revisit its restrictive regulation to reduce barriers to access for assistive vision technology.*

Individuals with low vision and other vision-related impairments (more than 7 million Americans according to the 2017 Annual Disability Status Report<sup>7</sup>) face significant obstacles in carrying out activities of daily living (“ADLs”). Literature also suggests significant association between visual impairment and a variety of physical and mental comorbidities, including depression, social isolation, incidence of falls, and dementia.<sup>8,9</sup> Various forms of assistive devices exist, such as hand-held magnifiers, video monitors, and other technologies that utilize lenses to enhance vision. These tools are often essential for individuals with visual impairments, and can allow these individuals to perform essential daily tasks that impact their health and degree of independent living such as reading prescription labels, physician reports, lab test results, mail, financial documents, and other important materials.

In 2008, CMS promulgated a regulation, referred to as the Low Vision Aid Exclusion, which preemptively and unnecessarily excluded all devices “irrespective of their size, form, or technological features that use one or more lenses to aid vision or provide magnification of images for impaired vision”<sup>10</sup> from Medicare coverage under the statutory eyeglass exclusion. CMS has stated its position that eyeglasses and low vision aids are the same in that they both use lenses to aid poor vision or provide magnification of images for impaired vision.

This unnecessarily restrictive reading of the statutory exclusion has resulted in the continuous denial of coverage of these essential assistive devices for beneficiaries with visual impairments and low vision. The narrow interpretation forces beneficiaries to self-fund such low vision aids, or for those without the means to do so, forces them to forego access to these devices which can impede their ability to perform ADLs and live an independent life.

***The ITEM Coalition recommends that CMS revisit its decision to define the eyeglass exclusion so expansively and provide regulatory relief so that individuals with visual impairments may have reasonable access to devices and technologies that enhance low vision for purposes of performing activities of daily living and avoiding secondary complications such as falls, depression, and social isolation.***

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<sup>7</sup> Erickson, W., Lee, C., & von Schrader, S. (2019). 2017 Disability Status Report: United States. Ithaca, NY: Cornell University Yang-Tan Institute on Employment and Disability (YTI).

<sup>8</sup> See, e.g., Court H., McLean G., et al. (2014). Visual Impairment is Associated with Physical and Mental Comorbidities in Older Adults: a Cross-Sectional Study. *BMC Med.* 12:181. Doi: 10.1186/s12916-014-0181-7.

<sup>9</sup> Wood, J., Lacherez, P. et al. (2011) Risk of Falls, Injurious Falls, and Other Injuries Resulting from Visual Impairment among Older Adults with Age-Related Macular Degeneration. *Investigative Ophthalmology & Visual Science* 52 (5088-5092). Doi: 10.1167/iops.10-6644.

<sup>10</sup> Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; and Payment for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); Final Rule, 73 Fed. Reg. 224, p. 69909-69910 (Nov. 19, 2008).

#### **IV. Access to Disposable Negative Pressure Wound Therapy**

*Onerous Medicare billing requirements imposed on home health agencies currently curtail patient access to disposable negative pressure wound therapy. CMS should implement alternative requirements that reduce the burden on providers and remove obstacles to providing this important therapy to Medicare beneficiaries with serious and intractable wounds.*

For Medicare beneficiaries with mobility impairments who are susceptible to serious skin breakdowns and decubitus ulcers, there is significant value in the use of negative pressure wound therapy (NPWT). This is particularly important for individuals with paralysis and other conditions that limit mobility and ambulation. NPWT was traditionally reimbursed as durable medical equipment (“DME”) until CMS imposed a 3-year useful life on durable medical equipment. This threatened to eliminate coverage of the *disposable* version of this therapy (“dNPWT”) until Congress intervened. In 2015, Congress created a statutory benefit to reimburse home health agencies for dNPWT as a separate benefit, rather than being included in the home health episodic payment rate. Regulations governing the billing requirements for home health agencies utilizing dNPWT were established in the CY 2017 Home Health Prospective Payment System final rule.<sup>11</sup>

Disposable negative pressure wound therapy provides a cost-effective, convenient, and patient-centered alternative to traditional negative pressure wound therapy. Since the introduction of this benefit, dNPWT remains underutilized by Medicare beneficiaries in the home setting due to burdensome billing requirements imposed by CMS on home health agencies. Specifically, CMS requires home health agencies to bill for dNPWT using non-standard forms with which home health agencies have no prior experience. This creates confusion that often prompts home health agencies to simply not utilize this valuable treatment. In addition, CMS will not allow a home health visit to be reimbursed under the prospective payment system if the visit is solely for the purpose of providing dNPWT, and not other needed home health services. The effect of these regulations is to decrease availability of dNPWT for patients who could benefit from its use, and to create additional barriers to access for the treatment.

Given our prior correspondence on the issue, we were disappointed that CMS did not propose any provisions in the CY 2020 Home Health Prospective Payment System rule to address the ongoing implementation challenges with the dNPWT benefit for Medicare patients.

***The ITEM Coalition recommends that CMS develop and implement alternative billing methods that will remove barriers to patient access like those outlined above.*** Such alternative methods could include permitting home health agencies to use the standard home health form when billing for dNPWT, and allowing a home health visit exclusively for the purpose of furnishing dNPWT to be appropriately billed under the home health prospective payment system. Reducing the burden of these billing regulations will allow patients greater access to cost-effective dNPWT, fulfill the intent of Congress and CMS in instituting the separate

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<sup>11</sup> Medicare and Medicaid Programs; CY 2017 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; and Home health Quality Reporting Requirements, 81 Fed. Reg. 76,702 (Nov. 3, 2016).

reimbursement policy, and remove the related disincentive for physicians and medical technology manufacturers to innovate in the area of disposable technologies.

## **V. Access to Cochlear Implants in Medicaid**

*State Medicaid programs have complicated and often inconsistent policies governing coverage of cochlear implants. CMS should prioritize simplified and transparent coverage policies on cochlear implantation when reviewing state plan amendments and waiver requests.*

The Early and Period Screening, Diagnosis, and Treatment (“EPSDT”) program requires states to cover conditions that impact a child’s growth and development under Medicaid. Pediatric hearing loss falls under this category, and therefore cochlear implants (“CI”) for children are covered by Medicaid in all 50 states. Additionally, approximately 60% of states cover CI for adults as well.

However, significant barriers exist in state Medicaid programs across the country that limit access to CI and related services. Survey data<sup>12</sup> found that one of the top concerns for access to CI is the impact of burdensome state regulations that restrict the availability of CI. While some states employ reasonable usable lifetime requirements for CI devices and cover upgrades at regular intervals, other states utilize restrictive policies such as battery limits, onerous paperwork and documentation requirements, limitations on related services such as speech language pathology services, difficult outcome demonstration demands, and preapproval specifications that diminish access to cochlear implants and related devices and services. While the specifics of regulation in state Medicaid programs are left to the determination of the state agencies, CMS has the authority to oversee state programs through the review of state plan amendments and waiver applications.

***The ITEM Coalition recommends that CMS prioritize limiting regulatory burden as it relates to CI access when examining proposed changes to state Medicaid coverage and payment policies.*** Reducing unnecessary regulatory burden in Medicaid will allow greater access to much-needed CI and related hearing technology and reduce demands on provider time as they attempt to help patients navigate bureaucratic and time-consuming authorization processes and regulatory requirements.

## **VI. DMEPOS Proposed Rule 2020 Changes**

*CMS’ 2020 proposed rule regulating durable medical equipment, prosthetics, orthotics, and supplies (“DMEPOS”) (published on August 6, 2019 in the Federal Register) would dramatically expand the Master List of prosthetic and orthotic L-codes eligible for onerous requirements including prior authorization. The rule would also significantly expand CMS’ use of gap-filling to set fee schedule amounts for new DMEPOS items in a manner that may inappropriately depress reimbursement levels and stifle innovation and technology development. We urge CMS not to finalize the rule as proposed, as the expanded scope of this proposed regulation runs counter to CMS’ goal of reducing unnecessary burden on patients and providers.*

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<sup>12</sup> Sorkin, DL. (2019). Impact of Medicaid on Cochlear Implant Access. *Otology and Neurotology*, 40(3), e336-e341. doi: 10.1097/MAO.0000000000002142

On July 29, 2019, CMS initially released the proposed rule containing updates to the DMEPOS regulations. The rule includes various proposals to change the regulation of DMEPOS items, specifically expanding the eligibility of items for new burdensome requirements. Additionally, the rule would expand the use of gap-filling to set fee schedule amounts for new items in the market.

Since 2012, CMS has required various categories of DMEPOS items to include face-to-face encounters with practitioners and written prescriptions before furnishing the items to beneficiaries. Additionally, certain DMEPOS items are eligible to be made subject to prior authorization requirements, currently listed on a “Master List of Items Frequently Subject to Unnecessary Utilization.” Many of the items eligible for prior authorization have not had the requirement imposed on the items by CMS at this time.

The proposed rule would adopt a new, singular “Master List” of DMEPOS potentially subject to prior authorization and/or the face-to-face encounter and written order requirement. The expanded Master List is proposed ostensibly to streamline regulation, but would instead dramatically increase the number of DMEPOS items potentially eligible for these requirements. CMS admits that more than 300 new items, including 145 orthotic and prosthetic (“O&P”) L-codes and 75 DME E- and K-codes, would be added to the proposed Master List that are not currently eligible for prior authorization. CMS provides little evidence to support this far-reaching expansion of prior authorization eligibility. In addition, such a Master List suggests that in future years, CMS may work to extend face-to-face encounter requirements to O&P items, even though there is no reason to do so currently.

***The ITEM Coalition strongly recommends that CMS refrain from finalizing the DMEPOS rule as proposed.*** The goal of the Patients over Paperwork initiative is to reduce unnecessary regulatory burden and allow providers to spend more time caring for patients. This unwarranted expansion of regulatory oversight in the DMEPOS Medicare benefit not only runs counter to this goal, but threatens to restrict access to DMEPOS items in the name of streamlining rules. There is no need to create a unified Master List that may extend regulatory burden to the hundreds of items proposed to be added to the Master List.

The FY 2020 proposed rule also includes significant changes to CMS’ use of “gap-filling,” the process by which fee schedule amounts are set for new technology. The proposed rule includes a provision that would allow CMS to perform the gap-filling process a second time if prices drop after an item is introduced into the market. Specifically, if the supplier or commercial prices used in the first round of gap-filling decrease *by any amount* below 15 percent at any time within 5 years of establishing the initial fee schedule amounts, CMS could conduct a second round of gap-filling. This would empower the agency to reduce prices even when the “inherent reasonableness” process that already exists is not triggered by price changes. The stated rationale for this adjustment is that new, lower prices would likely represent a more stable and competitive market, but the proposed process would likely result in further reduced reimbursement levels for new technologies once they enter the marketplace and destabilize the market for new O&P technologies.

***The ITEM Coalition recommends that CMS refrain from finalizing the proposal to conduct a second round of gap-filling for DMEPOS items, refrain from creating a unified DMEPOS Master List, and dramatically limit the number of codes eligible for prior authorization.***

## **VII. Definition of Orthotics**

*Recent contractor publications have suggested that CMS is considering categorizing powered orthoses as durable medical equipment and reimbursing these new technologies under the DME benefit through a capped rental payment structure. CMS should maintain its longstanding interpretation of the definition of “orthosis” and the accompanying lump sum payment structure for powered orthoses, rather than furnishing a new interpretation that limits access to new technology and deters medical innovation.*

O&P care requires significantly more provider education, training and experience than the provision of durable medical equipment. O&P care is a combination of clinical services that culminate in the provision of an orthosis or prosthesis that is custom-fabricated and fitted to the unique needs of each patient. DME, however, is far-more commodity-based. DME suppliers do not typically provide direct patient care, and are not required to be licensed professionals or to demonstrate clinical competencies.

Despite this, there appears to be a trend in DME MAC publications indicating that certain orthoses that apply power across the joint of a limb fall within the DME benefit category, even if they have been assigned “L” codes, which are traditionally reserved for orthotics and prosthetics and require lump sum payment, as opposed to capped rental payment. An overly restrictive definition of “orthosis” may limit access to orthotic care, stifle innovation, and represents a regulatory overreach that will act as a significant burden to patients and providers.

Through statutory and regulatory definitions, Medicare currently defines orthoses as “leg, arm, back, and neck braces... including replacements if required...”<sup>13</sup> Sub-regulatory guidance further defines orthoses as “rigid and semi-rigid devices which are for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body.”<sup>14</sup>

In 2016, a DME MAC publication concerning the coding of powered lower limb exoskeletons “principally provided for supervised use in rehabilitation settings” determined that, for Medicare coding purposes, “brace-like products that exert a powered force across a joint are not coded as orthoses with HCPCS ‘L’ codes but rather are coded using other HCPCS codes.”<sup>15</sup> The rationale and legal basis for this policy is unclear, yet the MACs concluded that claims for a powered exoskeleton must be submitted using a non-covered HCPCS code. Another DME MAC publication in 2018 determined that a line of powered orthoses (developed by Myomo, Inc.) falls within the DME benefit category, despite the fact that the orthoses were assigned “L” codes by

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<sup>13</sup> 42 U.S.C. § 1395x(s); 42 C.F.R. § 414.202.

<sup>14</sup> Medicare Benefit Policy Manual, Pub. 100-02, 15 § 130.

<sup>15</sup> Powered Exoskeleton Products – Correct Coding, published by CGS Administrators (May 19, 2016).

CMS.<sup>16</sup> Even more recently, the CMS HCPCS workgroup requested public comment on several questions regarding whether a new orthosis developed by Ottobock—and specifically its “powered” feature—meets the Medicare definition of an orthosis.

CMS seems to be contemplating adoption of a new interpretation of the definition of an orthosis. It appears that CMS may be asserting that an orthosis that *assists* the individual in moving their joint does not technically *support* the diseased limb and, therefore, does not meet the definition of an orthosis. If this is the case, it would constitute a major re-interpretation of the definition of an orthosis with no evidence base or reasonable rationale for this new interpretation. For the record, CMS has routinely interpreted orthoses that assist joints in performing their function as orthoses, valuable precedent that dates back to at least the 1980’s. In 1982, CMS determined that a “wrist, hand, finger orthosis, external powered, electric, custom-fabricated,” was, in fact, an orthosis. It was granted an orthotic L-code (i.e., L-3904) and has since been paid on a lump sum basis.

An overly restrictive interpretation of the definition of orthosis would have significant implications for the coding, coverage, and payment of powered orthoses, and on the beneficiaries that require them. Typically, Medicare pays for DME on a rental basis. Custom-fabricated powered orthoses cannot be rented, by virtue of the fact that they are fabricated to meet the needs of individual patients. If such orthoses were to be categorized as DME, the payment would likely be insufficient, and O&P clinical practices are not organized to bill CMS’s DME contractors on a monthly rental basis. In addition, DME suppliers are not educated and trained to custom fabricate orthoses and would be empowered to bill Medicare for very sophisticated orthoses.

If coverage of powered orthoses were to be restricted in this way, patient access to innovative powered technology would be hindered, infringing on their ability to achieve the best functional outcomes. Orthotic patients could be relegated to being prescribed only existing orthotic technology, despite the fact that advanced technology exists and may produce better outcomes for patients. Lastly, such a restrictive definition would seriously deter medical innovation and research investment in the area of orthotics.

***The ITEM Coalition recommends that CMS refrain from re-interpreting its long-standing interpretation of the definition of “orthosis.”*** CMS should define custom-fabricated powered orthoses as orthoses, not DME, assign powered orthoses HCPCS “L” codes, and reimburse powered orthoses on a lump-sum basis. This would ensure that patients have access to technology that best meets their medical and functional needs and receive clinical care from an orthotic clinician with the appropriate level of education, training, and competency. Implementing a new and restrictive interpretation of the orthotic definition would not only provide a new burden on patients and providers, but would run counter to CMS’ goal of putting the focus on patient-centered care, innovation, and outcomes.

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<sup>16</sup> Correct Coding – MyoPro (Myomo, Inc.) Assist Device – Revised, published by CGS Administrators (Dec. 13, 2018).

We greatly appreciate your attention to the proposals included in our comments. Should you have any further questions, please contact Peter Thomas, ITEM Coalition coordinator, at [Peter.Thomas@PowersLaw.com](mailto:Peter.Thomas@PowersLaw.com) or by phone at 202-466-6550.

Sincerely,

**The Undersigned Members of the ITEM Coalition**

ACCSES  
ALS Association  
American Academy of Physical Medicine & Rehabilitation  
American Association on Health and Disability  
American Cochlear Implant Alliance  
American Congress of Rehabilitation Medicine  
American Medical Rehabilitation Providers Association  
American Occupational Therapy Association  
American Physical Therapy Association  
American Therapeutic Recreation Association  
The Arc of the United States  
Association of Assistive Technology Act Programs  
Caregiver Action Network  
Center for Medicare Advocacy  
Christopher and Dana Reeve Foundation  
Clinician Task Force  
Hearing Loss Association of America  
Institute for Matching Person and Technology  
Lakeshore Foundation  
National Association for the Advancement of Orthotics and Prosthetics  
National Association for the Support of Long Term Care (NASL)  
National Coalition for Assistive and Rehab Technology  
National Multiple Sclerosis Society  
National Registry of Rehabilitation Technology Suppliers  
Paralyzed Veterans of America  
Spina Bifida Association of America  
Unite 2 Fight Paralysis  
United Spinal Association