AAHOMECARE
American Association for Homecare

Final Rule Summary

MEMORANDUM

Date: October 31, 2019

Subject: 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 (CMS-1713-F)

On October 31, 2019, CMS published the final rule to the End-Stage Renal Disease (ESRD) proposed rule, which includes changes to the DMEPOS Medicare benefit.[1] This rule finalizes the framework for pricing new DMEPOS items and streamlines some payment conditions by developing a Master List that would include items that may be subject to face-to-face (F2F) encounters, written order prior to delivery (WOPD) requirements, and/or prior authorization. CMS also finalizes changes to the timeline for contract winners to notify CMS on change of ownership under competitive bidding. Below is the summary of the proposals and ***CMS' final rule action can be found in red.***

FRAMEWORK FOR ESTABLISHING FEE SCHEDULE FOR NEW HCPCS CODES

Currently, when a DMEPOS item is assigned a new HCPCS code, CMS uses the gap-fill methodology to calculate the allowable of the HCPCS. This methodology requires CMS to identify comparable item(s) and use each item's fee schedule to deflate prices back to the base year of July 1, 1986-June 30, 1987. Then the median price is identified amongst all of the comparable item(s) and that single median price is then re-inflated to calculate a current year payment rate for the new HCPCS code. The proposal in this section CMS introduces: (1) the framework for identifying comparable items; (2) identify the payment rate to use for gap-filling purposes; (3) use of technology assessment when there are no payment rates available for gap-filling; and (4) adjust payment rates for items that used supplier/commercial prices.

Newly Introduced DMEPOS Items

CMS introduces a framework for new DMEPOS HCPCS codes that do not have pricing history. First, CMS will identify comparable older DMEPOS item(s) and use the older DMEPOS items' payment rate to conduct the gap-filling calculation. CMS developed five components to compare the new item to an older item: physical, mechanical, electrical, function and intended use, and additional attributes/features. The table below shows the different components and attributes that fall under those components for the comparison analysis:

[1] The proposed rule will be published in the August 6, 2019 *Federal Register*.

TABLE 9: Comparable Item Analysis (Any combination of, but not limited to, the categories below for a device or its subcomponents)

Components	Attributes
Physical Components	Aesthetics, Design, Customized vs. Standard, Material, Portable, Size, Temperature Range/Tolerance, Weight
Mechanical Components	Automated vs. Manual, Brittleness, Ductility, Durability, Elasticity, Fatigue, Flexibility, Hardness, Load Capacity, Flow-Control, Permeability, Strength
Electrical Components	Capacitance, Conductivity, Dielectric Constant, Frequency, Generator, Impedance, Piezoelectric, Power, Power Source, Resistance
Function and Intended Use	Function, Intended Use
Additional Attributes and Features	"Smart", Alarms, Constraints, Device Limitations, Disposable Parts, Features, Invasive vs. Non-Invasive

The new item can fit into multiple categories and can have multiple comparable items. If it is determined that the new item has a comparable older item(s), CMS will use the fee schedule of the older item(s) for gap-filling purposes.

If it is determined that there are no comparable items, CMS is proposing to use supplier/commercial price lists, if they are available or useable. Supplier/commercial price lists can be catalogs, internet retail prices, and other retail price lists that have verifiable information.

If supplier/commercial price listings are not available or verifiable, CMS introduces the technology assessment method to determine the fee schedule of the new HCPCS. This assessment would be conducted by biomedical engineers, certified orthotists/prosthetists and other experts at CMS and the DME MACs. Under this proposal, CMS will review the supplier cost of furnishing the new items and compare the cost of furnishing the older items and will determine the relative difference. From there, CMS will establish a pricing percentage and will multiply the percentage to the existing item to calculate the new DMEPOS item's fee schedule. For example, if CMS finds that the cost of furnishing a new DMEPOS items is twice the cost of the existing item(s), the pricing percentage would be set at 200%. If the existing DMEPOS item has the payment rate of $500, 200% of $500 is $1,000 and that would be the new fee schedule rate for the new DMEPOS item. Conversely, if CMS finds that the cost of furnishing the new item is 75% of the existing DMEPOS item(s), the new DMEPOS item's fee schedule will be $375. CMS is proposing to use technology assessment whenever they see it is appropriate. For example, if a new manual hospital bed code is added and CMS finds that the supplier/commercial prices are 30 times higher than the fee schedule amounts for existing manual hospital beds, CMS will use technology assessment to establish the fee schedule amount for the new manual hospital bed code.

CMS proposes some guidance on pricing different types of new codes. When an existing single code is divided into several new codes, the single existing code's fee schedule amount would be applied to each of the new codes. When multiple codes are combined to create a single global code, the fee schedule amount for the new global code will be created based on the sum of the multiple existing codes. However, when multiple codes are combined into one code, the average fee schedule of the multiple codes, weighted by allowed services, will establish the fee schedule of the new code.

FINAL RULE ACTION: CMS IS NOT FINALIZING THE TECHNOLOGY ASSESSMENT. THE REST OF THE PROPOSAL IS FINALIZED AS IS.

Interim Pricing and Timeframes for New HCPCS Codes
For a new HCPCS that is awaiting a national fee schedule amount but is already available to beneficiaries, the DME MACs and other contractors will be responsible for establishing an interim local fee schedule. CMS anticipates these interim rates will be in effect for six months to a year depending on the complexity of the assessments for determining the fee schedule. Corrections to any errors to the fee schedule will be adjusted on a quarterly basis and can be found in the fee schedule files and claims processing edits.

FINAL RULE ACTION: FINALIZED

Adjusting Payment Rates for Items That Used Supplier/Commercial Prices
In situations where supplier/commercial prices were used to determine the price of a new DMEPOS item and the supplier/commercial prices have subsequently decreased, CMS is proposing a one-time adjustment of the fee schedule amount. If a HCPCS code that used supplier/commercial prices for gap-filling and the supplier/commercial price has since decreased by less than 15% within five years of establishing the initial payment rate, the payment rate is eligible to be gap-filled again using the new lower supplier/commercial prices. CMS does not believe recalculation is necessary if the supplier/commercial prices increases within the five years.

FINAL RULE ACTION: FINALIZED

CHANGES TO PAYMENT CONDITIONS

Master List
CMS is proposing to create a single list of items that would combine the items that are eligible for F2F encounters, WOPD, and prior authorization, to be known as the "Master List of DMEPOS Items Potentially Subject to Face-To-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements." Currently, the three different payment conditions have their own separate lists that were established by different rules and legislative mandates.[2,3,4] The goal of this proposed single list is to streamline these requirements. Below are the proposed criteria for the new Master List:

- Any DMEPOS item that has either:
  - An average purchase fee schedule of $500 or more.
  - An average monthly rental fee schedule of $50 or more.
  - Items that account for at least 1.5% of DMEPOS Medicare expenditures in the recent 12-months that are identified by OIG, GAO, or CERT for potentially having high improper payments/utilization.
- The annual updates need to include items with at least 1,000 claims and $1 million paid by Medicare in the recent 12-months that has experienced unusual billing patterns. Unusual billing patterns will be identified by the greater of:
  - The claim payments for the item has doubled from the previous 12-month period.

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[2] *"Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies" (80 FR 81674)*
[3] *"Medicare Program; Conditions for Payment of Power Mobility Devices, including Power Wheelchairs and Power-Operated Vehicles" (71 FR 17021)*
[4] *"Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013" (77 FR 68892)*

  - Payments exceeding 30% increase from the previous 12-month period.
- Any item that is statutorily required to have a F2F encounter, WOPD, or prior authorization.

CMS is proposing to only reference recent OIG, GAO, and CERT reports to determine items to include in the Master List. For OIG and GAO reports, the identifying items need to be reported by 2015 at the earliest, and CERT reports need to be published in 2018 or later.

This proposal would result in 413 items to be included in the new Master List. Although the creation of this new Master List will result in more items being eligible for prior authorization, CMS has stated that this does not necessarily mean they will all be added to the required prior authorization in the near future.

The Secretary has the discretion to update the Master List. The Master List will be self-updating and will be updated annually at a minimum. Items included on the Master List will be maintained on the list for 10 years from the date of the most recent publication of reporting by OIG, GAO, or CERT on the improper payments/utilization. If the item remains on the list for 10 years without any new reporting, the item will be removed. Any changes to the list will be published in the Federal Register and on CMS' website.

FINAL RULE ACTION: FINALIZED

Required Face-to-Face Encounter and Written Order Prior to Delivery List

Within the Master List, CMS is proposing to align payment conditions and creating a "Required Face-to-Face Encounter and Written Order Prior to Delivery List" (Required List). This would be a list of items that are required to have F2F and WOPD within a larger list of items potentially subject to the two payment conditions. CMS will announce the items moving from the Master List to Required List with a 60-day notice in the Federal Register. Currently, PMD is required to have both F2F and WOPD and therefore will be on the Required List. CMS is also proposing that all items in the Required List would need a F2F within 6 months of the WOPD. This proposal would even apply to PMDs, which are currently required to have a F2F within 45 days of the WOPD. However, this 6-month timeframe will not apply for items that specifically require more frequent F2F, such as the National Coverage Determination for oxygen therapy.[5]

FINAL RULE ACTION: CMS IS MODIFYING THE 60-DAY NOTICE TO "NO LESS THAN 60-DAYS" TO ACCOUNT FOR ITEMS THAT NEED MORE THAN A 60-DAY NOTICE.

Changes Specific to Prior Authorization

This proposed rule will allow CMS to implement prior authorization of item(s) nationally and locally, and to specific suppliers. CMS will collaborate with DME MACs to implement locally and to specific suppliers (nationally or within a DME MAC jurisdiction). CMS will announce these changes in the Federal Register and on the CMS website. CMS does not provide an official list of factors that would cause a prior authorization on a specific area or supplier but the proposal states that it can be due to "geographic location, item utilization or cost, system capabilities, emerging trends, vulnerabilities identified in official agency reports, or other analysis in selecting items for national or local implementation."

[5] *National Coverage Determination 240.2 titled "Home Use of Oxygen"*

Currently, there are accessories that are not eligible for prior authorization. CMS proposes to extend prior authorization to accessories that are ordered with a prior authorized item even if they are not included in the Master List. CMS states that if this proposal is finalized as is, it will become effective when the final rule is published. However, due to the complexity of updating the claims processing system, there may be a delay in adopting this proposal.

CMS proposes to maintain the current documentation requirements for prior authorization and CMS' ability to cease or suspend prior authorization requirements anytime without a formal rulemaking process. There will be no changes made to the required prior authorization list. Items currently requiring prior authorization will be grandfathered into the program.

FINAL RULE ACTION: FINALIZED

Changes Specific to Written Orders

This rule proposes to unify written order/prescription elements for all DMEPOS items. However, the required timeline of the orders will continue to differ depending on the item. Below are the proposed required elements:

- Beneficiary Name or Medicare Beneficiary Identifier
- General Description of the item
- Quantity to be dispensed, if applicable
- Date
- Practitioner Name or National Provider Identifier
- Practitioner Signature

CMS acknowledges these elements can be found in the beneficiary's medical record and is proposing that the DME MACs will need to review the physician order and beneficiary medical records when reviewing for compliance.

FINAL RULE ACTION: FINALIZED

CHANGES TO CHANGE OF OWNERSHIP (CHOW) NOTIFICATION TIMELINE

CMS is proposing to change the timeline contracted suppliers are required to notify CMS on CHOW from 60 days before the effective date to 10 days after the effective date. CMS no longer believes it is necessary to be notified of a CHOW 60 days in advance.

FINAL RULE ACTION: FINALIZED

REQUEST FOR INFORMATION ON DIABETIC TESTING STRIPS

CMS is required to review multiple data sources on measuring sales of diabetic testing strips under CBP. CMS is requesting comments on other possible data sources, besides data from the OIG, for their review.

CMS RESPONSE: CMS RECEIVED SIX COMMENTS BUT DID NOT RECEIVE SUGGESTIONS THAT ARE USEABLE DATA AT THIS TIME.