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From: Centers for Medicare & Medicaid Services <cmslists@subscriptions.cms.hhs.gov>
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To: Ronda Buhrmester
Subject: CMS Fact Sheet: CMS Finalizes Rule Creating Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies Items

CMS Finalizes Rule Creating Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies Items

OVERVIEW

The Centers for Medicare & Medicaid Services (CMS) today issued a final rule that would establish a prior authorization process for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items that are frequently subject to unnecessary utilization. This prior authorization process will help ensure that certain DMEPOS items are provided consistent with Medicare coverage, coding, and payment rules. CMS believes the final rule will prevent unnecessary utilization while safeguarding beneficiaries' access to medically necessary care.

Under the final rule, the prior authorization process will require the same information necessary to support Medicare payment today, just earlier in the process. It will not create new clinical documentation requirements. The prior authorization process assures that all relevant coverage, coding, and clinical documentation requirements are met before the item is furnished to the beneficiary and before the claim is submitted for payment. This helps ensure that beneficiaries are not held responsible for the cost of items that are not eligible for Medicare payment. CMS believes prior authorization is an effective way to reduce or prevent questionable billing practices and improper payments for DMEPOS items. Access is preserved in this rule by having both specified timeframes for review and approval of requests, and an expedited process in cases where delays jeopardize the health of beneficiaries.

BACKGROUND

CMS has had longstanding concerns about the improper payments related to DMEPOS items. The Department of Health and Human Services' Office of the Inspector General and the U.S. Government Accountability Office have published multiple reports indicating questionable billing practices by suppliers, inappropriate Medicare payments, and questionable utilization of DMEPOS items. CMS has addressed these issues in recent years through the implementation of the DMEPOS Competitive Bidding Program, as well as heightened screening of suppliers, as authorized by the Affordable Care Act.

In addition to those actions, CMS recently expanded a 3-year prior authorization demonstration program for power mobility devices (PMDs). The demonstration began in 2012 in 7 states with high incidences of fraudulent claims and improper payments. In 2014, the demonstration was expanded to 12 additional states. Based on claims processed from September 1, 2012 through August 14, 2015, monthly expenditures for the PMD codes included in the demonstration decreased from: $12 million to $3 million in June 2015 in the

original 7 demonstration states; $10 million in September 2012 to $2 million in June 2015 in the 12 additional expansion states; and $10 million in September 2012 to $3 million in June 2015 in the non-demonstration states. CMS believes the decrease in spending is due in part to national DMEPOS suppliers adjusting their billing practices nationwide (not just in the demonstration states) to comply with CMS policies based on their experiences with prior authorization in the demonstration states.

This final rule further addresses questionable utilization and improper payments by creating a prior authorization process for certain DMEPOS items beyond PMDs. Under Section 1834(a)(15) of the Social Security Act, the Secretary has the authority to develop and periodically update a list of DMEPOS items 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. The final rule implements this authority by creating: a "Master List" of items that meet specific criteria and are potentially subject to prior authorization; a "Required Prior Authorization List," a subset of items on the Master List; and a prior authorization program for the Required Prior Authorization List items.

THE MASTER LIST

The Master List is the set of 135 DMEPOS items identified as being frequently subject to unnecessary utilization. Items that meet the following criteria are included on the Master List and thus potentially subject to prior authorization: items on the DMEPOS Fee Schedule with an average purchase fee of $1,000 or greater, or an average rental fee schedule of $100 or greater, (adjusted annually for inflation) and the subject of:

- HHS Office of the Inspector General (OIG) or U.S. Government Accountability Office (GAO) reports that are national in scope and published since 2007, or
- Comprehensive Error Rate Testing Annual Medicare Fee-for-Service Improper Payment Report Durable Medical Equipment (DME and/or) Report's DMEPOS Service Specific Reports.

The list is self-updating annually such that items on the DMEPOS Fee Schedule that meet the payment threshold are added to the list when the item is the subject of an OIG or GAO report of a national scope or a future CERT DME Service Specific Report. Items will remain on the list for 10 years, but can be removed sooner if the purchase amount drops below the payment threshold. After 10 years, items can remain on the list or be added back to the list if a subsequent report identifies the item as frequently subject to unnecessary utilization.

REQUIRED PRIOR AUTHORIZATION LIST

Presence on the Master List does not automatically create a prior authorization requirement for that item. In order to balance minimizing provider and supplier burden with protecting the Medicare Trust Funds and beneficiary access, CMS will initially implement prior authorization for a subset of items on the Master List (referred to as "Required Prior Authorization List"). CMS will publish the Required Prior Authorization List in the Federal Register with 60-days' notice before implementation of prior authorization for those items.

PRIOR AUTHORIZATION PROCESS

Prior authorization will be required for those DMEPOS items on the Required Prior Authorization List. The process requires all relevant documentation to be submitted for review prior to furnishing the item to the beneficiary and submitting the claim for processing. CMS or its contractors will review the prior authorization request and provide a provisional affirmation or non-affirmation decision. A claim submitted with a provisional affirmation decision will be paid so long as all other requirements are met. A claim submitted with a non-affirmation decision or without a decision will be denied. Unlimited resubmissions of prior authorization requests are allowed.

Medicare or its review contractor will make a reasonable effort to render an initial prior authorization determination within 10 business days and will make a reasonable effort to render a resubmission prior authorization determination within 20 business days. These are maximum timeframes and will be adjusted downward for items that require less time for making a determination. An expedited review process will be available to address circumstances where applying the standard timeframe for making a prior authorization decision could seriously jeopardize the life or health of the beneficiary. The request for an expedited review must provide rationale supporting the request.

CMS will issue specific prior authorization guidance in subregulatory communications.

The final rule is currently on display at https://www.federalregister.gov/articles/2015/12/30/2015-32506/medicare-program-prior-authorization-process-for-certain-durable-medical-equipment-prosthetics.

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