Via Electronic Mail:

July 25, 2014

Marilyn Tavenner, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue
Washington, DC 20201

Re: Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items\(^1\), CMS 6050-P

Dear Administrator Tavenner:

The American Association for Homecare (AAHomecare) submits these comments in response to the Centers for Medicare and Medicaid's (CMS') request for comments on the above captioned proposed rule regarding a Medicare prior authorization program for certain durable medical equipment (DME), orthotics, prosthetics and supplies (collectively, DMEPOS). AAHomecare represents DME suppliers and manufacturers with over 600 members nationwide.

AAHomecare is uniquely positioned to provide CMS with comments on implementing a prior authorization process for DMEPOS. Our members have extensive experience in working with government and private sector payers\(^2\) who use prior approval for DMEPOS items. AAHomecare members have been closely involved in the development and implementation of CMS' new prior authorization program for power mobility devices. While AAHomecare is generally supportive of prior authorization procedures like the ones in place by private sector payers, the program under the proposed rule must be significantly revised in order to meet the needs of beneficiaries, referral sources, and DMEPOS providers. A properly crafted and implemented prior approval program could address some of the issues contributing to the current appeals backlog. A successful prior authorization process would also establish a degree of certainty for suppliers and beneficiaries on issues of medical necessity for DMEPOS.


\(^2\) Throughout these comments we will use the terms “private sector” or “private sector payers” to mean all private sector health insurance plans including Medicare Advantage, Medicare replacement, and Managed Medicaid plans.
A Medicare prior approval program must include several key components that either are not present or are not sufficiently robust in the program CMS described in the proposed rule. Importantly, AAHomecare cannot support a prior approval program that does not include the key criteria listed below.

In our experience a successful program must, at a minimum, meet the following criteria:

- Prior authorization decisions must be completed and communicated to the provider and beneficiary within 24 hours or sooner;
- A prior authorization request for equipment needed on an emergency basis is “fast tracked” and decided within 2 or fewer hours;
- Communication between the provider and the contractor must be electronic from end-to-end, easily accessible by all providers and free of charge to use;
- An affirmative prior authorization for a DMEPOS item must be conclusive with respect to the medical necessity of that item for that beneficiary, although claims could be audited subsequently for technical issues such as proof of delivery;
- An affirmative prior authorization for a DMEPOS item must be conclusive with respect to the medical necessity for all of the supplies that may be used with the item;
- Prior authorization must include options and accessories provided in addition to the base equipment to ensure the entire product provided to a patient is included.
- An affirmative prior authorization for a DMEPOS item must be conclusive with respect to the medical necessity for repairs to the DMEPOS item approved;
- When an item submitted for prior authorization is the same or similar to an item the beneficiary is using, the need for the new item should be considered as part of the prior authorization; and
- An affirmative prior authorization is specific to the beneficiary with respect to the DMEPOS item approved. If the beneficiary moves or changes providers he does not need a new prior approval for the item.

A properly executed prior authorization program would give CMS an opportunity to streamline medical necessity documentation and eliminate certificates of medical necessity (CMNs) and other duplicate paperwork. The Agency must also consider the many DMEPOS program integrity and quality initiatives already in place. These include accreditation, surety bonds, new supplier standards, extensive screening procedures including a pending fingerprinting requirement, PECOS requirements, and, most recently, the requirements for an in-person evaluation and a written order prior to delivery for specified covered items. Given that the Agency has already implemented these initiatives, CMS’ goal should be to ameliorate, not increase, the need for additional medical necessity documentation. AAHomecare could support a prior authorization program for DMEPOS that includes all of the elements we identify in these comments and which our members’ have experienced working with other payers’ prior authorization programs. We discuss our concerns in more detail below.

I. PRIOR AUTHORIZATION COMMENTS

A. Prior authorization decisions must be made and communicated within 24 or fewer hours;
   Emergency decisions must be made and communicated within two or fewer hours.
The proposed rule states that a contractor would make “reasonable efforts” to communicate a decision on a prior authorization request within 10 days of the date that the contractor receives all the necessary information. Ten days is an unreasonably long time for making a prior authorization decision. While this standard could be tolerable for items and services that are not necessary for a safe and timely transition from an inpatient stay to the home, this standard is unworkable for DMEPOS, the vast majority of which are necessary to facilitate a safe and timely discharge. CMS must keep in mind that beneficiaries and referral sources will bear the brunt of any delays in deciding a prior authorization request. To the extent that delays slow-down a discharge, CMS misses an opportunity to move a beneficiary’s care from costly inpatient facilities to a cost effective care setting like the beneficiary’s home.

A successful program must operate the way prior authorization programs work in the private sector. Private sector payers make a decision on a prior authorization within hours. “Fast-track” decisions for equipment needed urgently or on an emergency basis are made in 1-2 hours. Importantly, the private sector relies on an electronic process from the inception of a request through its conclusion, when a determination is communicated to the supplier. The means used to effectuate a prior approval in the private sector are also easily accessible and free of charge to use. It is crucial that CMS adopt an open system with industry standard communication protocols to allow existing systems in use by suppliers to communicate directly with the provider. This program, thus lowering costs to CMS, contractors and suppliers and expediting the flow of information.

AAHomecare is aware that 10 days is the standard response time for completing a prior authorization in the power mobility (PMD) demonstration. We understand that suppliers who use ESMD are able to receive a response to their requests within two days of when a decision is made. However, our understanding is that there is only one health information handler (HIH) that performs this function. In addition, there is a per page charge to use the system that, while seemingly modest, quickly adds up to large sums given the volume of documentation suppliers must submit. For example, our members report that the cost to submit records for one request using the ESMD can run as high $1,200, or more. The result is that, although the ESMD is an essential component of an efficient prior authorization program, it can be inaccessible or unaffordable for many suppliers who would otherwise use it.

Suppliers who do not, or cannot, use ESMD must wait to receive a response through in the United States mail. This can take 14 days or more from the date the decision is rendered in addition to the time it takes the contractor to make a decision. Clearly, the expansion of prior authorization to other items of DMEPOS would require CMS to quickly ramp-up its use of HIHs in order to issue decisions within 24 hours from the time a request is submitted, or, at the very least, within a reasonably prompt time frame that is significantly shorter than 10 days (plus another 14 days for receiving the response in the mail). We believe this is critical in order to have a program that meets the needs of beneficiaries and referral sources.

Prior approval programs in the private sector allow suppliers to submit documentation electronically, and give them an opportunity to speak directly to the decision maker. When a patient has an urgent or emergent need for equipment, prior approval programs in the private sector are able to accommodate this need. This is important from the perspective of the prescribing practitioner who determines the urgent nature of the patient’s medical necessity.

The private sector process also includes an opportunity for a patient or his provider to request a review of an unfavorable prior authorization decision. The process CMS implements should include an
opportunity for suppliers to communicate directly with the medical reviewer deciding the prior authorization request, at least for beneficiaries with an urgent or emergent need for a DMEPOS item. Otherwise the process runs the risk of becoming a mirror image of the claims review process where the inability to speak directly to a decision maker until the third level of appeal results in unnecessary delays in rendering an appropriate decision. CMS’ proposal to allow unlimited resubmissions of a prior authorization request cannot substitute for a one-on-one discussion between the reviewer and the supplier.

AAHomecare also recommends that CMS designate one contractor to perform all DMEPOS prior authorizations. We believe that segregating the process from a MAC contractor’s claims processing functions is the only way to achieve an efficient, transparent process where accountability for timeliness is clearly articulated. If CMS chooses to implement the prior authorization program with the DME MAC contractors, CMS must monitor them to ensure they meet standards that include criteria for the timeliness and consistency of their decisions.

B. An affirmative prior authorization for a DMEPOS item must be conclusive with respect to the medical necessity for all of the supplies that may be used with the item; Prior authorization must include options and accessories provided in addition to the base equipment to ensure the entire product provided to a patient is included; An affirmative prior authorization for a DMEPOS item must be conclusive with respect to the medical necessity for repairs to the DMEPOS item approved.

CMS’ proposal is that an affirmative prior authorization decision will be temporary pending claim submission for the item and a possible post payment review. AAHomecare agrees that some documentation issues cannot be reviewed until the DMEPOS item is delivered. However, we disagree that an affirmative prior authorization should only be temporary pending post payment review of the claim for technical deficiencies like a missing proof of delivery. AAHomecare cannot support a prior authorization process that renders only temporary initial authorizations pending a subsequent post payment audit of the claim.

An affirmative prior authorization decision must be conclusive with respect to medical necessity for the DMEPOS item that was approved. We also recommend that seemingly technical issues such as duplicate equipment should be resolved through the prior authorization process given that the need for same or similar equipment requires a medical necessity determination. After an item is approved through prior authorization, a claim may be subject to post payment review, but only for technical issues like proof of delivery that could not be addressed during the prior approval review.

Once a DMEPOS item has been prior approved for a beneficiary, the authorization should remain effective for the duration of the beneficiary’s medical need. If the beneficiary moves or changes suppliers, a new supplier should be able to confirm the prior approval in the same way he can check on the beneficiary’s eligibility or duplicate equipment. That is, a prior approval follows the beneficiary; an approval decided by one MAC jurisdiction is effective in the other three jurisdictions. A contrary rule would result in wasteful, duplicative efforts for suppliers and the Medicare program and would place
beneficiaries at risk of losing the equipment they have been using. Similarly, an affirmative prior authorization decision on a DMEPOS item must include all of the options, supplies or accessories, like PAP masks, and any repairs the beneficiary will need for the item.

Finally, if this proposed rule is finalized, CMS must implement the program prospectively. The requirement to obtain prior authorization must apply only to new prescriptions dated on or after the effective date of the program. Beneficiaries with equipment that was ordered and furnished before the effective date of the program must be grandfathered for that equipment. CMS should implement prior authorization for DMEPOS items that are not on the master list.

C. CMS should implement prior authorization for DMEPOS items that are not on the proposed master list.

Subject to our recommendations above, CMS should include high dollar, high volume DMEPOS on the “master list.” AAHomecare recommends that CMS should consider including oxygen and oxygen equipment, enteral nutrients, supplies and equipment and total parenteral nutrition in addition to the items the Agency identified under the proposed rule, as long as the PA process can occur expeditiously as we explained above. In addition we suggest that CMS include every product in a product category when placing DMEPOS on a prior approval list. For example, the proposed rule identifies only one kind of hospital bed on the prior approval list. AAHomecare believes that every HCPCS code in a product category should be subject to prior approval rather than picking just one or a few DMEPOS items for prior approval from a product category. Finally, CMS should include supply items used by beneficiaries with chronic conditions like diabetes or impairments that require them to use ostomy or urological supplies.

We disagree with CMS’ proposal to leave DMEPOS items on the master list for 10 years. Additions and deletions from the master list must occur annually. It would not be sufficient to give providers and beneficiaries 60 days’ notice of changes to the master list without also including an opportunity for public comments. Providers and their representatives are in the best position to advise CMS on how prior authorization for a type of DMEPOS might be implemented effectively. Given that CMS must publish a number of physician and provider payment rules annually, updates to the master list should be incorporated into one of those rulemaking procedures.

D. An affirmative Medicare prior authorization process should be effective if the beneficiary leaves Medicare for another payer and subsequently returns to Medicare. A Medicare prior authorization program must also include a streamlined procedure for considering prior approvals granted by other payers.

It is critically important that CMS ensure that an affirmative prior approval decision for a DMEPOS item follow the beneficiary. If the beneficiary moves or changes suppliers he or she should not be required to request a second authorization for the same equipment. The prior authorization must be recognized by the DME MACs uniformly. Otherwise, CMS would impose an unsupportable paperwork burden on suppliers and beneficiaries who need to continue using the DMEPOS item.

Equally important is that CMS recognize a prior approval granted by Medicare if the beneficiary leaves Medicare for a managed care payer but later returns to traditional Medicare and is still using the equipment. This situation is analogous to one where a DMEPOS item has been prior approved and the
beneficiary moves or changes suppliers. If the beneficiary is required to obtain a second prior approval when he re-enters Medicare, the paperwork burden would be wasteful and duplicative and would place him at risk of losing coverage for equipment that he has been using. Similarly, CMS should give weight to a prior approval granted by another payer, especially a Medicare Advantage plan. As in that situation, the beneficiary has a medical need for the equipment and would have been using it prior to entering the Medicare program.

II. PAPERWORK REDUCTION ACT COMMENTS

A. CMS grossly underestimates the paperwork burden of getting a prior authorization

As you know, the PRA requires agencies to justify the public burdens associated with a collection of information. The purpose of the PRA is to ensure that agencies give careful thought to the necessity and costs of imposing documentation requirements on the public. The law requires agencies to submit a proposed collection of information for the approval of the Office of Management and Budget (OMB). Prior to their submission to OMB, the agency is required to give 60-days’ notice in the Federal Register and solicit public comment on the burdens associated with the information collection. Specifically, agencies must solicit public comments on the following issues:

- Whether the information collection is necessary and useful to carry out the proper functions of the agency;
- The accuracy of the agency’s estimate of the information collection burden;
- The quality, utility, and clarity of the information to be collected; and
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

While a complete assessment of the paperwork burdens imposed under the proposed rule requires us to have a better understanding of the volume of documentation CMS will require for a prior approval, AAHomecare believes that CMS has underestimated the time it will take to collect and submit the documentation to support a prior authorization for a DMEPOS item. The necessary documentation rests with the physician or practitioner who ordered the DMEPOS item. The beneficiary and the supplier will depend on the ordering practitioner’s willingness and efficiency in providing the documentation. Much of the medical necessity will be in the beneficiary’s historical medical record which may require collecting information from multiple sources in order to provide a clear picture of the beneficiary’s medical need.

CMS estimates that this process will take roughly thirty (30) minutes per request. Thirty minutes is a gross underestimation of the time it takes to collect and prepare the documentation to support a prior authorization request. Our experience with the PMD prior authorization demonstration shows that the process is far more time consuming, costly and complicated than CMS’ estimate would suggest.

In addition, if CMS decides to require multiple prior approvals for the same equipment because of changes in suppliers, payers or DME MAC jurisdictions, the time and cost involved in obtaining prior authorizations increase to the point of being unsustainable. In these situations, the collection of information is duplicative and wasteful because the information already exists in CMS’s records. To the extent the Agency intends to require multiple prior approvals for the same piece of equipment, the collection of information request should be denied.
III. CONCLUSION

Finally, we reiterate that while AAHomecare would support the implementation of a prior approval process that incorporates all of our recommendations above, it is important for CMS to be mindful of the many DMEPOS program integrity and quality initiatives the Agency has implemented in the recent past. These include accreditation, surety bonds, heightened screening procedures including a fingerprinting requirement, PECOS requirements, and, most recently, the requirements for an in-person evaluation and a written order prior to delivery for specified covered items. CMS should view prior authorization as a way to streamline medical necessity documentation and the heavy audit burden carried by providers given that Agency has these other program integrity measures in place.

AAHomecare sincerely appreciates the opportunity to submit these comments. Please feel free to contact me if you have any questions about our recommendations above or I can be of any assistance to you.

Sincerely,

Kimberley Brummett, MBA
Vice President for Regulatory Affairs