September 25, 2019

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
US Department of Health and Human Services
Attn: CMS–1713–P
200 Independence Ave., SW
Washington, DC 20201

RE: Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics and Supplies Fee Schedule Amounts, DMEPOS Competitive Bidding Proposed Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements [CMS-1713-P]

Dear Administrator Verma:

On behalf of our more than 100,000 member physical therapists, physical therapist assistants, and students of physical therapy, the American Physical Therapy Association (APTA) appreciates the opportunity to comment on the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, DMEPOS Competitive Bidding (CBP) Proposed Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements proposed rule. The mission of APTA is to build a community to advance the physical therapy profession to improve the health of society. Physical therapists play a unique role in society in prevention, wellness, fitness, health promotion, and management of disease and disability by serving as a dynamic bridge between health and health services delivery for individuals across the age span. While physical therapists are experts in rehabilitation and habilitation, they also have the expertise and the opportunity to help individuals improve overall health and prevent the need for avoidable health care services. Physical therapists’ roles may include education, direct intervention, research, advocacy, and collaborative consultation. These roles are essential to the profession’s vision of transforming society by optimizing movement to improve the human experience.

In the following comments, we provide details to support our overarching concern related to this proposed rule, which is the impact it will unquestionably have on beneficiaries’ abilities to
access appropriate DME technology and services if finalized and implemented as written. We acknowledge the inadequacy of current gap-filling methodologies and the importance of establishing valid and reliable methods for establishing payment for new items. Our comments largely mirror those of the Clinician Task Force.

Overview

Complex rehabilitation technology (CRT) products, a subset of DME products, are defined as medically necessary, individually configured devices that require evaluation, configuration, fitting, adjustment, or programming. Examples of CRT relevant to the proposed rule include individually configured manual and power wheelchair systems, adaptive seating systems, and other “critical components” that CMS refers to as “wheelchair accessories.”

Physical therapists recommend DME and CRT systems based on a complete evaluation of each person, their routine activities, environment, and roles and responsibilities, with the goal of maintaining or improving their health, function, independence, and access to their community. Once delivered, these items need to be supported with ongoing access to repair, maintenance, and adjustment by Medicare-qualified suppliers. Access to appropriate DMEPOS products and technology-related services for initial provision and ongoing service and support is paramount for beneficiary safety, function, and health outcomes.

CRT products and services are used by individuals with a primary diagnosis resulting from a congenital disorder, progressive or degenerative neuromuscular disease, or certain types of injuries or trauma. As CRT is currently coupled with the more general DME benefit, beneficiaries requiring CRT are facing serious challenges trying to access appropriate technologies and services, many of whom who obtain necessary technology only by paying for it themselves. We are concerned that provisions in the proposed rule will magnify the access issues this population faces.

Please find below our detailed comments responding to CMS’ proposals. APTA’s comments and recommendations that follow are limited to how concepts and provisions in the proposed rule would impact clinical outcomes and beneficiary access to medically necessary DME and CRT used by aging adults and individuals with disabilities.

Basing a new pricing methodology on an outdated HCPCS coding system is flawed

The proposed rule uses the currently outdated and flawed HCPCS coding system as the foundation for a new and future pricing and payment methodology for DME. Basing a new pricing methodology on an outdated HCPCS coding system is unsound and will continue to systematically limit beneficiary access. It also will greatly deter innovation that would answer currently unmet medical needs for all individuals with disabilities, not solely for those who are enrolled in the Medicare program.

The current HCPCS code set includes broadly defined codes that are often ambiguous and imprecise, resulting in dissimilar products and technologies being lumped into the same code with the same fee schedule reimbursement. The use of codes that are not sufficiently granular to
describe the items and related services being provided leads to improper payments and barriers to access of medically necessary devices and technologies. The current system is not sensitive enough to the range of dissimilar products within one HCPCS code to recognize that the higher-level items with more complex intended uses exceeding the lowest common denominator of the code description are no longer readily accessible.

It is critical for CMS to recognize and factor into a new payment system the difference in costs of components/items (products and services) when provided at initial onset versus when provided as part of a repair or replacement. A provision in a new pricing methodology must include a mechanism to allow for higher reimbursement for replacement parts and related services.

For years, manufacturers and suppliers of CRT have attempted to obtain HCPCS codes that reflect homogeneous technologies. The proposals submitted to CMS have delineated products based on features and functions as well as clinical indicators for use and intended populations. Repeatedly, however, CMS has responded by (1) stating that the current HCPCS code structures are working, and no new code is needed; or (2) adding a descriptor to an existing HCPCS code to include “any type.” The use of “any type” in code descriptors to group several products into a single code (and fee schedule) fails to acknowledge different clinical applications to meet different needs, technology differences, and variations in cost to provide technologies with more complex features and functions. The current system often also fails to recognize the difference between prefabricated and custom-manufactured items.

It also is important to note that, historically, when CMS has added new products to an existing HCPCS code, the agency has not reexamined or adjusted the fee schedule amount, even when more costly products and related services were relegated to a HCPCS code with dissimilar lower-level and lower-cost technologies.

With the recent reduction in payment related to competitive bidding pricing, there are particular technologies that are becoming increasingly difficult to obtain unless clients or their families can buy them, such as CRT manual wheelchair components (accessories). In many cases, users of CRT are dual-eligible beneficiaries. Private pay is not an option for the dual-eligible population, so in instances of inadequate reimbursement, beneficiaries are forced to go without or pay out of pocket. Frequently, beneficiaries are unable to access the full range of products within one HCPCS code. Furthermore, APTA members frequently encounter beneficiaries in the clinic who are no longer able to replace items that they previously received from Medicare due to inadequate payment amounts rendering the item inaccessible.

To summarize, the problems and unintended consequences from the flawed HCPCS system include the following:

- Pricing based on median payments of a range of product complexity and product cost within one HCPCS code does not ensure access to the more complex products within that code.
• A long-held belief by CMS that the use of the median price within a code provides equitable reimbursement overall is totally inaccurate when the range of products within a single code varies significantly. In many cases, the cost of acquiring a product exceeds the published fee schedule amount for the code.

• CMS is unable to adequately distinguish coverage and payment policies for items with different features and functions in the same HCPCS code.

• Medicare and Medicaid have insufficient data and information to accurately monitor true beneficiary access at the product level when items in the same code are not equal in ability to meet the clinical/medical needs of the beneficiary.

APTA recommends that CMS create new HCPCS codes grouping homogeneous products and separating DME and CRT codes:

• CMS should delay a final rule on DME payment methodologies until further work is completed on modernizing the HCPCS coding system. The risk of negatively impacting beneficiary access to critical DME and CRT is high.

• The outdated HCPCS coding system/fee schedule methodologies that group heterogeneous products together must be replaced with a modernized system that groups homogeneous products based on functions, features, clinical indicators, population, and cost; and must separate DME and CRT codes.

• CMS should recognize and factor into a new payment system the difference in the costs of components/items when provided at initial issue versus when provided as part of a repair or replacement. The agency could consider either establishing a replacement fee schedule or a payment modifier that allows for higher reimbursement for replacement parts when there does not exist a separate code for replacement.

• A modernized HCPCS coding system is needed to allow CMS to develop appropriate coverage and payment policies that better match available technology to a beneficiary’s current needs.

• A modernized HCPCS coding system will facilitate improved monitoring of beneficiary access to the full range of available products and enable comparative effectiveness research between HCPCS codes.

• CMS should convene a work group of stakeholders to collaborate on, discuss, and recommend options for modernizing the existing DMEPOS HCPCS system.
• A modernized HCPCS coding system must support the coding needs of all payers to perform the Secretary’s congressionally intended role of developing and maintaining a uniform code set that all payers can use.

**Proposed new methodologies to restructure and modernize the gap-filling process for DMEPOS pricing must ensure beneficiary access and outcomes**

APTA supports the need to develop a new payment methodology for determining payment amounts for new HCPCS codes including those created for new technology. The CMS-proposed methodologies focus primarily on minimizing reimbursement by using a budget-neutral approach linking new payments to older technology.

The gap-filling methodology used to establish fees for new DMEPOS is antiquated, as it is based on a formula that deflates rates to a 1987 base year and includes 10 years of reductions and freezes mandated by Congress. APTA is concerned that the proposed rule appears biased toward cost reduction with no notable provisions focused on improving beneficiary access to a range of high-quality technologies, improving beneficiary outcomes, and decreasing overall costs to the health care system over time. The agency should not be focused merely on the cost of an item but rather on the overall cost for the beneficiary. While it may initially cost the Medicare program more to provide the technology, the overall cost of care for the beneficiary will ultimately decrease due to an improved clinical outcome.

While CMS states it is seeking a level playing field between old and new technologies, the agency is failing to recognize that for technology required for individuals with disabilities, the selection and recommendation is completed by a team that includes the physician and one or more clinicians who have no financial tie to the technology. Technology is recommended based on the product that meets the individual’s identified medical and functional needs. CMS should be focused on ensuring that payment allows adequate access to the recommended technology. Market share should be earned based on product quality, features, and options and services, not based on an artificial level playing field created by a payment methodology.

**APTA recommends that CMS modernize the DMEPOS gap-filling methodology and eliminate the base year requirement:**

• CMS must work with Congress to eliminate or modify the 1987 base year requirement for payment for DMEPOS and explore alternate options. Simply putting a gap-filling methodology that is greater than 30 years old is ineffective and outdated. A serious effort to study and modernize the DMEPOS gap-filling methodology is urgently needed.

• CMS should prioritize in a new payment methodology the goals of (1) ensuring beneficiary access to medically necessary technology, and (2) promoting innovation that improves beneficiary outcomes and reduces overall health care cost.

• We recommend that CMS delay efforts to implement alternative payment methodologies for new DMEPOS. Prior to publishing a final rule, the agency should engage a work
group of DME and CRT stakeholders and experts in developing and evaluating payment methodologies that can achieve the above-stated goals for new technologies.

Cross walking or linking fee schedule amounts for old HCPCS codes to new HCPCS codes to ensure continuity of pricing is an assumption with no basis

CMS is proposing to add a provision to the regulations (at §414.236) that to ensure continuity of pricing if a new HCPCS code is added, CMS or contractors would determine the fee schedule for the new code by linking fee schedule amounts for the old code(s) to the new code(s), known as “cross walking.”

The need to create the new code is due to heterogeneous products, such as CRT and DME, in the same code or due to technology advancement and innovation. Establishing new HCPCS codes that will facilitate appropriate coverage policy by developing payment policies that link fee schedule amounts to old codes is inappropriate. Simply put, the concept of ensuring continuity of pricing by linking a 30-year-old fee schedule to new technologies is uninformed and faulty.

APTA recommends that CMS establish a new pricing methodology for new HCPCS codes that fosters innovation and ensures beneficiary access:

- To directly crosswalk payment, the items should have the same clinical indicators and should be interchangeable.

- A new methodology should be created to establish appropriate reimbursement that promotes innovation to address unmet medical needs and ensures beneficiary access.

A second gap-filling process to further reduce prices is unwarranted

CMS proposes that if the supplier or commercial prices used to establish fee schedule amounts for a new item decrease by any amount below 15% within 5 years of establishing the initial fee schedule amounts, and the amounts calculated using the new prices would be no more than 15% lower than the initial amounts, CMS would conduct a second round of gap-filling. In other words, if the inherent reasonableness (IR) process is not triggered by supplier and commercial prices for a particular item or service, CMS is empowering itself to use a second gap-filling process to reduce prices, as long as the decrease is less than 15%.

APTA recommends that CMS use the current IR process to adjust pricing if necessary—either downward or upward—if the fee schedule level for a particular DMEPOS item or service is found excessive or grossly deficient compared with supplier or commercial prices.

Calculating fee schedule from comparable DMEPOS technology is ill-defined and subject to arbitrary interpretation

CMS has proposed to establish a set framework and basis for identifying comparable items in regulation. In the proposed rule, CMS states, “We believe using the relative cost of new items
versus older items keeps all DMEPOS items (old and new) on a level playing field and priced in
accordance with the historic reasonable charges for DMEPOS in general.” [84 Federal Register
38330, p166]

CMS proposes that if a HCPCS code is new and describes items and services that do not have a
fee schedule price history:

- The fee schedule amounts for the new code would be established whenever possible using
  fees for comparable items with existing fee schedule amounts. The agency proposes that
  items with existing fee schedule amounts are determined to be comparable to the new items
  and services based on a comparison of components (physical, mechanical, electrical);
  function and intended use; and additional attributes and features.

- If no items with existing fee schedule amounts are comparable to the items and services
  under a new code, the fee schedule amounts for the new code would be established using
  supplier or commercial price lists, or technology assessments if supplier or commercial
  price lists are not available or verifiable or do not appear to represent a difference in
  supplier costs of furnishing the new DMEPOS item relative to the supplier costs of
  furnishing DMEPOS items from the fee schedule base period.

APTA is concerned about the impact this proposed policy will have on beneficiaries’ ability to
access new DMEPOS items. Current CMS practices already group many items as “comparable”
in the same HCPCS code, yet they are not “interchangeable,” they vary greatly in acquisition
costs, and they do not have the same intended use. Adding new technologies into current HCPCS
groups has and will continue to adversely affect beneficiaries by limiting access to the full range
of needed interventions if not homogeneously grouped. We are concerned that simply because a
new technology has “same or similar” attributes does not mean the product, its costs, features
and functionalities, and clinical indicators are equivalent to the other product. Our experience is
that beneficiaries are regularly unable to access products that exceed the minimum requirements
of a code. “Comparable” must equate to “interchangeable.”

CMS proposes to use supplier price lists including catalogs, other retail price lists including
internet retail prices, and commercial pricing information from other Medicare and non-
Medicare payer data to establish fee schedule amounts for new technologies. All proposed
sources of pricing data are not equivalent and are generally below MSRP, and some do not
account for services, overhead, and other technology-related service costs beyond product
acquisition. Using payers who historically discount off the Medicare fee schedule to set their
payment rates will only serve to further reduce Medicare payments versus ensuring appropriate
and adequate payment to promote access.

**APTA recommends that CMS only use “comparable” products as a standard to establish
payment if a technology is truly “interchangeable”:**

- Only homogenous products that are “interchangeable,” based on features and function,
  clinical indicators for use, and intended patient populations should be considered
“comparable” for the purpose of grouping multiple items in a specific HCPCS code and for pricing purposes as stated in the proposed framework.

- Transparency in the process is essential. Stakeholders, including manufacturers, suppliers, and clinicians who recommend technology, should be included in determining comparability and interchangeability of new products.

- CMS must be willing to establish new HCPCS codes in order to develop appropriate payment and ensure that Medicare beneficiaries can access the new technologies they require. This is currently a major barrier in Medicare payment today, limiting beneficiary access to new and innovative technologies.

**Comparative effectiveness research, health care outcomes, and impact on beneficiaries will be impossible**

CMS is ill-equipped to effectively evaluate the impact of the proposed rule and make true comparisons of outcomes unless the HCPCS coding system is modernized. The agency will be unable to track at a granular level the impact payment changes have had on beneficiaries, because utilization data is limited to the HCPCS code. It is not sensitive to the range of dissimilar products within the HCPCS code to recognize the higher-level items that exceed the lowest common denominator of the code description.

Until HCPCS codes identify homogeneous items and services, it is impossible to measure actual clinical outcomes data at the code level. CMS’ claim that access issues are not a concern with the current DME fee schedule are incorrect; our members encounter access barriers to DME items on a daily basis due to an inadequate Medicare fee schedule. Such inaccessibility creates insurmountable barriers to comparative effectiveness research and impedes the ability of payers to effectively use claims data to inform improvements to coverage and payment decisions in the future.

**APTA recommends that CMS remove barriers to comparative effectiveness research by modernizing the HCPCS coding system to ensure homogeneous grouping of technologies in each code by:**

- Transforming the HCPCS coding system.

- Removing barriers to comparative effectiveness research for grouping homogeneous technologies in each code, which would allow for meaningful use of claims data for the purposes of informing health care service delivery.

**Innovation and investment in medical technologies will be thwarted**

The United States spends millions of dollars each year on research and development to create technological solutions to solve real-life problems for people with disabilities. Yet even with novel and necessary technology innovation, researchers and manufacturers are mostly unable to bring new products to market due to the barriers previously identified related to HCPCS coding,
coverage, and payment policy. Furthermore, continually declining payment rates have resulted in a contraction in the marketplace; rather than promote the development of new solutions, many products have left the market and others have been replaced with technologies that are less expensive and made with lower-quality materials and componentry to adjust to reduced payment amounts.

The proposed rule links reimbursement of new and emerging technologies to a level equal to technology available 30 years ago. This is a disincentive that does now and will in future negatively impact innovation necessary to improve outcomes to meet beneficiary medical and functional needs.

**APTA recommends that CMS ensure that new payment methodologies facilitate innovation in medical technologies and beneficiary access:**

- CMS must work with Congress to eliminate or modify the 1987 base year requirement for payment for DMEPOS and explore alternate options. Simply put, a gap-filling methodology that is greater than 30 years old is ineffective and outdated. A serious effort to study and modernize the DMEPOS gap-filling methodology is urgently needed.

- CMS should abandon the premise that innovation should be reimbursed at a level equal to technology available 30 years ago, linking new and old technology from a pricing perspective.

- CMS should establish a stakeholder work group to collaborate and discuss alternatives for DMEPOS pricing methodologies and understand all of the associated technology and technology-related service costs.

- CMS should establish new methodologies to restructure and modernize the gap-filling process for developing pricing for DMEPOS.

- CMS should improve monitoring of impact of fee schedule adjustments.

**CMS should establish a separate policy to address the DME Reasonable Useful Lifetime Standard for medically necessary, custom fabricated, low-temperature thermoplastic orthoses provided to Medicare beneficiaries**

APTA recommends that CMS establish a separate policy that addresses the Durable Medical Equipment Reasonable Useful Lifetime Standard for medically necessary, custom fabricated, low-temperature thermoplastic orthoses provided to Medicare beneficiaries.

Physical therapists prescribe, apply, and, as appropriate, fabricate devices and equipment, including orthoses, when the examination findings, diagnosis, and prognosis indicate their use to decrease edema and swelling; enhance health, wellness, and fitness; enhance performance and independence in activities of daily living; enhance or maintain physical performance; increase alignment, mobility, or stability; prevent or remediate impairments, functional limitations, or
disabilities to improve physical function; protect body parts; or reduce risk factors and complications.

Orthoses are used by physical therapists to meet the therapeutic needs of their patients and are easily modified to accommodate postoperative or postinjury volume changes, improvements in tissue length or reduce the level of required protection as healing progresses. The use of custom-fabricated, low-temperature thermoplastic orthoses is integral to the successful management of upper and lower extremity injuries and ailments through the prevention of faulty movement; maintenance of structural alignment; immobilization or protection of repaired, injured, or diseased structures; support of weak or impaired structures; redirection of multi-joint forces; or gradual modification of shortened musculotendinous or connective tissues. Removable orthoses facilitate skin and wound care, allowing for early protected motion. Compliance with orthosis use is significant, especially for individuals who have difficulty tolerating a cast due to climate, skin conditions, cast weight, or claustrophobia. Custom-fabricated orthoses offer many advantages over prefabricated and off-the-shelf supports, especially with respect to accommodating the variations in limb size and shape, fracture alignment, accommodation of percutaneous fixation, and the modification potential. These devices are easily maintained and cleaned.

Orthoses are described through the HCPCS II codes based on the body segments and joints included in the orthosis or the presence or absence of moveable joints, springs, or hinges. However, unlike other DME, such as hospital beds or walkers, the expectation of a 5-year lifespan for many of these custom fabricated orthoses is unreasonable, as it is wholly dependent on the orthosis and how it is used. Although some orthoses to prevent faulty movement secondary to hypermobility or osteoarthritis can provide long-term support, the majority of orthoses are intended to serve as shorter-term supports, with 6 months being most typical.

The 5-year reasonable useful lifetime for upper and lower extremity thermoplastic orthoses presents billing and reimbursement challenges, as orthoses spanning the same joints and therefore coded identically may be required for different episodes of care to achieve a variety of goals. Due to the 5-year policy, providers are required to obtain an Advance Beneficiary Notice for the orthosis in order to bill the beneficiary and obtain payment, should the claim for the orthosis be denied and the appeal be unsuccessful. The result is greater out-of-pocket costs for the beneficiary.

For example, L3808, *wrist hand finger orthosis, rigid without joints, may include soft interface material; straps, custom fabricated, includes fitting and adjustment*, may be required following flexor tendon or nerve repair of the digits. Use of this orthosis is typically based on the dorsum of the affected hand to block movement at specific joints and in specific directions until the repairs are strong. This same patient could subsequently develop carpometacarpal arthritis or a scaphoid fracture, unrelated to the tendon injury, and require an orthosis that immobilizes the wrist and thumb, which also would be coded as L3808. Per Medicare coverage and reimbursement rules, this second orthosis would be denied, forcing the provider to navigate the appeals process in order to receive payment. This not only takes time away from direct patient care, but it also leads to greater personnel costs for the provider, in addition to the uncertainty of
payment for services already provided. In the meantime, the wrist and thumb must be immobilized to ensure fracture healing.

The reasonable useful lifetime of 5 years for low-temperature thermoplastic orthoses is ostensibly mismatched with the purpose of these orthoses. Therefore, pursuant to Social Security Act Section 1834(a)(7)(c), we recommend that CMS establish an alternative reasonable lifetime for low-temperature thermoplastic custom-fabricated orthoses.\(^1\) A more appropriate reasonable useful lifetime will protect access to these services and improve care efficiency. Representatives of APTA would welcome dialogue regarding this issue and the options for establishing a policy addressing durable medical equipment lifetime usefulness more appropriate to low-temperature thermoplastics.

**Master List of DMEPOS Items and Prior Authorization Requirements**

CMS proposes to develop one Master List of DMEPOS items potentially subject to a face-to-face encounter, written orders prior to delivery, and/or prior authorization requirements under the authority provided under sections 1834(a)(1)(E)(iv), 1834(a)(11)(B), and 1834(a)(15) of the Act.\(^2\)

As a general rule, physical therapists are opposed to prior authorization, as they have witnessed its negative effects firsthand. Earlier this year, we surveyed physical therapists to determine their experience with prior authorization, among other things. Our findings are summarized here. Our survey found that more than 80% of front desk staff spent more than 10 minutes to complete a prior authorization for each patient enrolled in a health plan, regardless of payer. We found that current prior-authorization requirements contribute to significant delays in medically necessary care. Nearly three-quarters of respondents agreed or strongly agreed that prior authorization negatively impacts patients’ clinical outcomes.

APTA believes that any workable prior-authorization model should focus on managing outlier cases and recognize a clinician’s ability to render patient-centered care using evidence-based guidelines, clinical judgment and decision-making, and full scope of licensure. This would help ensure streamlined administrative processes and timely patient access to the services patients need.

APTA advises that CMS implement sensible prior authorization reforms, including:

- Developing and incorporating standard language within its contracts, requiring MA plans to use the same standardized request form for prior authorization, which undergoes the information collection comment request process;
- Adopting a required response period for prior authorization and repeat authorization requests;
- Exempting from prior authorization providers who participate in standardized data collection and are willing to share data demonstrating their value;

---

\(^1\) See also Medicare Benefit Policy Manual Chapter 15 Section 110.2.

- Adopting a standard for initial authorization of care, applied universally across MA plans, that allows a specified number of visits upfront for nonsurgical care and a different number for postsurgical care; and
- Requiring plans to use existing data to identify egregious providers for outlier management, thereby reducing burden on those who are historically compliant.

**Conclusion**

APTA thanks CMS for the opportunity to provide comments on the DMEPOS proposed rule. We support the need to establish a new process for calculating payment amounts for DMEPOS items and services including new technologies. We strongly urge CMS to delay a final rule until the multitude of issues with the HCPCS coding system is first addressed.

Should you have any questions, please contact Steve Postal, senior specialist, regulatory affairs, at stevepostal@apta.org or 703/706-3391. Thank you for your consideration.

Sincerely,

Sharon L. Dunn, PT, PhD
Board-Certified Clinical Specialist in Orthopaedic Physical Therapy
President

sld: SP