In phase one of implementation, which begins as specified in the **DATES** section of this document, we will implement a prior authorization program for these seven HCPCS codes for PMDs nationwide. The nationwide prior authorization program for these seven HCPCS codes will continue during phase 2. We believe prior authorization of these seven additional HCPCS codes for PMDs will help further our program integrity goals of reducing fraud, waste, and abuse, while protecting access to care.

The following five HCPCS codes for Support Surfaces are also being added to the Required Prior Authorization List:

HCPCS code	Description
E0193 ...	Powered Air Flotation Bed (Low Air Loss Therapy).
E0277 ...	Powered pressure-reducing air mattress.
E0371 ...	Nonpowered advance pressure reducing overlay for mattress length and width.
E0372 ...	Powered air overlay for mattress, standard mattress length and width.
E0373 ...	Nonpowered advanced pressure reducing mattress.

The CMS' Comprehensive Error Rate Testing (CERT) program continues to estimate high rates of improper payments for support surface codes. Since 2015, the estimated improper payment rate for these codes is over 59 percent, with an estimated improper payment rate of 75.2 percent, or over $18 million in projected improper payments for fiscal year 2018.

We will implement a prior authorization program for these five HCPCS codes for Support Surfaces in two phases. This phased-in approach will allow us to identity and resolve any unforeseen issues by using a smaller claim volume in phase one before nationwide implementation occurs in phase two. In phase one of implementation, which begins as specified in the **DATES** section of this document, we will limit the prior authorization requirement to one state in each of the four DME Medicare Administrative Contractors (MAC) geographic jurisdictions, as follows: California, Indiana, New Jersey, and North Carolina. In phase two, which begins as specified in the **DATES** section of this document, we will expand the program to the remaining states.

We believe prior authorization of these five HCPCS codes for Support Surfaces will help further our program integrity goals of reducing fraud, waste, and abuse, while protecting access to care.

These additional 12 HCPCS codes will be subject to the requirements of the prior authorization program for certain DMEPOS items as outlined in § 414.234. All 33 HCPCS codes currently on the Required Prior Authorization List (81 FR 93636 and 83 FR 25947) will continue to be subject to the requirements of prior authorization as well.

Prior to furnishing the item to the beneficiary and prior to submitting the claim for processing, a requester must submit a prior authorization request that includes evidence that the item complies with all applicable Medicare coverage, coding, and payment rules. Consistent with § 414.234(d), such evidence must include the order, relevant information from the beneficiary's medical record, and relevant supplier-produced documentation. After receipt of all applicable required Medicare documentation, CMS or one of its review contractors will conduct a medical review and communicate a decision that provisionally affirms or non-affirms the request.

We will issue specific prior authorization guidance in subregulatory communications, including final timelines, which are customized for the DMEPOS items subject to prior authorization, for communicating a provisionally affirmed or non-affirmed decision to the requester. In the December 30, 2015 final rule (80 FR 81694), to allow us to safeguard beneficiary access to care, we stated that this approach to final timelines provides the flexibility to develop a process that involves fewer days, as may be appropriate. If at any time we become aware that the prior authorization process is creating barriers to care, we can suspend the program.

The updated Required Prior Authorization list is available in the download section of the following CMS website: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/DMEPOS/Prior-Authorization-Process-for-Certain-Durable-Medical-Equipment-Prosthetic-Orthotics-Supplies-Items.html.* We will post additional educational resources to the website.

III. Collection of Information Requirements

This document announces the addition of DMEPOS items on the Required Prior Authorization List and does not impose any new information collection burden under the Paperwork Reduction Act of 1995. However, there is an information collection burden associated with this program that is currently approved under OMB control number 0938–1293 which expires on March 31, 2022.

Dated: March 19, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS–6078–N2]

Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items; Update to the Master List of Items Frequently Subject to Unnecessary Utilization

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Master list additions.

SUMMARY: This document announces the addition of four Healthcare Common Procedure Coding System (HCPCS) codes to the Master List of Items Frequently Subject to Unnecessary Utilization that could be potentially subject to Prior Authorization as a condition of payment.

DATES: This action is effective on May 22, 2019.

FOR FURTHER INFORMATION CONTACT: Erica Ross, (410) 786–7480, Emily Calvert, (410) 786–4277.

SUPPLEMENTARY INFORMATION:

I. Background

In the December 30, 2015 final rule (80 FR 81674) titled ''Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS),'' we implemented section 1834(a)(15) of the Social Security Act (the Act) by establishing an initial Master List (called the Master List of Items Frequently Subject to Unnecessary Utilization) of certain DMEPOS that the Secretary determined, on the basis of prior payment experience, are frequently subject to unnecessary utilization and by establishing a prior authorization process for these items. The Master List

includes items that meet the following criteria:

- Appear on the DMEPOS Fee Schedule list.
- Have an average purchase fee of $1,000 or greater (adjusted annually for inflation) or an average monthly rental fee of $100 or greater (adjusted annually for inflation). (These dollar amounts are referred to as the ''Payment Threshold'').
- Meet either of the following criteria:

++ Identified in a Government Accountability Office (GAO) or Department of Health and Human Services Office of Inspector General (OIG) report that is national in scope and published in 2007 or later as having a high rate of fraud or unnecessary utilization.

++ Listed in the 2011 or later Comprehensive Error Rate Testing (CERT) program's Annual Medicare Fee-For-Service (FFS) Improper Payment Rate Report DME and/or DMEPOS Service Specific Report(s).

The rule described the maintenance process of the Master List as follows:

- The Master List is self-updating annually. That is, items on the DMEPOS Fee Schedule that meet the Payment Threshold are added to the list when the item is listed in a future OIG or GAO report of a national scope or listed in a future CERT DME and/or DMEPOS Service Specific Report(s).
- Items remain on the Master List for 10 years from the date the item was added to the Master List.
- Items are updated on the Master List when the Healthcare Common Procedure Coding System (HCPCS) codes representing an item have been discontinued and cross-walked to an equivalent item.
- Items are removed from the list sooner than 10 years if the purchase amount drops below the Payment Threshold.
- Items that age off the Master List because they have been on the list for 10 years can remain on or be added back to the Master List if a subsequent GAO/OIG, or CERT DME and/or DMEPOS Service Specific Report(s) identifies the item to be frequently subject to unnecessary utilization.
- Items already on the Master List that are identified by a GAO/OIG, or CERT DME and/or DMEPOS Service Specific Report(s) will remain on the list for 10 years from the publication date of the new report(s).
- We will notify the public annually of any additions and deletions from the Master List by posting the notification in the **Federal Register** and on the CMS Prior Authorization website.

II. Provisions of the Document

In the December 30, 2015 final rule (80 FR 81674), we stated that we would notify the public annually of any additions and deletions from the Master List by posting the notification in the **Federal Register** and on the CMS Prior Authorization website. This document is to provide the annual update to the Master List of Items Frequently Subject to Unnecessary Utilization.

As noted previously, we adjust the Payment Threshold each year for inflation. More specifically, we stated in the preamble to the December 2015 final rule (80 FR 81679) that we will apply the same percentage adjustment to the Payment Threshold as we do to the DMEPOS fee schedule. In accordance with section 1834(a)(14) of the Act, certain DMEPOS fee schedule amounts are updated annually by the percentage increase in the consumer price index for all urban consumers (CPI–U), United States city average, for the 12-month period ending June 30 of the previous year. The CPI–U is then adjusted by the change in the economy-wide productivity equal to the 10-year moving average of changes in annual economy-wide private non-farm business multi-factor productivity (MFP). We use this same methodology to adjust the Master List Payment Threshold for inflation.

For calendar year (CY) 2018, the adjusted Payment Threshold was $1,018 and the adjusted monthly rental threshold was $102. For more information about how we arrived at these figures, see the March 30, 2018 **Federal Register** notification (83 FR 13677).

For CY 2019, the MFP adjustment is 0.6 percent and the CPI–U percentage increase is 2.9 percent. Thus, the 2.9 percentage increase in the CPI–U is reduced by the 0.6 percentage increase in the MFP resulting in a net increase of 2.3 percent to be used as the update factor. We applied the 2.3 percent update factor to the CY 2018 average purchase fee of $1,018, resulting in a CY 2019 adjusted payment threshold of $1,041.41 ($1,018 × 1.023). Rounding this figure to the nearest whole dollar amount resulted in a CY 2019 adjusted payment threshold amount of $1,041. We also applied the update factor of 2.3 percent to the CY 2018 average monthly rental fee of $102, resulting in an adjusted payment threshold of $104.35 ($102 × 1.023). Rounding this figure to the nearest whole dollar amount resulted in a CY 2019 adjusted monthly rental fee threshold of $104.

This update reflects the addition of four new items that meet the updated Payment Threshold that are listed in an OIG or GAO report of a national scope or a CERT DME and/or DMEPOS Service Specific Report(s). The following four HCPCS codes are included on the Master List of Items Frequently Subject to Unnecessary Utilization because they have a DMEPOS fee schedule amount of $1,041 or greater or an average monthly rental fee of $104 or greater, and are listed in the 2018 Medicare FFS Supplemental Improper Payment Report [1]:

HCPCS	Description
E1390	Oxygen concentrator, single delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate.
E0466	Home ventilator, any type, used with non-invasive interface, (e.g., mask, chest shell).
E0784	External Ambulatory infusion pump, insulin.
L0650	Lumbar-sacral orthosis, sagittal-coronal control, with rigid anterior and posterior frame/panel(s), posterior extends from sacrococcygeal junction to t–9 vertebra, lateral strength provided by rigid lateral frame/panel(s), produces intracavitary pressure to reduce load on intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, prefabricated, off-the-shelf.

The full updated list is also available in the download section of the following CMS website: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/DMEPOS/Prior-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/Downloads/2018MedicareFFSSuplementalImproperPaymentData.pdf.*

[1] The 2018 Medicare FFS Supplemental Improper Payment Report can be found at *https://www.cms.gov/Research-Statistics-Data-and-*

Authorization-Process-for-Certain-Durable-Medical-Equipment-Prosthetic-Orthotics-Supplies-Items.html.

III. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

IV. Regulatory Impact Statement

We have examined the impact of this action as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This document does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this document will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this action will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold is approximately $154 million. This action will have no consequential effect on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this action does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017 and requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' OMB's interim guidance, issued on April 5, 2017, *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2017/M-17-21-OMB.pdf,* explains that for Fiscal Year 2017 the above requirements only apply to each new ''significant regulatory action that imposes costs.'' It has been determined that this document is not a ''significant regulatory action'' and thus does not trigger the aforementioned requirements of Executive Order 13771.

In accordance with the provisions of Executive Order 12866, this document was reviewed by the Office of Management and Budget.

Dated: March 19, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

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