M E M O R A N D U M

**To: American Academy of Physical Medicine & Rehabilitation (AAPM&R)**

**From: Peter Thomas and Joe Nahra**

 **Date: February 10, 2022**

**Re: 2021 DMEPOS and HCPCS Policy Issues Final Rule**

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On December 28, 2021, the Centers for Medicare and Medicaid Services (CMS) published a final rule implementing various outstanding proposals related to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) benefit and Healthcare Common Procedure Coding System (HCPCS) policies. The rule finalizes several provisions that had initially been proposed in 2020 but, unlike prior years, a DMEPOS final rule was not issued in 2020 due to the ongoing impact of the COVID-19 pandemic and other delays within CMS. The full text of the rule can be found [here](https://www.federalregister.gov/documents/2021/12/28/2021-27763/medicare-program-durable-medical-equipment-prosthetics-orthotics-and-supplies-dmepos-policy-issues), and a CMS fact sheet summarizing the major provisions in the rule can be found [here](https://www.cms.gov/newsroom/fact-sheets/medicare-durable-medical-equipment-prosthetics-orthotics-and-supplies-dmepos-final-rule-cms-1738-f).

**Benefit Category and Payment Determinations for DMEPOS**

*Proposed Rule*

CMS proposed to codify in regulation the processes for obtaining public input on Benefit Category Determinations (BCDs) as well as payment determinations for new items and services under the DMEPOS benefit. Under the proposal, the BCD and payment determination process would be incorporated into the biannual HCPCS coding cycle. This process would include the issuance of a preliminary BCD by CMS after consideration of relevant information, including an application for a BCD from a manufacturer or innovator. Similar information would be used to issue a preliminary payment determination if the item or service was placed in a Medicare benefit category under the preliminary BCD.

*Final Rule*

The majority of the proposed BCD and payment determination processes were finalized without revision. Under the new process, once a manufacturer submits an application for a new item or service, or when CMS decides to undertake a new BCD review under its own authority, the process will unfold as follows:

* At the start of the coding cycle (typically shortly after January 1 and July 1 of each year), CMS will review whether the item or service is statutorily excluded from Medicare coverage. If not, the agency will make a preliminary BCD to decide whether the new technology or device qualifies under the DME or O&P benefit. CMS states that this process will typically take between 1 week and 2 months, though it could take several months for more complex items or services.
	+ For this determination, CMS may review information about the item or service including the description included in the HCPCS application, past codes utilized to bill for the item or service, information on the manufacturer’s website, and information related to the Food & Drug Administration (FDA) clearance or approval process for the item or service.
* If the preliminary BCD affirms that the item falls within a Medicare benefit category, CMS will make a preliminary payment determination regarding how fee schedule amounts will be established. This process will typically take another 1 week to 2 months, or up to several months for more complex items.
* After both preliminary determinations are established, they will be posted publicly 2 weeks before the applicable public meeting of the HCPCS Workgroup. At that meeting, applicants and other stakeholders may testify before the HCPCS Workgroup and present additional information and support for their position, after which the Workgroup will issue final determinations to be established through program instructions to the Medicare Administrative Contractors (MACs).
	+ CMS noted that many stakeholders found the 2-week timeline to make preliminary decisions public too short; the agency believes, however, that this timeline strikes the right balance. This means that a negative preliminary decision on a BCD or pricing determination will necessitate intensive efforts from applicants and other stakeholders to address the reasons why the preliminary decision is viewed as incorrect.

BCD and pricing determinations for new technologies and devices were traditionally handled by CMS staff in an informal process, usually as an adjunct to a new coding application or, in the case of a pricing determination, after a new code had been created. The final rule increases the level of transparency and public input into both of these determinations by subjecting them to the same HCPCS Workgroup review that new coding applications undergo. This could produce better results for manufacturers, innovators, and other participants in this process, potentially easing the path for new technologies to be accessible to beneficiaries.

However, the only appeals mechanism to applicants who are dissatisfied with their BCD or pricing decisions appears to be a resubmission of the application itself for review by the same HCPCS Workgroup that makes the first decision. There is also concern that the HCPCS Workgroup members, whose expertise relates to Level II coding, may not have the expertise to determine benefit categories and pricing calculations.

*Additional Clarifications*

* CMS notes that in the future, manufacturers who request a BCD outside of the new process, including as part of a request for informal advice from the agency, will instead receive a BCD and payment determination issued through this newly established, more formal process.
* CMS notes that the BCD process is separate from the HCPCS application process, although both processes are handled by the HCPCS Workgroup. In addition, manufacturers and other stakeholders may request a BCD without an associated request for a new or revised HCPCS code. BCDs can also be requested through the broader National Coverage Determination (NCD) process without having to go through the HCPCS Workgroup.
* CMS acknowledges that BCD reviews have “slowed down the past few years,” attributing the delays to the lack of formalization of the BCD process. The agency anticipates being able to make more consistent and timely decisions moving forward.
* Several coding applications in the past two years yielded temporary HCPCS coding assignments for new technologies due to internal CMS concerns with the process. CMS is expected to make permanent BCD and coding recommendations in the first round of HCPCS Workgroup consideration later this spring for these temporary codes.

**HCPCS Level II Code Application Process**

*Proposed Rule*

In the 2020 proposed rule, CMS offered several revisions to the HCPCS Level II code application process, including codifying a biannual coding cycle for DMEPOS and other non-drug, non-biological items; a quarterly cycle for drug and biological products; and a new specified process for evaluating code applications. Among other provisions, the proposed evaluation would allow CMS to make initial determinations regarding whether an item is “primarily medical in nature” before the coding application is brought before the HCPCS workgroup.

*Final Rule*

After reviewing stakeholder comments, CMS decided **not** to finalize any of the proposed revisions to the HCPCS Level II code application process. The rule notes that stakeholders raised significant concerns about the HCPCS proposals, In particular, the agency cites “overwhelming” negative stakeholder response to certain provisions, such as the proposed explanation of “claims processing need,” the proposal to allow CMS to assess whether an item is “primarily medical in nature” as part of the initial code application review process, and the proposed ability for CMS to indefinitely delay a preliminary or final decision on a given application. The agency will continue to evaluate the HCPCS process to identify necessary improvements.

**DMEPOS Fee Schedule Adjustments**

*Proposed Rule*

CMS proposed an extension of existing adjustments in fee schedule payments for DMEPOS items and services furnished in non-competitive bidding areas (non-CBAs) following the expiration of the public health emergency. Current law requires CMS to revise payments for items in non-CBAs based on competitively bid prices, with certain adjustments to account for complexities and regional variations in delivering DMEPOS in rural, non-rural, and non-contiguous non-CBAs. Currently certain items and services furnished in certain non-CBAs are paid with a “blended” rate between both the adjusted and historic unadjusted fee schedule amounts.

CMS proposed to permanently extend a 50-50 blended rate for items and services furnished in non-contiguous and rural, contiguous non-CBAs. For all other non-CBAs, CMS proposed to fully implement the adjusted payment amount.

*Final Rule*

The final rule implements the three methodologies for fee schedule adjustments as proposed. These new methodologies will go into effect beginning with the end of the federal public health emergency declaration. Contrary to the recommendations of many stakeholders, CMS will **not** be extending the blended payment rate methodology to items provided in non-rural, contiguous, non-CBAs. Instead, once the PHE ends, items in these areas will be paid at the fully adjusted payment amount. For OTS orthoses specifically, CMS states that the agency has not detected any issues with the fee schedule adjustments, and states that in their opinion, paying the unadjusted fee schedule amounts for these orthoses would be “fiscally imprudent.”

Additionally, CMS noted that the agency continues to receive feedback from industry stakeholders expressing the belief that the fully adjusted fee schedule amounts are too low, and that full implementation would have an adverse impact on beneficiary access to items and services furnished in rural areas. Further, stakeholders have commented that the fully adjusted amounts are insufficient to cover supplier costs, especially for delivering items in rural areas. CMS, however, disagrees with these notions, stating that the agency’s analyses have found no decline in allowed services for items subject to the fee schedule adjustments at any point in time thus far, including 2017 and the first half of 2018, when payments in rural and non-contiguous areas were based on the fully adjusted fee schedule amounts. CMS states that while the proposed adjustment methodologies will be finalized at this time, the agency is “likely” to revisit overall methodologies for all items in all areas again in the future.