

Final Rule Summary

MEMORANDUM

Date: December 23, 2021

Subject: Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues and Level II of the Healthcare Common Procedure Coding System (HCPCS) [CMS-1738-F]

On December 21, 2021, CMS posted online the [DMEPOS final rule](#) [CMS-1738-F].¹ The rule finalizes changes to the DMEPOS fee schedule that would go into effect after the public health emergency (PHE); classification of adjunctive continuous glucose monitors; and benefit determination and payment procedures. CMS is not finalizing several sections of the proposed rule. It is not codifying the application process for Healthcare Common Procedure Coding System (HCPCS) Level II Coding and expanding coverage for external infusion pumps.

The official publication date of the final rule is December 28, 2021, and the effective date of the provisions of this rule is expected to be around January 27, 2022. Below is the summary of the provisions from the proposed rule followed by the **final rule decision in red**.

CHANGES TO THE DMEPOS FEE SCHEDULE METHODOLOGY

In competitive bidding areas (CBAs) for items not in Round 2021, CMS ‘seriously’ considered continuing with the current PHE relief rates (the blended rates in rural and non-rural areas) and requested stakeholder feedback. CMS did not present a formal proposal for competitive bidding program (CBP) item rates in CBAs in the proposed rule.

Starting April 1, 2021, or immediately after the end of the COVID-19 PHE, whichever is later, CMS proposed to implement the following payment methodologies:

- **Rural Areas:** Make the current methodology of 50/50 blended rates permanent
- **Non-Contiguous, Non-CBAs:** Make the current methodology of 50/50 blended rates permanent
- **Non-Rural, Non-CBAs:** Maintain 100% adjusted rates

FINAL RULE: CMS finalized the proposal to continue to pay the 50/50 blended rates for rural and non-contiguous areas post-PHE. CMS believes the 50/50 blended rates may be excessive and will consider making changes in future rulemaking. CMS will continue to monitor the rural and non-contiguous areas.

Due to the ongoing PHE, the effective date of the proposal will be the effective date of the final rule.

Although not proposed, CMS shared alternative payment methodologies that were considered:

1. Adjust to 120% of non-rural fee schedule amounts for super rural and non-contiguous areas.
This alternative would have adopted the ambulance fee schedule definition of “super rural area” when distinguishing non-CBAs. CMS considered eliminating the current ‘rural area’ definition used for DMEPOS.
2. Create a phase-in period to fully adjusted fee schedule rates for rural and non-contiguous areas.
CMS considered phasing-in the fully adjusted rates for rural and non-contiguous areas by

¹ The proposed rule published in the December 21, 2021, *Federal Register*.

implementing 75% adjusted and 25% unadjusted rates for a 3-year period starting April 1, 2021, or immediately after the end of the PHE, whichever is later.

3. Extend the PHE relief rates to items included in Round 2021.

CMS considered applying the current relief rates of 75/25 rates in non-rural, non-CBAs for OTS back and knee braces until the end of the PHE.

FINAL RULE: CMS did not finalize the alternatives. CMS will continue to reimburse 100% of the adjusted fee schedule for non-rural areas and SPAs in CBAs. CMS will continue to monitor the non-rural areas and will consider revising rates in the future.

CMS RESPONDED TO 2018 INTERIM FINAL RULE COMMENTS

CMS took the opportunity in the proposed rule to respond to comments received for CMS' Interim Final Rule (IFR) titled, "Medicare Program; Durable Medical Equipment Fee Schedule Adjustments to Resume the Transitional 50/50 Blended Rates to Provide Relief in Rural Areas and Non-Contiguous Areas" that was published on May 11, 2018.²

FINAL RULE: CMS finalized the 2018 IFR.

BENEFIT CATEGORY AND PAYMENT DETERMINATIONS

CMS proposed to put into regulations the benefit category and payment determination procedures for new DMEPOS and other items and services under the Part B benefit. CMS proposed to hold public meetings to make benefit category determinations (BCDs) and payment determinations. CMS proposed the public meetings will be part of the bi-annual HCPCS Level II public meetings. CMS also proposed to "specifically solicit and invite consultation on preliminary BCDs for each item or service in addition to the consultation on preliminary payment and coding determinations for new items and services."

CMS proposed to define benefit category determination as "a national determination regarding whether an item or service meets the Medicare definition of prosthetic device at section 1861(s)(8) of the Act or is a splint, cast, or device used for reduction of fractures or dislocations subject to section 1842(s) of the Act and the rules of this subpart and is not otherwise excluded from coverage by statute" at §414.114 and "a national determination regarding whether an item or service meets the Medicare definition of durable medical equipment at section 1861(n) of the Social Security Act, a prosthetic device at section 1861(s)(8) of the Social Security Act, an orthotic or leg, arm, back or neck brace, a prosthetic or artificial leg, arm or eye at section 1861(s)(9) of the Social Security Act, is a surgical dressing, or is a therapeutic shoe or insert subject to sections 1834(a), (h), or (i) of the Act and the rules of this subpart and is not otherwise excluded from coverage by statute" at §414.240.

FINAL RULE: CMS finalized the proposed policy on BCDs with some technical modifications to remove references to the proposed HCPCS related regulations.

CLARIFICATION ON CLASSIFICATION OF CONTINUOUS GLUCOSE MONITOR (CGM)

CMS proposed classifying all CGM systems that use a receiver as routinely purchased DME. This includes CGM systems that are both adjunctive and non-adjunctive. CGM systems would need marketing authorization by FDA. Due to CGMs having some of the same functions as blood glucose monitors, CMS proposed continuing to use the fee schedule rates in CMS-1682-R which is based on the 1986/87 average

² The interim final rule is published in the May 11, 2019 *Federal Register*.

reasonable charges for blood glucose monitors.³

For supplies and accessories used with CGMs, CMS proposes two separate monthly payments for 2021:

1. For supplies and accessories used with adjunctive CGMs: [supplier prices for sensors and transmitter] – [monthly fee schedule amounts for average quantity and types of blood glucose monitoring supplies]
 - a. 2020 fee schedule amounts to be increased by 2021 fee schedule update factor
2. For supplies and accessories used with non-adjunctive CGMs: 2020 fee schedule amount

FINAL RULE: CMS finalized the classification of adjunctive and non-adjunctive CGMs under Medicare Part B. However, due to the evolving technology for CGMs, CMS did not finalize the proposed fee schedule amounts for supplies and accessories. CMS will establish the fee schedule for supplies and accessories used with adjunctive CGMs using the gap-fill methodology.

CMS RESPONDS TO MAY 2020 INTERIM PRICING IN THE CARES ACT

In the final rule, CMS responded to comments to the IFR titled, “DME Interim Pricing in the CARES Act.” that was published on May 2020⁴ and finalized the IFR. The May 2020 IFR set the 50/50 blended rates in rural areas and 75/25 blended rates in non-rural areas during the PHE.

FINAL RULE: CMS finalized the May 2020 IFR with some technical changes to the regulation text.

EXCLUSION OF COMPLEX REHABILITATIVE MANUAL WHEELCHAIRS AND CERTAIN OTHER MANUAL WHEELCHAIRS FROM THE DMEPOS CBP

This proposed rule incorporated the changes set in the Further Consolidated Appropriations Act, 2020 (Pub. L. 116-94) that was signed into law on December 20, 2019, into regulation. The Act made two changes:

1. Permanently excluded complex rehabilitative manual wheelchairs and certain other manual wheelchairs from CBP. [HCPCS codes: E1235, E1236, E1237, E1238, and K0008 and any successor codes and related accessories]
2. Exempts wheelchair accessories (including seating systems) and seat and back cushions furnished with complex rehabilitative wheelchairs (HCPCS codes: E1161, E1231, E1232, E1233, E1234, and K0005) and certain manual wheelchairs (HCPCS codes: E1235, E1236, E1237, E1238, and K0008) from CBP rate adjustments from January 1, 2020 to June 30, 2021

CMS does not propose any additional changes, the Agency simply places the changes made in the Act into regulation.

FINAL RULE: CMS addressed this section in the FY 2022 Inpatient Rehabilitation Facility (IRF) final rule⁵ published in August 2021. In the IRF final rule, CMS permanently excluded complex rehabilitative manual wheelchairs and certain other manual wheelchairs and associated accessories from bidding derived pricing.

HCPCS LEVEL II CODING APPLICATION

³ Classification of Therapeutic Continuous Glucose Monitors as Durable Medical Equipment under Medicare Part B (CMS-1682-R). Published January 12, 2017.

⁴ The interim final rule is published in the May 11, 2019 *Federal Register*.

⁵ 86 FR42362

CMS proposed to codify the current HCPCS Level II coding application and evaluation process. Most of these processes have existed for many years but have not been in federal regulation. In November 2019, CMS announced that the Agency will move to holding no less than two public meetings for DMEPOS items and other non-drug and non-biological applications. In the same announcement, the Agency announced that they will no longer hold public meetings for drug and biological applications and will instead hold a quarterly review cycle. The Agency explained that less review time is needed for drugs and biologicals because the U.S. Food and Drug Administration (FDA) have already reviewed the products and CMS can rely on the studies and finding by the FDA. Conversely, DMEPOS and other non-drug applications have not previously been vetted by the FDA and as a result, CMS needs this application review process to conduct a more comprehensive review.

In the proposed rule, CMS proposed to allow for delays on preliminary and final coding decisions. CMS believed the ability to extend the evaluation of an application may be necessary to account for complex applications.

CMS proposed that drug and biological applicants who are dissatisfied with their final coding decision may choose to be included in the bi-annual public meeting for re-evaluation, which would provide an opportunity for additional input. If an application is included in a public meeting, CMS proposed to publish the preliminary recommendation for the application prior to the meeting. However, for drugs and biologicals that are to be included in a public meeting, the preliminary decision would not be made if the public meeting is held in the same quarter.

Although not proposed, CMS considered publishing decisions on drug and biological applications on CMS' website instead of including applicants in the bi-annual public meeting. CMS considered this internet-based public input process to be conducted bi-annually with a comment window of 15-days.

CMS proposed that the coding applications must be timely and complete to be considered. Incomplete applications must wait until the following coding cycle to be considered for review. However, for biosimilar biological products, CMS proposed a 10-business day extension. CMS only offered extensions for biosimilars and no other products or services because biosimilars encourages a stronger marketplace by increasing access, patient choice, and competition. Biosimilars also encourages innovation. CMS noted that if this extension is finalized and if the Agency receives many extensions for biosimilar applications, the 10-day extension may be reconsidered.

In the proposed rule, CMS proposed to limit the resubmission to no more than two times. There would be no requirements for new information in the first resubmission, but it would have been strongly encouraged. CMS proposed that the second resubmission would need to include significant new information and reports on how the new information directly relates to the previous coding decision. CMS clarified that the resubmission limitation will continue to stay with the product even if there is a change in ownership of the product. CMS proposed that resubmitted applications for drugs and biologicals will be included in the bi-annual public meeting to allow for additional input.

CMS clarified that the HCPCS Level II code set is intended to be broad and not be manufacturer specific. The code set needs to be administratively simple for claims processing purposes, but also be able to

differentiate products/services. In short, CMS refers to this as “claims processing needs.” CMS states that HCPCS Level II code set is maintained primarily to support the “claims processing needs” of Medicare, but CMS recognizes that other payers also uses the HCPCS Level II code set as well.

CMS proposed to maintain current practices used in coding evaluations and maintain current practices used in discontinuing existing codes.

FINAL RULE: CMS is not finalizing any of the proposals on HCPCS Level II code application process. CMS will continue to evaluate the process as stakeholders become more accustomed to the newer frequent coding cycle.

COVERAGE FOR EXTERNAL INFUSION PUMPS

CMS proposed to expand the coverage of external infusion pumps by revising its interpretation of the “appropriate for use in the home” requirement in the definition of DME as it relates to external infusion pumps. CMS proposed to interpret the “appropriate for use in the home” requirement to be met if:

1. *the Food and Drug Administration (FDA)-required labeling requires the associated home infusion drug to be prepared immediately prior to administration or administered by a health care professional or both;*
2. *a qualified home infusion therapy supplier (as defined at §486.505) administers the drug or biological in a safe and effective manner in the patient’s home (as defined at §486.505); and*
3. *the FDA-required labeling specifies infusion via an external infusion pump as a possible route of administration, at least once per month, for the drug.⁶*

CMS also proposed that if the above three requirements are met, the external infusion pump will satisfy the definition of DME, even if the beneficiary and/or caregiver is not able to administer the drugs. If finalized, CMS expects more drugs and biologicals will be covered as supplies under the DME benefit and it will also impact home infusion therapy services.

If finalized, DME MACs would need to update LCDs for external infusion pumps.

FINAL RULE: CMS is not finalizing the proposed expanded classification of external infusion pumps due to feedback from stakeholders that the proposal is unclear and needs more development.

⁶ The proposed rule published in the November 4, 2020 *Federal Register*.