DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS–6080–N3]

Medicare Program; Update to the Required Prior Authorization List of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items That Require Prior Authorization as a Condition of Payment

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

ACTION: Update to list and phases.

SUMMARY: This document announces the continuation of prior authorization for 45 Healthcare Common Procedure Coding System (HCPCS) codes on the Required Prior Authorization List of DMEPOS Items that require prior authorization as a condition of payment, as well as the addition of six HCPCS codes to this list. Prior authorization for the additional codes will be implemented in two phases.

DATES: Phase one of implementation is effective on May 11, 2020. Phase two of implementation is effective on October 8, 2020.

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SUPPLEMENTARY INFORMATION:

I. Background

Sections 1832, 1834, and 1861 of the Social Security Act (the Act) establishes that the provision of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) are covered benefits under Part B of the Medicare program.

Section 1834(a)(15) of the Act authorizes the Secretary to develop and periodically update a list of DMEPOS items and supplies that the Secretary determines, on the basis of prior payment experience, are frequently subject to unnecessary utilization and to develop a prior authorization process for these items.

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,'' we implemented section 1834(a)(15) of 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.

On November 8, 2019, CMS published a final rule (84 FR 60648) titled ''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 Program (CBP) 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.'' Through this rule we harmonized the lists of DMEPOS items created by former rules and established one ''Master List of DMEPOS Items Potentially Subject to Face-To-Face Encounter and Written Orders Prior to Delivery and/or Prior Authorization Requirements'' (the ''Master List''). This rule was effective January 1, 2020.

II. Provisions of the Document

In the November 8, 2019, final rule (84 FR 60648), we stated that the items currently subject to prior authorization would be grandfathered into the prior authorization program until the implementation of the first Required Prior Authorization List published subsequent to this rule, to avoid the administrative and stakeholder burdens associated with the termination of the current prior authorization program and the implementation of a revised program created under this rule. This rule also maintained the process established in the December 30, 2015, final Rule that when items are placed on the Required Prior Authorization List, we would inform the public of those DMEPOS items on the Required Prior Authorization List in the **Federal Register** with no less than 60 days' notice before implementation, and post notification on the CMS website (84 FR 60753).

The Required Prior Authorization List specified in § 414.234(c)(1) is selected from the Master List (as described in § 414.234(b)), and those selected items require prior authorization as a condition of payment. Additionally, we stated that CMS may elect to limit the prior authorization requirement to a particular region of the country if claims data analysis shows that unnecessary utilization of the selected item(s) is concentrated in a particular region.

The purpose of this document is to inform the public that all 45 Power Mobility Device (PMD) and Pressure Reducing Support Services (PRSS) HCPCS codes currently on the Required Prior Authorization List will continue to be subject to the requirements of prior authorization (see 81 FR 93636, 83 FR 25947, and 84 FR 16616). In addition, we are updating the Required Prior Authorization List to include six Lower Limb Prosthetic (LLP) HCPCS codes. To assist stakeholders in preparing for implementation of the prior authorization program, we are providing 90 days' notice.

The following six HCPCS codes for LLPs are added to the Required Prior Authorization List:

HCPCS	Description
L5856	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type.
L5857	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing phase only, includes electronic sensor(s), any type.
L5858	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, stance phase only, includes electronic sensor(s), any type.
L5973	Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, includes power source.
L5980	All lower extremity prostheses, flex foot system.
L5987	All lower extremity prosthesis, shank foot system with vertical loading pylon.

We believe prior authorization of these six additional HCPCS codes for LLPs will help further our program integrity goals of reducing fraud, waste, and abuse, while also protecting access to care. LLPs have been identified by

CMS' Comprehensive Error Rate Testing (CERT) program as one of the top 20 DMEPOS service types with improper payments over the past several years.[1] The 2018 Medicare Fee-for-Service Supplemental Data reported over $46 million in projected improper payments for LLPs.[2] Additionally, the Office of Inspector General (OIG) has previously reported that Medicare has inappropriately paid for LLPs that did not meet certain Medicare requirements.[3]

These codes will be subject to the requirements of the prior authorization program for certain DMEPOS items as outlined in § 414.234. We will implement a prior authorization program for the six newly added codes for LLPs in two phases. This phased-in approach will allow us to identify 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 on the date specified in the **DATES** section, 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, Michigan, Pennsylvania, and Texas. In phase two, which begins on the date specified in the **DATES** section of this document, we will expand the program to the remaining states in all four DME MAC jurisdictions. The prior authorization program for the 45 codes currently subject to the DMEPOS prior authorization requirement will remain in place uninterrupted in all states.

Prior to furnishing the item to the beneficiary and submitting the claim for processing, a requester must submit a prior authorization request. The request must include 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 customized for the DMEPOS item 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 81692), we stated that this approach to final timelines provides flexibility to develop a process that involves fewer days, as may be appropriate, and allows us to safeguard beneficiary access to care. If at any time we become aware that the prior authorization process is creating barriers to care, we can suspend the program. For example, we will review questions and complaints from consumers and providers that come through regular sources such as 1–800–Medicare.

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.*

III. Collection of Information Requirements

This document announces the continuation of prior authorization for 45 HCPCS codes, and the addition of six HCPCS codes for LLPs 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 March 31, 2022.

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 one 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 one 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

[1] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/CERT-Reports.html?DLSort=0&DLEntries=10&DLPage=1&DLSortDir=descending.*

[2] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/Downloads/2018MedicareFFSSuplementalImproperPaymentData.pdf.*

[3] *https://oig.hhs.gov/oei/reports/oei-02-10-00170.pdf.*

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: November 5, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Editorial note: This document was received for publication by the Office of the Federal Register on February 5, 2020.

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