December 12, 2018

Seema Verma, MPH
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert Humphrey Building
200 Independence Ave, SW
Washington, DC 20201

Submitted electronically

RE: Competitive Bidding Product Categories

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) is writing to thank the Centers for Medicare and Medicaid Services (CMS) for extending the public comment period related to new product categories and codes under consideration for the next round of Medicare durable medical equipment prosthetics orthotics and supplies (DMEPOS) competitive bidding. This extension was necessary to give stakeholders the time they need to provide meaningful input on this extremely important issue. APTA has concerns that the addition of ventilators and off-the-shelf (OTS) back braces and knee braces to the DMEPOS competitive bidding program (CBP) will have a significant impact on the care that physical therapists furnish to patients who have undergone surgery, experienced a serious injury, or suffer from certain degenerative diseases. Competitive bidding often leads to a disruption in care due to an access issue. Consequently, Medicare beneficiaries often forgo medically necessary items or are forced to pay out of pocket, and/or experience adverse health outcomes.

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.

APTA appreciates the opportunity to comment on the new product categories CMS has proposed to include in the next round of DMEPOS competitive bidding and respectfully requests the agency consider our more detailed comments below.

**Ventilators (E0465, E0466, E0467)**

APTA has concerns that CMS’s proposal to include ventilators in the DMEPOS CBP, which are used by highly vulnerable Medicare beneficiaries, will result in significant patient access barriers. Rather than including ventilator devices within the DMEPOS CBP, we recommend that CMS establish more specific coverage criteria for ventilators, to better ensure providers and patients have a better understanding of the Medicare program’s coverage criteria for such items. Currently, the CMS National Coverage Determination Manual (Internet-Only Manual, Publication 100-03), Chapter 1, Part 4, Section 280.1 provides that ventilators are covered for the following conditions: neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease. However, such limited and vague terminology offers little guidance to providers when determining whether a patient satisfies the Medicare program’s coverage criteria for ventilator devices. Therefore, we recommend that CMS consider instructing the Medicare Administrative Contractors to establish a Local Coverage Determination that provides greater clarity to providers and patients on the coverage policy for ventilators.

We also question why CMS is proposing to add ventilators, devices classified in the frequent and substantial servicing payment category, to the DMEPOS CBP, when to date, no other items in the frequent and substantial servicing payment category have been included in the CBP. The frequent and substantial servicing category is comprised of items for which there must be frequent and continual servicing in order to avoid risk to the patient’s health, recognizing the intensive and continual services these items require.

For the aforementioned reasons, APTA strongly recommends CMS not move forward with its proposal to add ventilators to the next round of the DMEPOS CBP.


The Medicare Modernization Act of 2003 established requirements for competitive bidding for certain DMEPOS. While OTS orthotics are included in competitive bidding, Congress defined “off-the-shelf” as requiring minimal self-adjustment. It is apparent by this definition that Congress intended to ensure that Medicare beneficiaries have access to the clinical services necessary to properly fit certain orthoses, even though they are considered OTS, that require significant clinical services to enable beneficiaries to achieve their therapeutic purpose.

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2 42 CFR §414.222.
APTA has concerns that although categorized as OTS products, the OTS back and knee braces proposed for inclusion within the DMEPOS CBP may, in fact, require the customization services of a health care professional such as a physical therapist to ensure functionality and support for the beneficiary. Therefore, APTA recommends that CMS closely assess the OTS products proposed to be included within the DMEPOS CBP and limit the addition of products to solely OTS orthotics that do not require the clinical services or customization that physical therapists and other health care professionals provide. To ensure that beneficiary access is not hampered by the CBP, it is critical that only those orthotics that can be safely used by the beneficiary and require only minimal self-adjustment be included in the DMEPOS CBP.

**Conclusion**

CMS is in the process of implementing reforms to the DMEPOS CBP, including changing the bidding methodology to lead item pricing. Therefore, to minimize the complexities and burdens associated with these changes, we recommend CMS not introduce new product categories to the DMEPOS CBP during this period. APTA thanks CMS for the opportunity to comment on the new product categories proposed to be phased-in for the next round of the DMEPOS CBP. Should you have any questions regarding our comments, please contact Kara Gainer, director of regulatory affairs, at karagainer@apta.org or 703/706-8547. Thank you for your consideration.

Sincerely,

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

SLD: krg