King & Spalding
Client Alert

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For more information, contact:

David Farber
+1 202 626 2941
dfarber@kslaw.com

Seth Lundy
+1 202 626 2924
slundy@kslaw.com

Juliet McBride
+1 713 276 7448
jmcbride@kslaw.com

Preeya Noronha Pinto
+1 202 626 5547
ppinto@kslaw.com

Igor Gorlach
+1 713 276 7326
igorlach@kslaw.com

King & Spalding

Washington, D.C.
1700 Pennsylvania Avenue, NW
Washington, D.C. 20006-4707
Tel: +1 202 737 0500

CMS Proposes New DMEPOS Coverage Policies and Payment Rates, and Seeks to Codify HCPCS Application, Benefit Category and Payment Determination Processes

On November 4, 2020, the Centers for Medicare & Medicaid Services (CMS) published a proposed rule (the Proposed Rule) outlining proposals for the coverage and payment for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).[1] Notably, CMS proposes to expand Medicare coverage under the durable medical equipment (DME) benefit to adjunctive or non-therapeutic continuous glucose monitors (CGMs) and to certain drugs and biologicals administered via an external infusion pump by a health care professional in the home. CMS also proposes to codify the more frequent cycles for HCPCS Level II code applications implemented in 2020, and processes for benefit category and payment determinations. Further, CMS proposes adjustments to the DMEPOS Fee Schedule in accordance with the input that it received pursuant to section 16008 of the 21st Century Cures Act, including continuing the higher rate paid for items sold in rural areas.

Although the expansion of Medicare coverage and the codification of coding, benefit category, and payment determinations are positive developments, there are certain areas where CMS's proposals could be improved that may be addressed in comments to the Agency.

The deadline for the submission of comments is January 4, 2021.

1. Coverage and Payment for Adjunctive Continuous Glucose Monitors

CMS proposes to expand the DME Medicare benefit category to CGMs that are adjunctive or non-therapeutic, as long as they otherwise meet the definition of DME. To meet the classification, a CGM system must be granted marketing authorization by the Food and Drug Administration (FDA), but its FDA-required labeling would *not* need to indicate that the CGM is appropriate or indicated for use in place of a blood glucose monitor for making diabetes treatment decisions in order to be classified as DME. In other words, a CGM could be classified as DME even if patients use it to check their glucose levels and trends, but then verify that information with a blood glucose monitor in order to make diabetes treatment decisions.

CMS's proposed policy would replace its 2017 CMS Ruling (CMS-1682-R), under which coverage is available *only* for non-adjunctive or therapeutic CGMs whose FDA-required labeling indicates that the CGM is appropriate or indicated for use in place of a blood glucose monitor for making diabetes treatment decisions.

Because CMS considers CGM to be a newer technology version of blood glucose monitors, CMS proposes to establish fee schedule amounts for CGM receivers under the "routinely purchased equipment" payment category using 1986/87 average reasonable charges for comparable blood glucose monitors, updated in accordance with the Social Security Act.[2] For CGM supplies and accessories, which CMS considers to be very different technology from BGM supplies, CMS proposes to establish separate monthly fee amounts for the supplies and accessories used with the three different types of class II and class III CGMs on the market: (i) automatic, non-adjunctive CGMs, (ii) automatic, adjunctive CGMs, and (iii) manual, adjunctive CGMs. Notably, the proposed payment rate for automatic, adjunctive CGM systems is calculated by reducing the payment by the amount that is paid separately for blood glucose monitor and supplies (which would not be needed for non-adjunctive CGM systems). According to CMS, this would avoid a situation where the Medicare program and beneficiaries would pay twice for glucose testing equipment and supplies.

Overall, this proposal is a welcome step toward the coverage of and payment for technology-driven preventive care, although manufacturers and supplies of adjunctive CGM systems may wish to provide comment on the proposed reduced payment rates for those systems.

2. Expansion of Coverage under the DME Benefit to Certain Drugs and Biologicals Administered Via an External Infusion Pump by a Health Care Professional in the Home

Under current regulations, in order for an external infusion pump and associated supplies to be covered under the Part B DME benefit, the pump must, among other requirements, be "appropriate for use in the home." CMS has interpreted this requirement as limiting coverable items to those which can be used by a patient or caregiver in the home without the assistance of a healthcare professional.

In the Proposed Rule, CMS proposes to expand its interpretation of the "appropriate for use in the home" requirement to cases where assistance from a skilled home infusion therapy supplier is necessary for safe infusion in the home. Specifically, the requirement would be satisfied if: (i) FDA labeling requires the associated home infusion drug to be prepared immediately prior to administration or administered by a health care professional or both; (ii) a qualified home infusion therapy supplier administers the drug or biological in a safe and effective manner in the patient's home; and (iii) the FDA labeling specifies infusion via an external infusion pump as a possible route of administration, at least once per month, for the drug. Under the proposal, a drug could be covered as a supply necessary for the effective use of the external infusion pump under the DME benefit even where an individual is unable to self-administer the drug. This proposal was prompted by the new Medicare home infusion therapy services benefit, covering professional services associated with the provision of home infusion therapy, created by section 5012 of the 21st Century Cures Act.

CMS noted that, if the proposal is finalized, it would be up to the DME Medicare Administrative Contractors (DME MACs) to create and maintain the lists of covered eligible drugs that can be infused using external infusion pumps, under the Local Coverage Determination (LCD) process. However, since the LCD process takes time, industry stakeholders may consider requesting that CMS facilitate a more centralized process, whether as an initial list or a centralized process for an initial list. CMS also requests information about infusion drugs or biologicals that may be covered as supplies under the DME benefit if this proposal is finalized.[3]

3. Codification of HCPCS Level II Code Application Process

CMS administers the process for assigning, revising, and discontinuing HCPCS Level II codes for items and services not described by CPT codes. To date, the process has been governed by periodic sub-regulatory guidance from CMS. In the Proposed Rule, CMS proposes to codify the HCPCS Level II code application process, including recent changes that modify the coding cycles to quarterly (for drugs and biologicals) or bi-annually (for non-drug and non-biological items and services).

a. Products and Services Subject to the HCPCS Coding Process

The HCPCS application process applies to products "paid separately as drugs or biologicals" and non-drug, non-biological items and services.

CMS proposes that the term "products paid separately as drugs or biologicals" refers to products that are separately payable by Medicare under Part B (and potentially by other payers, such as private insurers) as drugs or biologicals as that term is defined in section 1861(t) of the Social Security Act. These products typically fall into one or more of the following three categories:

- Products furnished incident to a physician's services under sections 1861(s)(2)(A) and (B) of the Act, excluding products that are usually self-administered (for example, tablets, capsules, oral solutions, disposable inhalers).
- Products administered via a covered item of DME.
- Other categories of products for which there is another Part B benefit category as specified by statute or regulations, for example, drug or biological products described elsewhere in section 1861(s) of the Social Security Act, such as immunosuppressive drugs; hemophilia blood clotting factors; certain oral anticancer drugs; certain oral antiemetic drugs; and pneumococcal pneumonia, influenza and hepatitis B vaccines.

Non-drug, non-biological items and services include the following:

- Medical and surgical supplies, such as splints, casts and therapeutic shoes.
- Dialysis supplies and equipment.
- Ostomy and urological supplies.
- Surgical dressings.
- Prosthetics (artificial legs, arms and eyes) and prosthetic devices.
- Orthotics (leg, arm, back, and neck braces).
- Enteral/parenteral nutrition.
- DME (and related accessories and supplies other than drugs), such as oxygen and oxygen equipment, wheelchairs, infusion pumps, and nebulizers.[4]

- Vision items and services, such as prosthetic lenses.
- Other items and services that are statutorily excluded from Medicare coverage for which CMS or other government or private insurers have identified a claims processing need for a HCPCS Level II code, such as hearing aids.

These HCPCS processes would not apply to items and services described in the oral health and dentistry codes that begin with the letter "D" (CDT codes), nor would then apply to items and services coded internally by CMS and that are not based on an external coding application.

b. HCPCS Coding Cycles

CMS proposes to establish a bi-annual coding cycle for non-drug, non-biological items and services with application deadlines in January and June. CMS will issue preliminary recommendations on the applications and hold public meetings to provide the public with an opportunity to provide input on the coding applications and preliminary recommendations. In most cases, final coding decisions will be issued within 6 months of the application deadline, and will be effective approximately 3 months after issuance. Although CMS considered proposing quarterly cycles for these items and services, section 531(b) of BIPA requires procedures for coding determinations for new DME that permit public consultation, and CMS did not believe that a quarterly coding cycle would allow enough time to fulfill this requirement. CMS further stated that, even for non-DME items and services in this category, a bi-annual coding cycle would be more appropriate to address the complexities associated with applications for these items and services. And in circumstances where the applications raise complex or significant issues that require additional time, CMS has the discretion to push the coding application to future bi-annual coding cycles for determination.[5]

For drugs and biological products, CMS proposes a quarterly coding cycle with application deadlines in January, April, June and September. CMS will issue final coding decisions within approximately 3 months of the code application deadline. Coding changes would become effective approximately 3 months after issuance of the final coding decisions. CMS believes that quarterly cycles are appropriate because drug or biological applications tend to be more straightforward and take less time to assess than many of the other applications. Many of these applications are largely evaluated based on Medicare statutory requirements consistent with section 1847A and the coding applications include detailed FDA documentation. There is also no statutory requirement to hold public meetings for drug or biological products applications, which would make more time necessary. Nevertheless, CMS is seeking comment on whether it would be appropriate or preferable to instead adopt bi-annual coding cycles for drug or biological product applications, which would enable CMS to issue preliminary recommendations and solicit input at public meetings.

As with non-drug, non-biological items and services, CMS maintains discretion to delay issuing a decision on a drug or biological product coding application for one or more coding cycles in cases where the application raises complex or significant issues or considerations. In some of these situations, CMS may add the application to the agenda for a public meeting to obtain further input and public discussion of the application and the preliminary recommendation that would be issued prior to the public meeting. In such case, the coding application would be considered on the bi-annual coding cycle with non-drug, non-biological items and services. CMS specifically notes that any determination to include an application in a public meeting would be initiated by CMS and would not be granted based on requests from an applicant, although CMS requests comment on whether CMS should consider such requests from applicants. CMS also seeks comment on whether public input on coding applications should be solicited through the CMS website (during a 15-day comment window) rather than through a public meeting. Such comment periods would also necessitate a coding cycle on a bi-annual basis.

c. HCPCS Application Requirements

CMS proposes that a HCPCS application must be timely and complete to be considered in a given coding cycle. If an application is incomplete, then it will be declined and may be submitted in a subsequent coding cycle. For an application to be complete, it must contain FDA documentation of the item's current classification and FDA marketing authorization (or information regarding why the item is exempt from the premarket notification requirement). For biosimilar biological products, however, CMS proposes to allow a 10-business day extension past the application deadline to provide a complete application, including FDA marketing authorization documentation. CMS is permitting this exemption to support the goal of a competitive market by facilitating faster assignment of a separate HCPCS code to biosimilar biological products, which CMS believes will increase access to these products and further President Trump's goal of lowering drug costs.

For non-drug, non-biological items and services, a HCPCS application must include evidence that the item or service is available in the U.S. market for use and purchase at the time of the application deadline. This is a modification from the requirement for 3 months of marketing data in an application that was in effect prior to 2020. CMS will continue to allow applicants to supplement a complete application with additional materials up to the time of close of business on the date of the public meeting at which the application is discussed.

d. HCPCS Application Resubmission and Reevaluation

CMS proposes to continue to allow applicants to resubmit code applications for reevaluation of prior final coding decisions. However, in the interest of reaching an appropriate coding decision and supporting efficient and expeditious review of all coding applications, CMS is proposing limitations on this process. An applicant who is dissatisfied with a final coding decision may resubmit their application for reevaluation by CMS no more than two times. The first resubmission must be timely and complete and must include: (1) a description of the previous application submission; (2) a copy of the prior coding decision; and (3) an explanation of the applicant's reason for disagreement with the prior final coding decision. CMS does not require, but strongly encourages, providing new information with the first resubmission. If a second resubmission is necessary, CMS requires "significant new information" not previously submitted to CMS that could potentially change the final coding decision and an explanation of how this information supports the request for a different coding decision. These limitations would apply to resubmissions of applications for the same item or service with the same FDA marketing authorization submitted with the original application and would continue to apply to a code application for that item or service regardless of whether the applicant or manufacturer undergoes a change of ownership, a new manufacturer begins manufacturing the item or service at issue, there is a change of or new supplier of that item or service, or the item or service is renamed. All resubmissions will be evaluated during the next bi-annual coding cycle.

4. Benefit Category and Payment Determinations for DME, Prosthetic Devices, Orthotics and Prosthetics, Therapeutic Shoes and Inserts, Surgical Dressings, Splints, Casts, and Other Devices Used for Reductions of Fractures and Dislocations

CMS proposes to codify procedures for making benefit category determinations and payment determinations for items for which a HCPCS Level II code has been requested. Specifically, at the start of the coding cycle, CMS would determine whether the item or service is excluded from Medicare coverage under Section 1862 of the Social Security Act, and if not, whether it falls within a defined Medicare benefit category under the statute and regulations. To do this, CMS would consider information from a variety of sources, including the description of the item or service in the HCPCS coding application, HCPCS codes used to bill for the item or service in the past, product brochures and literature, information on the manufacturer's website, information related to the FDA clearance or approval of the item or service for marketing or related to items that are exempted from the 510(k) requirements or otherwise

granted marketing authorization by the FDA. CMS notes that this step could take anywhere from 1-2 weeks to 1 or 2 months, and for complex cases that take longer, public consultation would slip to a subsequent coding cycle.

If a preliminary determination is made by CMS that the item or service falls under a Medicare benefit category, that CMS makes a preliminary payment determination regarding how the fee schedule amounts will be established for the item or service and, for DME items, under what payment class that item falls. This step may also take as long as 2 months, and if particularly complex, may need to be subject to public consultation in a subsequent coding cycle.

About 4 months into the coding cycle (about 2 weeks prior to the public meeting), CMS would post the preliminary benefit category and payment determinations on the CMS website and consider any public comments that are submitted. CMS would then finalize the benefit category and payment determinations through program instructions issued to the MACs and DME MACs.

The Medicare benefit category and payment determination processes have never been transparent, and codification of these processes with opportunity for formal comment through public meetings should provide manufacturers and suppliers with additional ability to understand and impact CMS decision-making. CMS fails to propose a detailed appeals process for these determinations, however, which may be an area on which stakeholders would like to submit comments to the Agency.

5. Changes to the DMEPOS Fee Schedule Adjustments – Maintaining Higher Pay for Rural Areas

Section 1834(a)(1)(F)(ii) of the Social Security Act requires the Secretary of Health and Human Services to use information on the payment determined under the Medicare DMEPOS Competitive Bidding Program (CBP) to adjust the fee schedule amounts for DME items and services furnished in all non-Competitive Bidding Areas ("non-CBAs") on or after January 1, 2016. In the Proposed Rule, CMS proposes to establish methodologies for adjusting the fee schedule payment amounts for DMEPOS items furnished in non-CBAs on or after April 1, 2021 or the date immediately following the COVID-19 public health emergency period, whichever is later. Section 16008 of the 21st Century Cures Act requires CMS to take into account a number of factors in making any fee schedule adjustments for items and services furnished on or after January 1, 2019, including: (1) shareholder input solicited by CMS on adjustments to the fee schedule amounts using information from the DMEPOS CBP; (2) the highest bid by a winning supplier in a CBA; and (3) a comparison of each of the following factors with respect to non-CBAs and CBAs: the average travel distance and cost associated with furnishing items and services in the area, the average volume of items and services furnished by suppliers in the area, and the number of suppliers in the area. Upon analyzing these factors, CMS proposes to continue paying a 50/50 (adjusted/unadjusted) blended rate in rural and non-contiguous non-CBAs, and 100% of the adjusted payment amount established under 42 C.F.R. § 414.210(g)(1)(iv) in non-rural non-CBAs in the contiguous U.S. According to CMS, "[t]he purpose of the 50/50 blend is to ensure payment rates are sufficient to maintain access to DME in areas where suppliers often furnish a lower volume of DME, such as rural areas of the country and non-contiguous areas."[6]

CMS considered three alternatives to this proposal: (i) adjusting fee scheduling amounts for "super rural areas"[7] and non-contiguous areas based on 120 percent of the fee schedule amounts for non-rural areas, (ii) establishing an additional three-year phase-in period (75/25 blend of adjusted and unadjusted rates) for rural areas and non-contiguous areas, and (iii) extending the current fee schedule adjustments for items and services furnished in non-CBAs and former CBAs that were included in product categories removed from Round 2021 of the CBP.[8] Although CMS decided not to propose any of these three alternatives, CMS requests comments on these methodologies and whether there are aspects that warrant further consideration. For example, DME suppliers and other stakeholders should provide input to CMS on the immediate and long-term challenges caused by the COVID-19 pandemic and

how alternative payment methodologies in light of these factors may affect Medicare beneficiary access to items and services.

Additionally, CMS plans to finalize the May 11, 2018 interim final rule[9] that resumed transitional 50/50 blended rates for items furnished in rural areas and non-contiguous areas from June 1, 2018 to December 31, 2018. The interim final rule also codified the exclusion of infusion drugs from the DMEPOS CBP as required by Section 5004(b) of the 21st Century Cures Act.

[1] 85 Fed. Reg. 70358 (Nov. 4, 2020).
[2] Social Security Act, § 1834(a)(14).
[3] In the Proposed Rule, CMS identified only one product that would be eligible for coverage under the DME benefit if this proposal was finalized—patisiran.
[4] This category includes gaseous or liquid oxygen put into oxygen equipment, but does not include drugs put directly into nebulizers or infusion pumps, which are considered "drugs or biological products."
[5] These circumstances would include, but are not limited to, situations where the code application involves a significant policy consideration (for example, a unique issue related to a specific item or service or group of items or services, such as appropriate coding for combination products that include a drug and a service component), involves a significant claims processing consideration (for example, operational issues arising from a coding action requiring significant revisions to the claims processing system, such as re-tooling to add another character to the price field to accommodate higher prices than contemplated when the system was established, including determining whether the claims processing system change could be made, and in what timeframe, to ensure that the coding solution would be viable, or whether an alternative solution needs to be implemented before publishing new codes), or requires in-depth clinical or other research.
[6] 85 Fed. Reg. at 70371.
[7] The term "super rural" refers to areas identified as "qualified rural areas" under the ambulance fee schedule statute at section 1834(l)(12)(B) of the Social Security Act (as implemented at 42 C.F.R. § 414.610(c)(5)(ii)).
[8] Although CMS solicited bids in a number of product categories, CMS recently announced that it will only award Round 2021 CBP contracts to bidders in the OTS back braces and OTS knee braces product categories.
[9] 83 Fed. Reg. 21912 (May 11, 2018).