



September 27, 2019

SUBMITTED ELECTRONICALLY VIA www.regulations.gov

Ms. Seema Verma, MPH
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1691-P
P.O. Box 8010
Baltimore, MD 21244-1850

**RE: Public Comments from the ITEM Coalition on the Durable Medical Equipment
Prosthetics, Orthotics and Supplies CY 2020 Proposed Rule (CMS-1713-P);
(RIN 0938-AT70)**

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’s”) proposed rule on durable medical equipment, prosthetics, orthotics, and supplies (“DMEPOS”) for calendar year 2020 (the “Proposed Rule”).¹ 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.

We have confined our comments to CMS’s proposed pricing methodologies when splitting, consolidating and assigning new Level II billing codes under the Healthcare Common Procedure Coding System (“HCPCS”), as well as proposed changes to the Master List for HCPCS codes eligible for prior authorization.

¹ Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, 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, 84 Fed. Reg. 38,330 (Aug. 6, 2019).

The ITEM Coalition urges CMS to adopt Medicare coding, coverage, and reimbursement policies that ensure continued access to and choice of quality care for those needing durable medical equipment (“DME”), related services, as well as orthotic braces and prosthetic limbs. We are concerned that this Proposed Rule has the potential to hinder patients’ ability to receive safe, appropriate, and cutting-edge DMEPOS items and services.

I. Proposed Pricing Methodology for Split, Combined, or New HCPCS Codes

A. Summary of Proposed Rule

Medicare fee schedule amounts for DMEPOS items and services are based on average “reasonable charges” from a historic base period (*i.e.*, 1986-’87), increased by annual update factors (*i.e.*, the Consumer Price Index for Urban Consumers (“CPI-U”)) and adjusted by a productivity adjustment factor. When base reasonable charge data does not exist, CMS uses a process referred to as “gap-filling” to fill the gap in the reasonable charge data for the base year in order to estimate what Medicare would have paid for the DMEPOS item at that time.

CMS is proposing to add a provision to the regulations that addresses the continuity of pricing when items are re-designated from one HCPCS code to another. CMS is proposing that if a new code is added, CMS or its contractors would determine whether the item is comparable to an already-existing code. In other words, CMS would determine whether the new HCPCS code has a fee schedule pricing history. If such a history exists, the previous fee schedule amounts for the old code(s) would be associated with, or “cross-walked” to, the new code(s), to ensure continuity of pricing through comparability.

CMS is proposing to clarify how CMS determines which items and services are comparable for the purpose of the gap-filling pricing methodology. CMS proposes to establish a set framework and basis for identifying comparable items and identifies five main categories upon which new DMEPOS items can be compared to older DMEPOS items. The categories include: (1) Physical components; (2) mechanical components; (3) electrical components (if applicable); (4) function and intended use; and (5) additional attributes and features.

This evaluation will be applied to new DMEPOS items without a pricing history. As already noted, if the new item is comparable to older existing item(s), CMS proposes to use the fee schedule amounts for the older existing item(s) to establish the fee schedule amounts for the new item. If there are no comparable items to use for gap-filling purposes, the fee schedule amounts for a new item would be based on other sources of commercial pricing data to establish Medicare payments, such as internet retail prices or information from supplier invoices.

The commercial prices would then be deflated to the fee schedule base period and updated by the covered item annual inflation factors. This is a process that results in a decrease in reimbursement because Congress withheld fee schedule annual updates in some years, which means that the reimbursement level CMS starts this analysis with will always be higher than the reimbursement level once it is deflated back to 1986-’87 and then re-inflated through the annual updates granted by Congress. Finally, when commercial pricing data is not available, unverifiable, or insufficient to determine fee schedule amounts, CMS proposes to utilize

technology assessments analyzing samples of the product(s), as well as older items to determine relative supplier costs of furnishing the item.

CMS notes that the proposed gap-filling method may result in excessively high fee schedule amounts when a competitive market for a given new item has not yet developed. Accordingly, CMS proposes that it perform a one-time adjustment by conducting gap-filling a second time if prices drop notably within the first 5 years on the market, but not greater than 15 percent. If a price for a code drops more than 15 percent, CMS has authority to use the regulatory process known as “inherent reasonableness” to reduce prices.

B. ITEM Coalition Comments

Although multiple areas of medical care continue to make great strides—and Medicare routinely finds ways to cover and reimburse even the most expensive drugs, procedures and technologies—advances in the field of DMEPOS have slowed to a crawl. Innovators are designing new technologies to fit existing HCPCS coding descriptors—instead of thinking more creatively—so they can avoid the unpredictable HCPCS coding, coverage and payment process. If DMEPOS innovators are unable to forecast and realize a reasonable return on investment, they will simply move to other areas of health care or unrelated areas to apply their talents. This would have a profound impact on access, quality, and choice of DMEPOS items and services for Medicare beneficiaries. We urge CMS to implement policies encouraging, not stifling, medical innovation in the area of DMEPOS.

1. Splitting/Combining Codes Should be Dictated by Patient Access to Care

As a general matter, the ITEM Coalition believes that instances of HCPCS codes being consolidated into one code or split into multiple codes should be rare. Before reasonable pricing methodology or gap-filling becomes an issue, the CMS HCPCS Workgroup renders a decision as to whether a new technology performs a significantly different function, operates differently, and provides a significant therapeutic distinction compared to existing coded treatments or products. It has come to our attention that new technologies that arguably meet the standard for a new HCPCS code are often being forced to fit into existing HCPCS codes, or being assigned codes that are slightly revised to broaden their scope to encompass the new technology at issue (*e.g.*, [code description], *any type*). In the vast majority of instances, this results in insufficient reimbursement levels that do not appropriately recognize advancements in technology and, therefore, curtail access to new innovations.

CMS’s proposal concerning consolidating and splitting codes would lock-in reimbursement levels for decades and would likely, over time, have the effect of impacting access to patient care. If reimbursement levels are arbitrarily depressed due to the consolidation and bifurcation of codes, practitioners will have a financial incentive to provide the patient with the less expensive component in order to make ends meet. Providers should not be placed in this situation, and patients should not be denied access to the technologies with which they may achieve optimal outcomes. Therefore, we urge CMS to recognize differences in separate components or devices when assigning codes, and determine reimbursement levels based on those differences so that patients can gain access to innovative DMEPOS items and services.

2. *Comparability of New Technologies to Older Technologies*

In proposing how CMS will compare a new technology or device to existing devices for purposes of setting reimbursement levels, CMS lists five major categories and includes a chart that describes in detail elements of each category that may be considered.

We are concerned that these categories and factors are so broad and comprehensive that CMS could use virtually any of these factors to tie a new technology to an item, product, device, or component that existed decades ago, and saddle a new technology with a reimbursement level that effectively denies patients' access to it. Moreover, these categories do not include patient-centric aspects of health care, such as patient preference, patient convenience, patient outcomes, level of clinical services, the capability of the new technology to physically monitor performance, patient use, patient satisfaction, and the likelihood that Medicare will avert longer term costs by ensuring patient access through a reasonable reimbursement level in the short term. Consideration of these categories will lead to more informed Medicare reimbursement levels.

3. *Proposed Changes to Gap-Filling and Pricing Methodology*

A. Second Opportunity for CMS to Conduct Gap-Filling Analysis

CMS's proposal to perform a one-time adjustment by conducting gap-filling a second time if prices drop less than 15 percent within a 5-year period from the initial gap-filling determination is problematic. CMS offers no meaningful rationale for this proposal other than an assertion that gap-filling often produces reimbursement levels for DMEPOS that are excessively high. However, it is our understanding that the gap-filling and deflation/re-inflation process often results in chronically and unrealistically low reimbursement levels for new technologies, which curtails patients' access to DMEPOS items and services.

This proposal gives CMS plenary authority to reduce fee schedule amounts for virtually all DMEPOS with impunity, and with little due process for providers and manufacturers. The rationale for the gap-filling-a-second-time proposal is that immature markets for new technologies tighten over time and prices decrease with competition in the marketplace. However, innovators and manufacturers need to realize a return on their investment. The ITEM Coalition is concerned that the Proposed Rule will disincentivize medical innovation in the area of assistive devices and technologies for people with disabilities.

B. Transparency and Accountability

The current reasonable price methodology and gap-filling process lacks transparency, validity, and reliability, and has insufficient mechanisms to obtain public input, gather appropriate data, and appeal decisions when necessary. The current process hinders the ability of clinicians, manufacturers, investors, and innovators to forecast the level of reimbursement for their new technologies. This uncertainty deters additional research, development, and investment in the advancement of DMEPOS, which ultimately impacts the ability of persons with injuries, illnesses, disabilities, and chronic conditions to achieve optimal outcomes.

The U.S. Supreme Court’s June 2019 holding in *Azar v. Allina Health Services*² is instructive to this reimbursement setting process. The *Allina* case held that CMS must provide public notice and a 60-day comment period for any rule, requirement, or other statement of policy that establishes or changes a “substantive legal standard” governing Medicare payment for services. Accordingly, CMS must consider *Allina* when implementing the requirements of this Proposed Rule to ensure it is complying with the Supreme Court’s decision. Moreover, CMS should institute an appeals process for manufacturers and/or clinicians to challenge reimbursement levels established by the reasonable pricing methodology and gap-filling process.

II. Master List for Prior Authorization, Physician Orders, and Face-to-Face Physician Visits

A. Summary of Proposed Rule

Since 2014, certain DMEPOS items have been 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. For instance, there are currently 82 prosthetic limb codes that are eligible to be subject to prior authorization, but CMS has not yet exposed any of these codes to the prior authorization process.

The Proposed Rule would adopt a new, singular “Master List” of DMEPOS HCPCS codes potentially subject to prior authorization and/or the face-to-face physician encounter and written order requirements. The new Master List would increase the number of DMEPOS items potentially eligible to be selected for the required prior authorization list, but CMS states in the rule that there are no plans to “exponentially increase the number of items subject to required prior authorization in the near future.”³ CMS admits that more than 300 new items, including 144 orthotic and prosthetic “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 proposes that the Master List would “self-update” according to a set of specified eligibility criteria at least annually, with the option to update the list more frequently on an as-needed basis.

B. ITEM Coalition Comments

The ITEM Coalition urges CMS to implement prior authorization in a manner that will ensure that individuals with disabilities and chronic conditions receive timely access to orthoses, prostheses, and specialized assistive devices, technologies, and related services. The timely use of medical devices and related services can enable an individual with a disability to improve or maintain his or her functional ability, and enable employment, educational and recreational pursuits which improve quality of life and health care status.

Although prior authorization can be appropriate for certain types of DME such as certain power wheelchairs, we are concerned that CMS is proposing a dramatic expansion of prior authorization for orthoses and prostheses without any meaningful rationale for doing so. There

² *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 204 L. Ed. 2d 139 (2019)

³ 84 Fed. Reg. at 38,381.

is little evidence to support the major expansion of prior authorization eligibility for either DME or orthotic and prosthetic HCPCS codes detailed in the Proposed Rule. The final prior authorization rule implementing the DMEPOS prior authorization program established a set of criteria that CMS would use in the future to add certain orthotic and prosthetic “L” codes to the Master List. For instance, the rule stated that such criteria would include the following:

- The code must be identified as being subject to frequent overutilization (through a Comprehensive Error Rate Testing (“CERT”) or Office of Inspector General (“OIG”) report); and,
- Have a payment threshold of an average purchase fee of \$1,000 or greater.

The Proposed Rule includes no discussion of these factors and no explanation for why or under what authority CMS is exponentially expanding prior authorization to 144 new HCPCS orthotic/prosthetic codes and 75 DME codes.

We are concerned that CMS is arbitrarily subjecting orthoses and prostheses and DME other than power wheelchairs to prior authorization, which may result in delayed clinical treatment to Medicare beneficiaries, jeopardizing patients’ access to timely and appropriate care. A delay in treatment may force the patient to endure unnecessary pain. Worse yet, such a delay could significantly compromise the long-term functional potential of certain patients, including non-ambulatory beneficiaries with limb loss.

Accordingly, we urge CMS to dramatically scale back those HCPCS “L” codes that are eligible for prior authorization and only add to the Master List those orthotic and prosthetic codes that have been the subject of an OIG or CERT report alleging overutilization and are greater than \$1,000 in value. CMS should consider a similar exercise for durable medical equipment. Only in this manner will CMS’s future final rule on this topic be in compliance with its own published criteria for adding HCPCS codes to the Master List.

We greatly appreciate your attention to this important issue. Should you have further questions regarding the information contained in our letter, please contact the ITEM Coalition at Peter Thomas, ITEM Coalition staff, via email at Peter.Thomas@PowersLaw.com or by calling 202-872-6730, or Joseph Nahra, coordinator of the ITEM Coalition by calling 202-466-6550 or Joseph.Nahra@powerslaw.com.

Sincerely,

ITEM Coalition Steering Committee Members

Christopher and Dana Reeve Foundation
National Multiple Sclerosis Society
Paralyzed Veterans of America
United Spinal Association

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ITEM Coalition Signatories

ACCSES

American Academy of Physical Medicine and 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

Association of Assistive Technology Act Programs

Brain Injury Association of America

Caregiver Action Network

Clinician Task Force

Institute for Matching Person and Technology

Lakeshore Foundation

National Coalition for Assistive and Rehabilitation Technology

National Registry of Rehabilitation Technology Suppliers

Rehabilitation Engineering and Assistive Technology Society of North America

Spina Bifida Association of America

The Simon Foundation for Continence